HEALTH GOVERNANCE, MEDICAL PLURALISM AND THE POLITICS OF INTEGRATION
A LEGAL THEORY FOR INCREASING ACCESS TO HEALTHCARE

by

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ABSTRACT

This thesis investigates why and how extant systems of health governance and the associated boundaries of legitimacy imposed by these systems impact on the realization of key healthcare objectives. It contends that while purporting to represent a universally valid approach to healthcare delivery, the transposed laws/institutions that underlie these governance systems are of themselves designed to address health and health systems-related problems through methods often unsuited to the unique experiential dynamics that ought to shape governance in any given society. This thesis responds to this disparity between governance regimes and societal realities by advancing dual healthcare reform initiatives.

First, it espouses the concept of medical integration—consistent with the recommendations of the World Health Organization, which involves the systemic synthesis of indigenous, complementary, alternative and biomedical healthcare resources. Second, since medical integration faces legal complications—which are products of decontextualized governance systems that are incompatible with the pluralistic nature of healthcare usage/delivery in underserved populations – this thesis proposes that health equity is dependent on a new approach to governance sustained by a reformed legal process in which legal policies reflect socio-economic, geo-cultural, and political-historical dynamics. Drawing insights from Lon Fuller’s interactional law theory and Felix Cohen’s functional jurisprudence, this study propounds a theory of integral governance—herein denoted as Integrated Governance—which offers a legal and institutional framework for medical integration.

Integrated Governance is first a theory of law centering on the institutionalization of laws that embody empirical trends and a theory of democratic governance advancing an interactive and interdependent relationship between the state, health professionals of multiple healthcare paradigms, consumers, and relevant non-state actors. The thesis applies research outcomes from two Canadian cities and four Nigerian urban and rural communities to support its contentions. By identifying in both countries prevalent clinical practices that complement trends in consumer healthcare behaviour, and highlighting disparities between these practices/trends and extant governance regimes, the research substantiates the underlying thesis of this study – that this disparity represents a failure of governance. The research further supports the thesis that governance must be restructured to produce functional healthcare institutions that address the needs of legal subjects.
PREFACE

The research leading up to the completion of this thesis was conducted in six urban and rural communities in Nigeria and Canada. The University of Benin, Faculty of Law, approved the research in Nigeria. A Memorandum of Agreement between the Faculties of Law of the University of British Columbia and the University of Benin was drawn up for the purpose of the research. The Behavioural Research Ethics Boards (BREB) of the University of British Columbia approved the research in Canada. There are four Ethics Certificates from the Board: Certificate of Approval – Minimal Risk (UBC BREB Number H08-02767) approved December 18, 2008, Certificate of Approval – Minimal Risk Amendment (UBC BREB H08-02767) approved November 5, 2009, Certificate of Approval – Minimal Risk Renewal (UBC BREB H08-02767) approved November 17, 2009 and Certificate of Approval – Minimal Risk Amendment (UBC BREB Number H08-02767) approved December 3, 2009.
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To Mum, Patricia Otibhor Eromon Iyioha (nee Okokhere)
[22 June 1951 – 3 June 2005]
My Guardian Angel

and

Dad, Omon Osobase Iyioha Snr.
My Armour
Insofar as sicknesses are influenced by sociocultural systems, so are means of maintaining the health of individuals. Although much in illness is universal and biological, the health system within any culture is as artificial and changeable as anything else in human society. Indeed, the systems we take for granted can be related to special circumstances of the past century or two.


‘Traditional Medicine’ fulfills the four criteria of accessibility, availability, acceptability and dependability.

CHAPTER 1. INTRODUCTION: OF KNOWLEDGE SYSTEMS, ALTERNATIVE VALUES AND MEDICAL SCIENCE – DEFINING THE LAW PROBLEM

Given the limited fiscal sustainability of the current health care system, it is important that the insight, experience, and expertise of both complementary and alternative and conventional health care professionals be used to improve the health of the population and reduce the burden of disease.

D. J. Tataryn and M. J. Verhoef (2001).\(^1\)

Integrating modern and traditional medicine requires breaking down the legal and regulatory barriers that disadvantage the poor.

S. Lewis and D. Dickson (2010).\(^2\)

1.1. Health and the Economics of Care: The Search for Health Equity\(^3\)

The pursuit of an optimal state of health is an infinite quest and in between boundless healthcare needs and bounded resources are questions of what and how health products, services and systems should be managed, funded and regulated. In the midst of the pursuit and the questions, healthcare costs remain on a steady rise with minimal health gains to show for the escalation in costs.\(^4\) While centering its analyses on the benefits of pluralism in alleviating rising costs and inequities in healthcare delivery, this study investigates why and how extant

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\(^2\) S. Lewis and D. Dickson, The Imperative for Traditional Medicine, online: Science and Development Network <http://www.scidev.net/en/health/integrating-modern-traditional-medicine/editorials/the-imperatives-for-traditional-medicine.html#>.

\(^3\) See the contested World Health Organization’s definition of ‘health’ as a “state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity”: Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. The definition reflects different conceptions of what constitutes ‘health’. The discussion of medical pluralism and indigenous healthcare systems in the rest of this chapter, as well as in subsequent chapters, reflects the connection between the physical, psychosomatic and psychosocial aspects of ‘health’ as captured in this definition.

systems of health governance and the associated boundaries of legitimacy imposed by these systems impact on the realization of key healthcare objectives. The study applies its findings towards proposing a system of medical integration through a theory of Integrated Governance (appositely theorized as an integral system of governance based on its divergence from extant formulations and practices) for managing health systems in underserved populations. This chapter provides a précis of the thematic and organizational trajectory for arriving at medical integration as set out in the chapters of this study.

Countries of the global North and South\(^5\) face rising healthcare costs and dwindling returns in healthcare investments. However, other dynamics complicate the state of healthcare in the nations commonly described as ‘developing’ or ‘Third World’ countries. Some of these forces range from flawed governance, political unrests, economic upheavals, and perhaps to legacies from a colonial past. Perhaps the most critical example of a colonial legacy, which critical legal scholarship today conceives of as a burden to the post-colonial society, is the Westphalian state and its centralized legal structure.\(^6\) The modern state, with its paraphernalia of centralism, institutional closure, defined territory and positive law is charged with the business of administration. Some critical legal scholars and theorists allegiant to the ‘Third World Approaches to International Law’ (TWAIL) school of thought have linked many of the economic and political failures of formerly colonized territories to the state system.\(^7\) These theorists critique the internationalization of European law through the colonial encounter.\(^8\)

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\(^5\) These terminologies will be used consistently to denote those countries often categorized as ‘developed’ and ‘developing’ or the ‘First’ and ‘Third World’. See subsection 1.2.2 for a note on the terminologies employed in this work; the subsection also identifies the limitations inherent in the use of ‘South’ and ‘North’ and explains why I have adopted these terms in this study.


\(^7\) See *ibid*.

\(^8\) Anghie and Chimni, *supra* note 5 at 84.
The concept of law, it is argued, is “shaped by the relationships of power and subordination inherent in the colonial relationship”.⁹ Thus, the attempts by Southern or formerly colonized states to apply European or international law to promote their interests can “encounter unique difficulties and challenges”.¹⁰ Since law permeates all socio-economic and political affairs, these challenges are manifest in the inability of most Southern states to achieve functional and equitable health systems through the adoption of systems of health governance operative in the Northern hemisphere. As expounded in this study, state ‘law’ as it operates in many post-colonial countries is often dissociated from the unique histories and realities that ought to shape governance. Thus, the resultant social and economic institutions created by ‘law’ in Southern states often fail to achieve proposed objectives. The fragile health system in many Southern countries is one casualty of the failures of the post-colonial regulatory state. Today, the African continent and most Southern states are experiencing a crisis of inequitable healthcare delivery fuelled by workforce shortages, maladministration of health professionals, geographical discrepancies in access to healthcare, and rising out-of-pocket expenditures for health services and products. These factors have placed equitable healthcare beyond the reach of large populations.

Equitable healthcare implies “equal opportunities for health” and aims to reduce “health differentials” to the “lowest level possible” between different societal groups where the health status of the groups is neither natural nor inevitable.¹¹ The concept of ‘health equity’ generally encompasses the idea that every person “should have a fair opportunity to attain their full health potential” and at least that none should be deprived of realizing this potential, if it can be prevented.¹² Health inequities in the South are not simply the outcome of flawed governance and its political and economic corollaries. A major reason for the frailty of the healthcare

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⁹ Ibid.
¹⁰ Ibid.
¹² World Health Organization, Social Justice and Equity in Health: Report on a WHO Meeting. (Leeds, United Kingdom, 1985) (ICP/HSR/804/m02), WHO Regional Office for Europe, Copenhagen. For a further exposition on equity and economic issues in healthcare delivery, see Report of the Commission on Macroeconomics and Health, Microeconomics and Health: Investing in Health for Economic Development <http://www.paho.org/english/hdp/hdd/sachs.pdf>. However, this author does not necessarily endorse the Commission’s recommendation of a flow of income or resources from high-income to low-income countries on a continuous basis. See also the Report of the WHO Commission on Social Determinants of Health <http://whqlibdoc.who.int/publications/2008/9789241563703_eng.pdf>.
systems of Southern and post-colonial states is the lack of human resources in healthcare delivery, which are central to the functioning of health systems. The World Health Organization (WHO) has noted that in the struggle against various global healthcare crises, little attention has been paid to the people who actually deliver health services.\(^\text{13}\)

The WHO confirms that Africa faces an insidious crisis in human resources for healthcare.\(^\text{14}\) The crisis has eroded the “survival gains achieved after a century of the most spectacular health advances in human history”.\(^\text{15}\) Although Africa carries 25% of the world’s disease burdens, it has only 1.3% of the world’s health workforce.\(^\text{16}\) According to statistics, Africa needs 2.5 health workers per 10,000 inhabitants to achieve the Millennium Development Goals; however, the continent presently has a health workers/population ratio of 0.8 health workers per 10,000 inhabitants.\(^\text{17}\) Among the factors that contribute to the decline in human resources are financing arrangements and weak planning of health workforce in countries. However, these factors are perhaps less prejudicial to health systems than the major cause of the human resource crisis, which according to the WHO, is the international migration of biomedical healthcare practitioners to Northern countries.\(^\text{18}\) The evidence shows that most African countries have become “exporters” of human resources in healthcare.\(^\text{19}\) The West, particularly the United Kingdom and the United States, are the receiving countries. Data provided by the WHO indicate that Nigeria and South Africa have the highest number of medical doctors working in Northern countries.\(^\text{20}\) Statistics have shown that 21,000 Nigerian doctors were practicing in the United States alone in 1995. This was about the same number of

\(^{13}\) Crisis in Human Resources for Health in the African Region (2007) 7:1 African Health Monitor 1-49 (A WHO Regional Publication) [‘Crisis in Human Resources for Health in the African Region’]. In this issue, medical scholars and researchers with the WHO outlined the evidence of the crisis in human resources in healthcare in Africa.

\(^{14}\) Ibid.

\(^{15}\) Ibid.

\(^{16}\) L.G. Sambo, “The Human Resources for Health Crisis in Africa” in Crisis in Human Resources for Health in the African Region, ibid at 4 [‘Sambo, ‘The Human Resources for Health Crisis’’].

\(^{17}\) L. G. Sambo, “Working Together for Health” in Crisis in Human Resources for Health in the African Region, supra note 13 at 1.

\(^{18}\) Ibid.

\(^{19}\) Magda Awases, “Migration of Skilled Health Professionals in the African Region: An Overview” in Crisis in Human Resources for Health in the African Region, supra note 13 at 29 [‘Awases’].

\(^{20}\) Ibid at 30.
The problem of workforce shortages in Nigeria is emblematic of what the WHO has described as a “crisis in human resources in health”\(^2\) in the entire African region traceable to the migration of Nigerian physicians to North America and Europe.\(^3\)

The human resources shortage in the healthcare system is further complicated by the “inequitable spatial distribution of health workers,” which has resulted in serious “urban-rural imbalances” in African communities.\(^4\) The contributing scholars to the WHO’s 2007 publication on the crisis recommended a number of viable options on how countries should “treat, train and retain health workers” to cater to the healthcare needs of 736 million people in the African Region.\(^5\) However, the scholars failed to discuss the efforts of indigenous medical practitioners (IMPs)—who are healthcare professionals skilled in the delivery of medical care through natural and holistic therapeutic methods, and are knowledgeable about local needs and resources—to provide affordable healthcare services to their populations.\(^6\) Similarly, states have failed to address the IMP’s role in strengthening health systems. While there continues to be an influx of proposals for addressing the international migration of healthcare professionals and the human resources in healthcare problem,\(^7\) most of the solutions are limited to expanding

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\(^{22}\) See generally \textit{Crisis in Human Resources for Health in the African Region}, supra note 13.

\(^{23}\) Awases, supra note 19 at 30.

\(^{24}\) Sambo, “The Human Resources for Health Crisis”, supra note 16 at 4 (According to the author, another factor underlying the lack of health workers is the HIV/AIDS epidemic, which has increased the number of people who need care, treatment and support).

\(^{25}\) \textit{Ibid} at 5.

\(^{26}\) Note, however, that an article written by Seydou Coulibaly in the volume reports on using a locally developed community initiative in improving the availability of healthcare workers in rural Mali. The initiative improved the availability of health staff and had a positive impact on unemployment. The initiative showed that community participation in the management of healthcare services could increase the provision of health services throughout the country. The initiative supported the recruitment of locally-trained health workers so that the healthcare facilities were managed by people knowledgeable about the “socio-cultural realities” of the populations in their areas of service. Although Coulibaly’s work does not address indigenous healthcare workers, yet it provides evidence on how community and local resources could play an important role in improving healthcare delivery: Seydou Coulibaly, “Recruitment and Use of Health Staff by Communities in Mali” in \textit{Crisis in Human Resources for Health in the African Region}, supra note 13 at 41.

\(^{27}\) See the \textit{World Health Assembly Resolution} on the “International Recruitment of Health Personnel: Global Code of Practice” adopted at the 63rd World Health Assembly, Geneva, May 21, 2010. According to the Resolution, “[t]he code of practice on the international recruitment of health personnel aims to establish and promote voluntary principles and practices for the ethical international recruitment of health personnel. It provides Member States with ethical principles for international health worker recruitment that strengthen the health systems of developing countries. It discourages states from actively recruiting health personnel from developing countries that face
and/or retaining biomedical professionals. Proposals for an expansion of healthcare actors to include both public and private actors at both the national and international levels are an example. The scholarship on the approaches to health governance generally omits the category of actors, such as IMPs, who practice on the fringes of the health system. Since these practitioners play a major role in sustaining healthcare delivery in underserved communities, it is arguable that the most latent factor in the problem of inequitable healthcare access is government’s failure to coordinate national human and material healthcare resources towards achieving a functional or equitable healthcare system.

Statistics on the nature of the resources available to some Southern states further illustrate this view. The available data show that while more than 80 percent of Nigeria’s population rely on indigenous medical systems (IMS), there are only about 34,923 doctors for the country’s 140 million population. Ironically, a 1998 Report of the Joint United Nations Program on HIV/AIDS and Folk Medicine in Africa states that there are about 900,000 “traditional” healers registered with the Association of Folk Medicine Practitioners in Nigeria. South Africa is reported to have more than 700,000 “traditional” healers. The Zimbabwe National Traditional Healers’ Association has a list of 50,000 healers, while more than 450,000 healers are registered with the Senegalese Melango Union established in 1983.

Even in Western nations, such as Canada and the United States, a growing number of healthcare consumers are turning to IMS and invoking constitutional rights in the rising spate of legal challenges against the denial of government subsidy for use of indigenous and alternative medicines. A recent study by the Fraser Institute in Canada reveals that 74% of Canadians

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28 Indigenous Medical Systems (IMS) as explained below and as defined in subsection 2.2.1. comprise the totality of therapeutic knowledge, methods and systems, including the natural, psychosomatic, psychosocial and mystical, employed in maintaining health or preventing, diagnosing and treating illness, which are based on mechanisms and theories that may or may not be explicable through Western biomedical philosophy. See subsection 2.2.1 for the complete definition and for a further discussion of this definition.
30 Notably, women constitute half of the 450,000 practitioners in Senegal and they are said to practice in about 264 villages. See Report of the Joint United Nations Program on HIV/AIDS and Folk Medicine in Africa (1998).
utilize ‘complementary and alternative medicines’ (CAM). In another study funded by Health Canada, it was established that 71% of Canadians regularly use herbal medical products, homeopathic medicines, and related products that fall within the category of natural health products (NHPs). In spite of these impressive statistics on usage, no comprehensive study has yet been conducted to investigate how these alternative approaches to healthcare delivery might assist in reducing the burden on conventional healthcare delivery in the country. Given these statistics, it is not surprising that annual out-of-pocket expenditure on CAM in Canada and the US is about $3.8 and $34 billion respectively. There is presently no comprehensive insurance coverage of CAM in these countries. Similarly, most Southern states have neither comprehensive payment schemes nor legal frameworks to govern the use of indigenous medicine in the interest of the large number of citizens who rely on it. Indeed, the WHO reports that only twenty-five of a hundred and ninety one World Health Organization member states have national policies on indigenous medicine. Yet, more than 80% of the peoples in that part of the world conventionally denoted as the ‘Third World’ depend on indigenous therapies for their healthcare needs.

Indigenous medicine, commonly denoted as ‘traditional medicine’ in the South and as ‘complementary and alternative medicine’ (CAM) in the North, is internally eclectic and encompasses a broad variety of diagnostic and therapeutic methods or systems, including herbalism, naturopathy, homeopathy, osteopathy, acupuncture, massage therapy, chiropractic, traditional orthopedic surgery (otherwise known as ‘bone-setting’), amongst others. Some systems of medicine within the broad umbrella of indigenous medicine are built upon philosophies and mechanisms of action that are fundamentally different from the logics of

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Western allopathy.\textsuperscript{35} Each region of the world – whether Africa, Asia or the Americas – has its own unique therapeutic system closely modelled to suit its ways of life.\textsuperscript{36} However, one commonality between many of these systems is the practice of herbalism – the use of herbs in medical treatment. Herbalism could be described as indigenous pharmacopoeia.\textsuperscript{37} Notably, medical diagnosis and pharmaceutical expertise are unified within many indigenous health systems. Thus, the use of plants for therapeutic purposes in many indigenous communities is not limited to knowledge of the active compounds in plants. Herbal or plant medicinal resources are crucial to the survival of indigenous medical cultures, and are arguably the most essential part of the IMP’s armamentarium. Indeed, biological and botanical information belong to the class of the most important information types necessary for survival in any of the world’s cultures, indigenous or otherwise.\textsuperscript{38}

This study focuses on the role of these systems of medicine in achieving an equitable healthcare system and on the related approaches adopted by Northern and Southern states to the governance of health systems. The study is primarily concerned with how the medical cultures of the South could be integrated with the Western biomedical culture towards the creation of a derivative: “Integrated Medicine”. The proposal for an integrated healthcare system is directed at creating greater access to healthcare services and products in the South, as well as in underserved populations in the North, through the deployment of indigenous medical providers to specialized tasks within the national or provincial healthcare delivery system and the incorporation of natural health products (NHPs) into national or provincial drug formularies. Most discussions of this phenomenon have not duly acknowledged or dwelt on the legal nature of this proposal. The concept of medical integration is deeply intertwined with law and is reliant on the force of law for its implementation and success.

Laws and policies undergird the functioning of health systems, and these laws have a significant impact on medical practice. The centrality of the legal order to health systems is

\textsuperscript{35} The emphasis on ‘some’ is important considering that many indigenous therapies are based on observable and verifiable logic.
\textsuperscript{36} See generally Abayomi Sofowora, \textit{Medicinal Plants and Traditional Medicine in Africa} (Ibadan: Spectrum Books, 1993) [‘Sofowora’].
evident in law’s ability to “‘define’, ‘initiate’, and ‘buttress’ institutions’. Law is the state’s main instrument for systematic institutional reform. Thus, the discourse on a major institutional reform, such as medical integration, of necessity involves a treatise about the institutional function of law. Part of the objectives of this study is to address the legal, institutional and conceptual barriers that circumscribe the concept of medical integration. This study analyzes these barriers as corollaries of extant approaches to health systems governance. Hence, the discussion of these barriers is situated within the evolving discourse on health governance. Health governance itself denotes the management of health systems, and involves law and policymaking, as well as policy implementation. The other major objective of this study is to connect the elliptical relationship between health governance and integrated medicine while identifying the influences of the former on the realization of medical integration.

Thus, observing that health systems reform whether or not geared towards the creation of a specific model of healthcare requires the formulation of a theory for health governance, the study highlights the link between the failings of African health systems and the lack of a contingently-formulated theory of governance. While acknowledging that ‘theory’ ensures that laws and policies are grounded on the lived experiences of legal subjects, the study investigates whether there exists among current models of governance a feasible theory of governance for the specific reform initiative of medical integration. A feasible governance theory not only dictates the shape of laws and policies, it also guards against any incongruity between law and reality in the management of a country’s healthcare system. The South’s abundant medicinal resources and the accessibility of indigenous medical practitioners make this a subject long due for analysis.

40 Ibid.
41 See ibid at 64.
42 For example, the failure of the World Bank’s health policies for Sub-Saharan Africa in the 1990’s is traceable to the disparities between their capitalist policies and the social, cultural and economic realities in Africa. This will be revisited in chapters 2 and 5.
1.2. Medical Pluralism and Indigenous Knowledge

Medical pluralism is the co-existence of “differently conceived and designed” healthcare paradigms within a given society.\textsuperscript{43} These systems could exist together, and may either compete with, or complement, one another.\textsuperscript{44} Each system is composed of a set of explanatory theories about disease and illness and each adopts a different approach to the treatment of disease. These approaches, including the biomedical approach, are often tied to the prevailing culture of the people,\textsuperscript{45} as “no knowledge is exercised in a cultural vacuum”.\textsuperscript{46} Indigenous medical systems are entrenched within “a complex psychosocial paradigm”\textsuperscript{47} and this differs from Western allopathy which largely deemphasizes non-specific elements in the search for disease symptoms and causative agents. Non-allopathic healing systems have often been characterized, albeit too broadly and incorrectly, as “anti-scientific”.\textsuperscript{48} Scholars who hold this view attempt to place medical systems within regiments classifying Western biomedicine as “governed by objective and rational rules of proof” and indigenous medical systems as largely based on the “beliefs and choices of lay persons”.\textsuperscript{49} This insular view of the world is based on the Western belief that the non-allopathic healer belongs to “one single and indivisible compartment devoid of methodological or analytical scientific investigation”.\textsuperscript{50}

However, while the differences between Western allopathy and indigenous healing modalities have been variously theorized as vast and sometimes irreconcilable, other scholars have rightly noted that knowledge is itself a contested category.\textsuperscript{51} Perhaps, the central misunderstanding in the supposed schism between Western medicine and its Other is the ambiguity inherent in the term, ‘science’ or ‘scientific knowledge’. The expression, ‘scientific knowledge’, is “ambiguous” because “the word ‘science’ is often used as a synonym for

\textsuperscript{43} Obi Aginam, “From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World” (2002) 3:1 Chicago Journal of International Law 102, also online: Social Science Research Network <http://ssrn.com/abstract=319162> at 10 [‘Aginam’].
\textsuperscript{44} Ibid; see also D.R. Phillips, Health and Healthcare in the Third World (London: Longman, 1990) at 75.
\textsuperscript{46} Chidi Oguamanam, International Law and Indigenous Knowledge: Intellectual Property, Plant Biodiversity and Traditional Medicine (Toronto: University of Toronto Press, 2006) at 8 [‘Oguamanam’].
\textsuperscript{47} Ibid.
\textsuperscript{49} Ibid.
\textsuperscript{50} Aginam, supra note 43 at 9.
\textsuperscript{51} Oguamanam, supra note 46 at 14.
knowledge". Since “science is generally considered a way of knowing”, it is therefore arguable that “every knowledge system with a systematic and formulated basis is scientific”.

In spite of these debates on the validity of indigenous medical systems (IMS), there is heightened scholarly interest in the concepts of medical pluralism and integration. The scholarly interest in these concepts is traceable to global trends in the rising costs of healthcare delivery in both the North and South, and the rising consumer interest in indigenous medical systems. The global financial trends have influenced the increased advocacy for a health system that seeks first to prevent – using available resources – rather than simply to cure. The call is primarily for a redirection of research funds into the expanding market for indigenous medicines or CAM. Population health researchers argue that the investment of money and resources into these preventive ‘alternative’ initiatives is a more efficient healthcare management scheme than the investment of resources into the “fiscally inefficient” system of palliative care. Some other studies have positively identified the need for collaboration between healthcare providers of different medical cultures. For example, the International Development and Research Centre (IDRC) has noted that “health system policies that do not acknowledge and integrate traditional healers are likely to be inefficient”. This is because:

Traditional healers are...well aware of the various treatment options that are locally available and accessible as well as the physical, emotional and spiritual characteristics of individuals, knowledge which in turn allows them to influence their behaviour (UNAIDS: 2002)... Traditional healers...can also become “effective agents of communication on social and health issues. They can thus be used to play a major role in disease-prevention activities and in the development of a better public health policy”.

The role of indigenous medical practitioners in community healthcare delivery is particularly relevant in the context of the geographical discrepancies in accessing healthcare

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52 Ibid citing Gregory Cajete, Native Science: Natural Law and Interdependence (Sante Fe, NM: Clear Light Publishers, 1999) at 14.
53 Oguamanam, supra note 46 at 14.
54 Tataryn and Verhoef, supra note 1 at VIII.94.
55 Ibid.
56 See generally Tataryn and Verhoef, supra note 1. See also Anne-Marie Schryer-Roy and Sandy Campbell, eds., Towards an Ideal African Health System?, online: International Development Research Centre: <http://www.idrc.ca/uploads/user-S/11720008761Towards_an_Ideal_African_Health_System.pdf> at 19 ['Schryer-Roy and Campbell'].
57 See ibid, Schryer-Roy and Campbell.
58 Ibid citing Dr. Samuel Yonkeu, a contributor to the paper. Emphasis added.
facilities in many rural communities. This problem has led to a rising interest in community-based health services, which integrate a host of services delivered by different healthcare experts to meet the shortfalls in community healthcare delivery. The World Health Organization’s Commission on Microeconomics and Health (CMH) has termed these community-based initiatives the “close-to-client” services.\textsuperscript{59} The healthcare experts who work within such initiatives have often included nurses, physicians and other community health experts. Indigenous medical practitioners, who have become a primary healthcare resource for Southern countries, are usually not included in these initiatives.

The exclusion of indigenous medical practitioners and their systems of medical care from these types of initiatives may be traceable to the rise of Western scientific medicine in the beginning of the 19\textsuperscript{th} century. This historical era marked the period of the great philosophical upheaval when Cartesian scientific materialism was introduced into the theory and practice of healthcare.\textsuperscript{60} According to Robert Bannerman \textit{et al}:

\begin{quote}
The new way of looking at things subjected all assumptions to experiment and statistical validation and foresaw the future in terms of research and organization. Of necessity it introduced doubt where previously there had been belief; it emphasized intellect and logic and belittled emotion and intuition. Its method was to break up complex phenomena into their component parts and deal with each one in isolation. In diagnosis this approach resulted in search for a single cause; in pharmacology the search was for an active principle that could be isolated; and in the doctor-patient relationship the search for an efficient treatment of the physical cause of symptoms tended to exclude any serious interest in the complexity of the life situation in which the patient was immersed.\textsuperscript{61}
\end{quote}

The outcome of this trend over the years has been the marginalization of IMS by governments and international donors.\textsuperscript{62} Based on their espousal of scientific medicine, states make laws that undermine non-Western forms of knowledge. This is achieved through their tacit legitimization of rules that draw upon the medical understandings of sickness and health.\textsuperscript{63} Over the years, Western biomedicine has grown into an organized, influential system from its alliance with the

\begin{footnotes}
\footnote{Ibid.}
\footnote{Bannerman, \textit{et al.}, \textit{supra} note 45 at 11.}
\footnote{Ibid.}
\footnote{Schryer-Roy and Campbell, \textit{supra} note 56 at 19.}
\footnote{Sarah Cant and Ursula Sharma, \textit{A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State} (London: UCL Press, 1999) at 12 [‘Cant and Sharma’].}
\end{footnotes}
state and its espousal of the scientific research paradigm as the foundation for its claims to knowledge and expertise.\textsuperscript{64}

\textbf{1.2.1. Indigenous Knowledge, Intellectual Property Law and Medical Integration}

A crucial, interconnected issue to the concept of medical integration is the debate on how the medicinal plant resources of the South may be legally protected from expropriation by Western multinational and national pharmaceutical companies. The interconnection between both discourses arises in the context of the interest of the latter in bioprospecting in the South. Bioprospecting involves the search for plant genetic resources or natural compounds existing in nature for the purposes of drug production.\textsuperscript{65} The search for genetic resources in some Southern countries, such as Nigeria, has generated a major debate about the need to protect indigenous medicinal resources and products through intellectual property law. The practitioners’ concerns about juridical protection for their creative knowledge has led to a controversial trend involving secretive practice by IMPs and a decline in the number of practitioners who are willing to submit their health products to the National Agency for Food and Drug Administration and Control for review. This issue has been contentiously debated by both the national and international legal communities. This section introduces the debate and its impact on medical integration and healthcare in the South.

The South is rich in biodiversity. In fact, the African region is said to contain a quarter of the world’s biodiversity, which includes an extensive range of habitats from expansive savannah plains and tropical forests to some of the most outstanding freshwater systems in the world.\textsuperscript{66} Africa also has up to 60,000 plant species occurring on the continent, “including 35,000 endemics that occur nowhere else on earth”.\textsuperscript{67} These resources are conserved and developed by indigenous medical professionals (and agriculturists). Western multinational

\begin{thebibliography}{9}
\bibitem{64} Ibid at 11.
\bibitem{67} Ibid.
\end{thebibliography}
pharmaceutical corporations utilize the knowledge and skills of the practitioners and farmers in the production of drugs. A substantial number of medicinal products are said to have originated in Africa and these products are the origins of a significant number of the prescription drugs of the West. The products developed from bioprospecting are patented and marketed by the corporations at significant profits. It is noteworthy that the favoured products are often “drugs that pay”, and this is because of the huge financial investments needed for drug development. Thus, bioprospectors often focus on products, “such as anti-obesity drugs, anti-depressants, cardiotonics and cancer treatments”, for the more profitable Western markets which guarantee financial returns on drug investments. These products do not cater to the needs of millions of Africans and Southern peoples who suffer daily from malaria, typhoid, or cholera. Thus, regardless of the vast resources of the South, most Southern countries, especially in the African region, face a healthcare crisis complicated by the interest of Western pharmaceutical corporations in their resources.

The World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has further consolidated the bioprospecting activities of these corporations through its restrictive standards for patentability. The TRIPS Agreement requires that a patented product must be novel, inventive or non-obvious and capable of industrial application. The novelty requirement requires that patented products must be original. This prevents the patenting of indigenous medicinal knowledge that has either been published or openly used before the filing date of the patent application. The popular characterization of

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68 Wynberg, *ibid* at 83.
71 Wynberg, *supra* note 66 at 92.
72 *Ibid*.
75 See Art. 27(2), TRIPS Agreement.
76 C.M. Correa, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* (Geneva: South Centre, 2002) at 40 [‘Correa’].
indigenous medicine as existing in the public domain implies that it lacks novelty and, hence, fails to meet this standard for patentability in the TRIPS Agreement.\(^7\) The inventive step or non-obviousness criterion requires that the invention sought to be patented must be non-obvious to a person with ordinary skills in a given technical field. Although an invention may be found to be novel, it will not be patentable if it is proven to be obvious or lacks an inventive step.\(^7\)

Finally, the product must be capable of scientific reduction through the industrial process.

The assumption within both the TRIPS Agreement and the scholarship emanating from the North is that indigenous knowledge of medicinal plants does not meet the requirements of the TRIPS Agreement, and can at best be described as raw material for Western drug production. Thus, the question traded between the North and South is whether the pharmaceutical ‘innovations’ derived from indigenous knowledge can truly be considered novel products of the Western pharmaceutical companies who hold patents over the drugs; or whether the products are innovations of the indigenous farmers and healers whose expert knowledge of herbs, gained through years of practicing herbalism, led to the discovery and formulation of the new drugs. The charge against the North by the South is that the former appropriates the South’s expert knowledge of biodiversity. This charge is captured by the term biopiracy'. The term was conceived by Canadian activist, Pat Mooney.\(^7\) ‘Biopiracy’ captures the South’s angst over what they believe to be the unlawful appropriation or “pirating” of their natural resources without their due informed consent.\(^8\)

Biopiracy is facilitated by the patenting requirements of the TRIPS Agreement, which prohibit the patenting of products of indigenous knowledge.\(^8\) Products of indigenous


\(^8\) Correa, supra note 76 at 43.

\(^7\) Ikechi Mgbeoji, Global Biopiracy: Patents, Plants and Indigenous Knowledge (Vancouver: UBC Press, 2005) ['Mgbeoji, Global Biopiracy’] at 12.

\(^8\) Ibid.

\(^8\) See generally Mgbeoji, Global Biopiracy, ibid, where the author discusses the appropriation of the South’s medicinal resources as a process legitimized by current intellectual property regimes.
knowledge have to be industrially processed to be patentable under the third requirement for patentability. Carlos Correa has noted that patent offices are likely to assess indigenous medicinal knowledge through the lenses of Western knowledge “as long as they do not recognize TRM (Traditional Medicine) as a valid system of knowledge”. There is, therefore, an epistemological rift between the North and the South on what constitutes ‘medicine’ and on what is patentable. At the root of this epistemological controversy is the fact that the patent system is rooted in the Western scientific knowledge system, which insists that knowledge must be scientifically reducible to come within the legal protection offered by the patent system. Central to this issue is the question whether the patent system is suitable to protecting indigenous medicinal knowledge or whether a new intellectual property instrument should be fashioned for the latter. Notably, these dialogues are occurring against a backdrop of a globalizing market economy that values resources almost exclusively in terms of their monetary value.

These legal questions are also operative at the national level because most national patent laws are constructed on the principles of the international patent system and incorporate the legal requirements of the TRIPS Agreement. For example, general provisions governing patentable products in the Nigerian Patents and Designs Act are modelled after the Western patent system. In line with the TRIPS Agreement, an invention is patentable in Nigeria “if it is new, results from inventive activity and is capable of industrial application, or if it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application”. Therefore, indigenous medicinal knowledge often encounters the same difficulties under national patent laws as it has encountered under the international patent system.

Importantly, the standards for patentability stipulated by the TRIPS Agreement (and adopted by the Nigerian Patents and Designs Act) have particular implications for the concept of medical integration or integrated medicine at the national level. For example, the unacknowledged use of the medicinal knowledge of indigenous peoples for drug production in the North has had the effect, among others, of discouraging Nigerian herbalists from active

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82 Correa, supra note 76 at 43.
83 See Bratspies supra note 77.
85 Ibid, s. 1(1) (a) and (b).
participation in a regulation process that requires them to disclose the constituents of their medicines to the national drug regulation agency. The former Director-General of Nigeria’s National Agency for Food and Drug Administration and Control (NAFDAC) confirms that local practitioners have fought the regulation of herbal medicinal products and related therapeutic substances based on fear of losing their indigenous knowledge of medicinal plants, as well as their intellectual property rights to bioprospectors. Over the years, this insecurity has led to secretive practice by practitioners.

Fundamentally, neither the concept of integrated medicine nor indigenous medicine itself can thrive under such a closed system of practice. This oppositional attitude on the part of the practitioners constitutes a major barrier to the regulation of therapeutic products and consequentially, impedes the process of medical integration in Nigeria. Since health systems and products regulation are an integral part of any proposal to integrate medical systems, the need to provide a valid legal framework for the protection of the medicinal knowledge of indigenous medical practitioners is inseparable from the discourse on medical integration.

1.2.2. A Note on Terminologies

Indigenous medicine is commonly known as ‘Traditional medicine’. However, it has also been variously called unorthodox, unconventional, folk, ethno, native, fringe, unofficial, and complementary and alternative medicine (CAM). While each of these terms has been employed to identify the numerous diagnostic and therapeutic methods situated outside Western allopathic medicine, the subtexts of the definitions associated with the terms also carry specific opinions about the therapeutic practices falling within these terms. Each term identifies the form(s) of medical care to which it relates as a system(s) of therapeutic practice that exist(s) outside the more generally standardized Western allopathic system. The accompanying definitions fall into different categories. While some definitions have been merely descriptive and nonjudgmental, others have provided normative criteria, stating that non-allopathic therapies are yet to meet

86 Dora Akunyili, “Registration and Regulatory Requirements for Production and Marketing of Plant-Based Medicines” (November 29, 2005) at 2 and 3, paper presented by the Director-General of NAFDAC at a stakeholders meeting organized by the Nigerian Natural Medicine Development Agency on IP rights and traditional medicine knowledge and practice in Nigeria, on file with author.
87 See Ibid.
some biomedical or scientific standards of efficacy.\textsuperscript{89} Other definitions have been merely stipulative, providing a shopping list of therapies considered traditional, complementary or alternative without more.\textsuperscript{90}

The subtext of many definitions of ‘traditional’ or ‘complementary and alternative’ medicine, especially definitions in the normative category, is evocative of the ‘scientific’ and ‘unscientific’ dichotomy that supposedly exists between the medical systems, and endorses a specious hierarchy between Western biomedicine and indigenous medicine. Thus, the choice of the term ‘indigenous medicine’ in this study is strategic, so also is the choice of ‘indigenous knowledge’ to describe what is more commonly known as ‘traditional knowledge’ of therapeutic plants. Since this study addresses the so-called ‘traditional’ medicinal knowledge of indigenous peoples as part of the broader ‘indigenous medicine’ discourse, it is necessary to also discuss briefly the choice of ‘indigenous knowledge’ over ‘traditional knowledge’.

Besides the binary scientific/unscientific impression about the nature of indigenous medicine \textit{vis-à-vis} allopathic medicine created by the word ‘traditional’, the use of the term to describe therapies and medical practices that exist outside the allopathic system not only produces a jaundiced view of these systems of medicine, but more importantly, comes with a set of adverse legal implications in the area of health governance and intellectual property law. The terms, ‘traditional medicine’ and ‘traditional knowledge’ and the associated definitions convey the impression that the medical systems they represent are rudimentary, non-specialized, and uninventive. These connotations are evident in the legal treatment of these medical systems in the specific area of medical malpractice law and within intellectual property law. For example, indigenous medical practice is often perceived to be non-standardized. This denotation places non-allopathic therapeutic practices \textit{outside} or \textit{below} the standard operable in Western allopathic medicine. The effect of this is that physicians’ practice of indigenous medicine constitutes medical malpractice \textit{per se}.\textsuperscript{91}


\textsuperscript{91} See generally M.H. Cohen, \textit{Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution} (Ann Arbor: The University of Michigan Press, 2003) [‘Cohen, Beyond Complementary Medicine’].
Indigenous medical systems face a related set of problems within the scholarly and legal definition of ‘traditional knowledge’ under intellectual property law. ‘Traditional medicinal knowledge’ falls within the broad class of ‘traditional knowledge’. The common expression, ‘traditional knowledge’ has no fixed definition. It is commonly represented as “a multifaceted concept that encompasses several components”, which may include knowledge of the creative arts, medicinal knowledge or biodiversity, traditional songs and dances, traditional fashion designs, folklore, etc held traditionally and collectively by a people.92 These descriptions of ‘traditional knowledge’ imply that it is communally owned property. Other definitions suggest that ‘traditional’ knowledge exists in the public domain and is handed down from one generation to another.93 The characterization of ‘traditional knowledge’ as communal property and public or transgenerational knowledge has certain implications in law. These implications, as already noted, are related to the standards for patentability under the TRIPS Agreement. The attribute of ‘traditionality’ and the characterization of ‘traditional knowledge’ as communal, transgenerational, uninventive, and a public good are adversative to the requirements of novelty, inventiveness and industrial applicability stipulated by the TRIPS Agreement.94 By implication, indigenous medicinal knowledge is not patentable. Ironically, these attributes are not generally true depictions of the nature of the art forms grouped within the umbrella of ‘traditional knowledge’.

For this reason, this study employs the expressions ‘indigenous medicine’ and ‘indigenous knowledge’ to capture the medicinal knowledge and products generated by peoples of various communities and enclaves in both the South and North. Since all medical systems and practices are traceable to particular geographies, cultures, and times and, as argued in chapter two, can be spatially and temporally analyzed, the term “indigenous knowledge” is herein employed to denote the knowledge systems and practices indigenous to particular communities and nation-states in contradistinction to knowledge systems traceable to the Western biomedical tradition. As used in this study, the term ‘Indigenous’ carries its literal meaning. It is detached from the arguments in international law regarding what constitutes

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94 TRIPs Agreement, Art. 27(2), supra note 74.
‘indigenous peoples’ or ‘indigenous peoples’ knowledge’. It is noteworthy that there are debates about the applicability or suitability of the expression, ‘indigenous peoples’ knowledge’, to describe what is widely known as ‘traditional knowledge’. 95 Some scholars have noted that the use of the term is “restrictive” given the tenor of some definitions of ‘indigenous peoples’ in international law.96

Indigenous peoples are defined narrowly under international law.97 For example, in a Report for the United Nations, Martinez Cobo describes indigenous communities, peoples and nations as “those which having a historical continuity with pre-invasion, and pre-colonial societies that developed in their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them”.98 This definition bears some similarity to that proffered by the International Labour Organization Convention. Under Convention 169 of the International Labour Organization (ILO), indigenous peoples are defined as descendants of “populations that inhabited a country at the time of conquest, colonization, or the establishment of present state boundaries, and who irrespective of their legal status, retain some or all of their own social, economic, cultural, and political institutions”.99

Like Martinez Cobo’s definition, the description of indigeneity offered by the ILO Convention regards “historical continuity with pre-invasion”, subsistence of colonial invasion and socio-cultural, economic and institutional identity as the defining factors of indigeneity. This standard of indigeneity is unduly limiting as it disregards the historical experiences of Africans and Asians.100 Indeed, in many formerly colonized Southern states, there are marginalized indigenous nationalities whose dilemma bears no direct relation to conquest and colonization.101 The standard of indigeneity required by these definitions implies that indigenous peoples whose institutions and cultural lives were “disrupted” by colonialism are

95 Mgbeoji, Global Biopiracy, supra note 79 at 9-11. See also Oguamanam, supra note 46 at 20-26.
96 Mgbeoji, Global Biopiracy, ibid at 9.
97 Oguamanam, supra note 46 at 20.
101 Oguamanam, ibid at 21.
denied indigenous status “for no fault of theirs”. ¹⁰² Whether or not a link exists between colonialism and the present challenges faced by these peoples, many of these peoples continue to live with relics of the colonial experience. On the other hand, it should be noted that the restrictive definition of indigenous peoples in international law was framed within “the discourse about aboriginal peoples of the American continents and other culturally distinctive groups”. ¹⁰³ This is the source of the argument that the term ‘indigenous’ has no general application to indigenous peoples worldwide.

However, this study takes the position that the narrow usage of the term ‘indigenous peoples’ in international law should not preclude an inclusive understanding of the term ‘indigenous’ as used in this work. In other words, the technical term ‘indigenous peoples’ as developed in relation to a specific group of people in the Americas need not be interpreted to negative the use of the term to address issues affecting other groups of people who share the same historical experience by which the indigenous peoples of the Americas are defined. In fact, it is imperative that the technicality and limitations of the term be contested in the interests of post-colonial peoples in the South who experience one form of deprivation or another traceable to North-South relations today. The discourse on the exploitation of the biological resources of many Southern societies falls squarely within this context. As Patel has noted, the word ‘indigenous’ can be used “in its broader connotation, meaning native, or original; this covers much wider canvas, including all those people who were native to the lands where indigenous knowledge…originated”. ¹⁰⁴ The important debate ought to be about the need to reject the restrictive definition of ‘indigenous peoples’ in international law since the choice of the less suitable term ‘traditional knowledge’ to refer to the knowledge of indigenous peoples worldwide is due to this definitional limitation.

This study refrains from adopting the common expression ‘traditional knowledge’ even though it is “less offensive”¹⁰⁵ than most other terms such as folk knowledge, ethnobotany, and

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¹⁰² Ibid.
¹⁰³ Ibid at 22.
¹⁰⁴ Surrendra Patel, “Can IPRs System Serve the Interest of Indigenous Knowledge?” in S. Brush and D. Stabinsky, eds. Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights (Washington D.C.: Island Press, 1996) at 308. It is noteworthy that this thesis rejects any inferences to the effect that indigenous knowledge is ‘traditional’ or ‘non-scientific’ which may arise from Patel’s use of the word “native”. Indeed, past usages of the term ‘native’ have had underlying negative connotations about the knowledge and values of indigenous peoples: see generally Abayomi Sofowora, supra note 36.
¹⁰⁵ Mgbeoji, Global Biopiracy, supra note 79 at 10.
“tribal knowledge”. Beyond its pejorative connotations, the expression ‘traditional knowledge’ remains fraught with entrenched misconceptions about the creative life of indigenous, Southern and other non-Western peoples in different parts of the world. Rather than overlook its shortcomings, this thesis suggests an overt acceptance of the expression, ‘indigenous knowledge’ as a less cumbersome term. The choice of ‘indigenous knowledge’ is based on the need to eschew all prejudiced and flawed conceptions of the knowledge and values of Southern and non-Western peoples, which are inherent in the terminologies, ‘traditional’ or ‘native’ medicine or ‘traditional’ knowledge and similar terminologies. This need far outweighs the problems inherent in the technical definition of ‘indigenous’ in international law.

In the choice of the terms ‘indigenous medicine’ and ‘indigenous knowledge’, this study acknowledges that some of the systems that fall within the rubric of these terms may not be indigenous to the communities where they are practiced. It is in recognition of this that this thesis accepts the term ‘alternative medicine’ to capture the holistic medical systems practiced in different Southern and Northern societies, aspects of which are substantially different from biomedicine in terms of the philosophies of disease causation and treatment and the mechanisms of operation. In this sense, ‘alternative medicine’ is a broader term than ‘indigenous medicine’ as the former encompasses medical systems that are not necessarily indigenous to the particular society in which they are practiced. It is important to emphasize that ‘alternative medicine’ in this context is merely a generic term for different medical systems, including biomedicine. In other words, biomedicine is as alternative as other medical systems whose philosophies differ from biomedicine’s conceptualization of disease or illness. Therefore, where appropriate, medical systems traceable to specific cultures or geographies are identified in this work by the names of those places from which they have originated. For example, medical systems traceable to Africa are referred to (where necessary or appropriate) as ‘African Medical Systems’ and those from India as ‘Indian Medical Systems’. The dominant taxonomy in North America, ‘complementary and alternative medicine’ (CAM), is used.

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106 See ILO Convention 169, which employs the term “tribal knowledge”. See David Baronov, The African Transformation of Western Medicine and the Dynamics of Global Cultural Exchange (Philadelphia: Temple University Press, 2008) at 132 [‘Baronov’] who notes that some terms, such as “witch doctor or medicine man” employed in describing those who practice “African pluralistic medicine” are “outdated at best and strikingly ethnocentric at worst”.

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restrictively and interchangeably with ‘indigenous’ and ‘alternative’ medicine when the
discussion focuses on indigenous medical practice in North America.

As is the case with ‘indigenous medicine’, ‘integrated medicine’ has been theorized and
expressed in different terms, including ‘integrative medicine’ and ‘integrated’ or ‘integrative
healthcare’.107 Boon et al. have adopted the term “integrative healthcare” on the view that the
term ‘integrative’ depicts the process of integration as evolving rather than completed.108
‘Integrated medicine’, the expression employed in this study, simply captures an ideal around
which the current progressive collaboration between biomedical and indigenous health
providers revolves. Although many healthcare systems have not yet arrived at integration, this
expression captures the intended model rather than simply the ongoing process of ‘integrative
medicine’.

Finally, this thesis adopts the terminologies ‘South’ and ‘North’ to describe the peoples
or countries commonly referred to as ‘developing’ and ‘developed’ or ‘Third World’ and ‘First
World’. While most countries (with the exception of Australia and New Zealand) that belong to
the North are indeed located in the Northern hemisphere, this study recognizes that ‘North’ and
‘South’ have often been employed to create a socio-economic and political distinction between
countries. However, the study distances itself from such usage on the reasoning that the political
and economic criteria that are employed to classify nations as ‘developing’ or ‘Third World’ are
questionable. The variable usage of these terms to describe a broad range of countries with
widely different and evolving economic, political and cultural experiences is unconstructive in
describing the actual statuses and needs of different communities.109

Nonetheless, this study recognizes that the adoption of the terms ‘South’ and ‘North’ in
this work could also be problematized because when used as an economic or political
denominator there is arguably a ‘South’ in the North – for example, when we consider the
country of Mexico whose economy and level of development places it outside the ‘developed’
group of nations. There might also be some dissension on the chosen terminologies because of
the growing heterogeneity in the classification of nations based on perceived indices as to their

107 See generally Perspectives on Alternative and Complementary Health Care: A Collection of Papers Prepared
for Health Canada (Ottawa: Health Canada, 2001); Heather Boon, et al., “Integrative Healthcare: Arriving At a
108 Boon et al., ibid.
economic or political growth. For example, nations like Brazil, China, India, and South Africa are increasingly being recognized as ‘Newly Industrialized Countries (NICs)’, while countries previously categorized as ‘developing’ such as Saudi Arabia, Qatar, Kuwait and Oman have now been classified as ‘developed’ or ‘high income economies’.

It is in recognition of these variables in economic and political criteria and of the fluidity of the increasing list of taxonomies that are employed to distinguish between nations or peoples that this study adopts the ‘Southern-Northern’ categories. The choice of these terms is strategic and signals this author’s lack of conviction that the dominant labels are apposite for describing nations with vastly different traditions, epistemologies or approaches to life. While questioning the definition of ‘development’ itself—and at the same time recognizing that states in the Southern hemisphere are not homogenous, this study employs the ‘Southern-Northern’ taxonomies to capture the divide between those countries (predominantly located in the Southern hemisphere) whose present legal and political systems have in some manner been shaped by the colonial encounter – whether historically or through interactions governed at the international level by European legal norms. To the extent that some nations, such as Mexico, Australia and New Zealand constitute exceptions when the terms ‘South’ and ‘North’ are employed in a geographical sense, this study employs at various times the expressions ‘indigenous’ and ‘non-Western peoples’ to denote communities or nation-states that hold epistemologically distinct worldviews and whose present political and social institutions have at some point been influenced either by the colonial experience or by their membership in an international community dominated by European law.

1.3. Racing Back to the Starting Point: From Empirical Data to Policy Decisions

1.3.1. Legal Issues and Hiatus in Scholarship

Most of the literature on the controversy over the regulation, patenting and ownership of the South’s medicinal resources have had a common focus identical to that which drives the global market economy: a concentration on the commercial value of indigenous knowledge and resources. Most of the scholarship has focused on the issue of a fair monetary compensation for the owners of the resources. Unfortunately, the focus on commercial benefits – which are to be derived from a transfer of the South’s resources to the Northern hemisphere for further research and development – discounts the legal, ethical and public health issues involved in this
discourse. It overlooks the healthcare crisis in the South, particularly in Africa, and the need for human and material healthcare resources to be pulled together towards establishing an equitable healthcare system. The assumption that the immense healthcare challenges facing the South could be resolved through the commercialization of biological resources as raw materials for Western pharmaceutical companies underrates the extent of the healthcare problem facing most countries of the global South.

The important question in the face of the healthcare crisis is whether the commercialization of indigenous medicinal knowledge and continuous concentration of political and financial resources on organized medicine (to the neglect of the indigenous medical institution) are in the best interest of the healthcare systems of the ‘donor’ countries. Some countries, such as South Africa, are already critical of the current trend in which dividends are the primary reason for bioprospecting. These countries are beginning to identify the importance of developing and supporting home industries producing phytomedicines, personal care products and food supplements.110 This initiative, it is hoped, is part of a gradual shift in the post-colonial reliance of the South on the North. Underlying this initiative is the need for greater self-reliance and independence from foreign aid. This work is concerned with such a progressive approach to health systems management. The study is undergirded by the philosophy that the healthcare challenges of the South necessitate an alternative approach to managing health systems involving the development and utilization of readily available resources to achieve the desired health goals. This will involve the deployment of local resources, including biological and manpower resources available to the South to the pursuit of better outcomes in healthcare delivery. Simply, this approach primarily involves the pursuit of health equity within the recesses of the South’s knowledge systems and resources. The growing discrepancy between the South’s economic power and the escalating costs of healthcare provides support for this proposition.111


Notably, since 1972 the World Health Organization (WHO) has made calls for countries to adopt an integrated national health system.\textsuperscript{112} The World Health Assembly Resolutions that have called for medical integration in Member States have variously noted that indigenous medical practitioners represent a vast manpower resource for the healthcare systems of Southern nations.\textsuperscript{113} The WHO’s 2008 Beijing Declaration on “traditional medicine” reopens the important discourse on the need to integrate indigenous and allopathic medicine.\textsuperscript{114} The ‘Beijing Declaration’ calls on WHO Member States and other stakeholders to take steps to integrate indigenous medicine and complementary and alternative medicine (CAM) into national health systems.\textsuperscript{115} The Declaration urges Member States to take action towards integration in five areas: national policy on indigenous medicine and CAM, national regulation of indigenous and herbal medicines, indigenous medicine in primary healthcare, national regulation of indigenous medicine and CAM practice, and research on indigenous medicine and CAM.\textsuperscript{116}

It is noteworthy that the integrated healthcare concept does not discount the importance of biomedical and technological care. Rather, the initiative involves an integration of the best available approaches from both biomedicine and indigenous medical systems. The proposition for medical integration envisions that the race for biomedical and technological progress of necessity would continue. However, the South would be persisting on a problematic, if not futile trajectory, were it to fail to employ all available resources in its coffers to achieve better health outcomes and reduce its dependence on foreign medical aid. The rise of the debate on medical pluralism and medical integration is in effect a journey \textit{back} to an integral approach to healthcare delivery involving the adoption of the most effective healthcare practices from different world cultures. This approach, as explained in chapter two, was already in practice in Africa before the advent of colonialism.\textsuperscript{117} This initiative, perhaps better expressed as a philosophy of medical independence, is in effect a metaphorical race to the starting point.

\textsuperscript{112} See “Health Manpower Development: Training and Utilization of Traditional Healers and their Collaboration with Healthcare Delivery Systems” (1975); World Health Assembly Resolution WHA29.72 (1976); World Health Assembly Resolution WHA30.49 (1977); World Health Assembly Resolution WHA31.33 (1978).
\textsuperscript{113} See \textit{ibid}.
\textsuperscript{114} \textit{WHO Congress on Traditional Medicine, 7-9 November 2008, Beijing, China}, online: World Health Organization <http://www.who.int/medicines/areas/traditional/congress/en/>.
\textsuperscript{115} \textit{Ibid}.
\textsuperscript{116} \textit{Ibid}.
\textsuperscript{117} See generally Baronov, \textit{supra} note 106.
A major impediment to this initiative, however, is the lack of a comprehensive analysis of the necessary legal reforms that would facilitate the establishment of an integrated medical system. The processes, compromises and resolutions necessary to support medical integration are interlinked with the legal process. The legal process, encompassing though not limited to lawmaking, judicial adjudication, legal hermeneutics, and institutional administration, influences the form and content of health systems. States have constructed these interlinking processes largely along the tenets of the biomedical or allopathic approach to healthcare delivery. Considering that law itself very often draws the materials for its rules from non-legal fields – as is the case with its rules on medical practice, it is no surprise that the atypical concept of integrated medicine faces significant legal hurdles, manifesting primarily in the form of legislative and hermeneutical voids. These legal voids are themselves products of a decontextualized system of health governance involving the adoption by Southern states of foreign legal processes, norms and institutions that were designed to govern biomedicine and the associated healthcare research agenda of the North. These legal voids and flawed systems of governance drive the need for a body of research on the legal, institutional and conceptual implications of integrated medicine. This study focuses on this hiatus in the research and scholarship on integrated medicine.

1.3.2. Research Questions and Hypothesis

The framework of the current legal process imposes three major legal impediments on integrated medicine. These legal barriers include the problem of ‘regulation’—used in a restricted sense to refer to the legitimization of health systems and the validation of health products; the lack of intellectual property (IP) protection for natural health products; and the problem of decontextualized ‘governance’—employed broadly to denote the totality of activities related to health systems management including but not limited to law and policymaking, research and development, financing, educational training through state-approved institutions, and of course regulation. The research questions at the core of this study are framed around these legal impediments. These broad legal issues are the subjects of chapters two to six of this study; and these chapters focus on how reforms to the extant order can advance the agenda of medical integration.
On the first issue—regulation, the thesis addresses the question regarding how indigenous and alternative medicine can be effectively regulated to account for the unique epistemological differences between indigenous medical systems and biomedicine. The question—as addressed in chapter three—is what other types of evidence besides evidence of safety and efficacy are necessary for regulation? The second research question relates to the IP barrier, and the question examined in chapter four is whether natural health products can meet the standards of the patent regime. The chapter also examines the question whether there exists a viable alternative to the current IP regime. The final research question, based on the problem of decontextualized governance which is the subject of chapters two, five and six, is whether a new approach to health governance can be devised to improve the provision of healthcare. This research question specifically seeks to unravel an approach that transcends both a simple bifurcation of public and private governance and the expanded approach that involves a broader category of public and private healthcare actors. The governance model set out in chapter six problematizes these extant approaches and raises questions about the extent to which there are truly interactions between the actors. It also questions whether there is an account of how these interactions take place as well as how the interactions can be legitimated at different strategic levels of the health system. The integral approach proffered in this study further problematizes the non-identification of the centrality of state actors to any collaborative governance agenda geared towards addressing population needs. Thus, it questions whether what the scholarship currently offers is a combined approach as between actors—global and local—without more—an approach that is manifestly inadequate in addressing the healthcare needs of underserved Southern and Northern populations.

The problem of governance – as a concept that encompasses the broader category of problems (including economic, fiscal, and political issues as well as poor health systems and health workforce planning) that have beset the health systems of many Southern states – is at the core of the analyses in this study. Thus, while investigating the legal issues outlined above as well as the types of legal and institutional reforms that may be necessary for an integrated medical system, the study contends that the primary barrier to the development of this system lies with the general approach of states to governing health systems. Notably, lawmaking and institutional management are themselves part of the overall framework of governance. The thesis contends that the failure of states to recognize, as well as frame health governance along
the intersecting influences of economics, culture, geography, politics, and even history – all contextual factors influencing consumers’ needs and healthcare behaviour – is a major contributor to the inability of Southern nations to achieve health equity. The thesis observes that states, especially in the South, have governed their healthcare systems based on transplanted laws, policies, institutions and mandates that do not meet the needs of those whose lives are affected by the laws and institutions. While contending that the transposition of institutions and norms without regard to the unique socio-cultural, economic, political, and historical landscape of (post)colonial states continues to exacerbate the healthcare problems of the South, especially in formerly colonized African states, this study proposes that health equity might not be attained without states’ grounding health governance in the context of the experiences of legal subjects.

1.3.3. Grounding Policy Decisions on Empirical Data: The Research Journey

1.3.3.1. Empirical Methodology: Statutes, Case Law and Field Research

In furtherance of the above proposition, this study adopts a contextualized analysis of the associated issues of health governance and medical integration, drawing most of the data from Nigeria and Canada. While Canadian law and approaches to the governance of CAM and integrated medicine serve in some way as a comparative tool for analyzing the approaches in the South, the choice of Canada for analytical purposes is based primarily on the increasing body of Canadian case law on CAM. These precedents provide accounts of legal and social trends in the practice and usage of alternative medicine. Canadian case law and legislative trends, including the social and scientific studies and scholarship on alternative medicine, have also served as predictive tools providing invaluable resources and insights into the analysis of the novel, diverse and often complicated issues implicated in the concept of integrated medicine. The Canadian analysis further highlights the similarity of aspirations between healthcare consumers in Canada and Nigeria on the subject of medical integration. Analyses and conclusions drawn are, as much as possible, based on research data on local systems in Nigeria and Canada. Available data from other countries, including the United States, India, and China are also utilized.

The resources and materials employed for the analyses in the chapters thematically reflect the proposition that states need to ground policies and recommendations on empirical information where available. Thus, apart from the mandatory analysis of the literature,
healthcare laws, policies, case law, and validated studies which exposed the problems herein addressed, this study utilizes data from research conducted in two of Canada’s largest cities (Toronto and Vancouver) and three rural communities (Ogwa, Ewu and Ekpoma) and a city (Benin) in Edo State, Nigeria. Toronto and Vancouver were chosen as the locations for the research because of the presence of reputable integrated health centres in the two cities. Ogwa, Ewu, and Ekpoma are three Nigerian communities that are generally regarded as rural communities even though Ekpoma is arguably a city because it boasts of the presence of a university and some of the highlights of any modern city. These three communities are not different from any other Nigerian community. Much like other rural communities in Nigeria, residents in these three localities have a more limited access to biomedical care than they would have in the cities, and generally rely more on indigenous medical systems to meet their healthcare needs. These communities, as well as the city of Benin, were selected for this study because of the presence of well-known indigenous healthcare centres and highly respected indigenous medical practitioners in the localities, four of whom consented to partaking in the study. Furthermore, these communities constituted ideal locations for the study because the investigator and research assistants are familiar with the Esan and Bini languages spoken by the members of the four communities.

The Canadian study involved semi-structured interviews with the clinical directors and co-directors of four integrated healthcare institutions: the Integrative Health Institute and the Medcan Clinic in Toronto, and the Inspire Health Integrated Cancer Care Centre and the Qi Integrative Health Centre in Vancouver. These clinics were selected based on the presence of professionals from both the biomedical and the indigenous healthcare professions within the clinics. This was in keeping with the focus of the thesis on ‘integration’ as opposed to ‘indigenous’ or ‘biomedical’ healthcare exclusively. Prior to the interviews, the practitioners were contacted through formal letters of invitation to participate in the study. The consent forms were signed before the interviews commenced. The practitioners were interviewed on a broad range of questions on internal administration and task sharing within the integrated health clinic, education and knowledge exchange between professionals, regulation, licensing and

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118 As at the time of the interviews in November 2009, the Qi Integrative Health Centre had a biomedically-trained Naturopath working in the clinic in her capacity as a Naturopath, and not as a physician. At this time, the clinical director had arranged for a physician to join the clinic in 2011.
scope of practice, diagnosis, treatment, and referral tradition in the centre, and informed consent and malpractice regulation. Other questions addressed policy issues regarding the prospects of integrated medicine on a national scale in Canada, the foreseeable barriers to medical integration and the problem of financial access to, and lack of insurance coverage for, alternative medicines. The practitioners’ opinions on all aspects of these issues addressed in the body of this work are reproduced in chapters three, four and six. These chapters respectively address regulation and evidence-based health policymaking, knowledge construction and intellectual property protection, and integrated governance involving regulatory and other legal process reforms within all levels of the healthcare system.

Structured interviews were conducted with four indigenous medical providers (IMPs) in Edo State, Nigeria. The interviews were structured because they were conducted through the assistance of researchers located in the communities, and who are members of the communities. The researchers are trained medical and legal professionals—the legal professional being also a US-trained social scientist familiar with this type of research. The centres visited are Pax Herbal Clinic and Research Laboratories and the Ebohon Orthopaedic Clinic, as well as the health centres directed by Drs. Omon Oleabhele, JP and Ehinoma Aiguobarueghian, ND. The choice of these practitioners was based on the diversity of their areas of specialty and the status of the practitioners in the province. The first healthcare centre, the Pax Herbal Clinic and Research Laboratories, which is arguably Nigeria’s leading indigenous healthcare centre with branches in several African countries as well as in the United States, operates as a primary healthcare centre with 600 accredited indigenous healthcare practitioners. The centre also boasts of over 200 regular staff, 10 scientists and a 10-member medical team. The second clinic, the Ebohon Orthopaedic Clinic specializes in orthopaedics, which is often described as bone-setting. Dr. Omon Oleabhele, JP is a well known and highly respected traditional psychiatrist, who also practices as an indigenous general practitioner in the province of Edo State. Dr. Ehinoma Aiguobarueghian, ND has over 50 years experience as an indigenous medical practitioner (IMP), and practices as a general practitioner.

Prior to the interviews, the investigator established formal contact with the practitioners through written invitations to participate in the study. There were follow-up phone conversations with practitioners to ensure that there were no questions or concerns related to the study. The signed consent forms were handed to the interviewers at the start of the interviews.
All interviews were video- and audio-recorded, with the exception of one interview in Nigeria which the interviewee declined video recording.

The questions were elaborately formulated and standardized, and covered most of the foreseeable issues that needed to be addressed. Follow-up questions were asked for clarification and elucidation on points strictly related to the itemized questions. The questions asked focused on the qualifications of practitioners, regulation of practice and products, models of payment for services, methods of diagnosis and treatment, the existence of integrated practices among providers, referral practices, and malpractice regulation. The policy questions addressed the prospects of medical integration and participatory governance involving the inclusion of IMPs in healthcare decision-making bodies in Nigeria; they also addressed practitioners’ perspectives regarding the necessity for insurance coverage for indigenous medicines. Other questions focused on the intellectual property and indigenous knowledge discourse in Nigeria, and specific questions on the discourse inquired into the (non)existence of ‘formulas’ or ‘recipes’ for natural health products, (non)disclosure of information by indigenous healthcare providers to the National Agency for Food and Drug Administration and Control (NAFDAC), and practitioners’ perspectives on the intellectual property law regime. The opinions of the practitioners are juxtaposed, where necessary, with those of the Canadian IMPs in chapters three, four and six.

The research also incorporates consumers’ perspectives on questions of equity and access, intellectual property law (IP), and policy proposals on integrated medicine. Questionnaires were employed in Benin, Ogwa, Ewu and Ekpoma to survey consumers’ opinions on a broad range of issues. Besides the fact that these four localities were the most accessible to the investigator and researchers – in terms of their expertise in the local language – there were no special considerations in the choice of these localities as the locations for the research. The four communities are no different from any other city or rural community in Nigeria. Residents of the communities generally share a similar life-experience as those in other cities and villages in Nigeria. The opinions of respondents were sought on equity and access related issues regarding their usage of biomedicine and indigenous healthcare systems, the geographical and financial accessibility of the services, wait-times in biomedical clinics vis-à-vis indigenous healthcare centres, payment methods for indigenous medicine, and consumers’ knowledge of the contents and methods of administration of indigenous therapies. The IP-
related questions on consumers’ knowledge of the contents and of the administration of therapies were designed to investigate the popular characterization of indigenous knowledge as a public domain resource, knowledge of which is said to be possessed by most members of the community. The policy questions focused on consumers’ opinions about medical integration, insurance coverage for indigenous medicines and the role of IMPs in community healthcare delivery.

The questions in the Canadian and Nigerian interviews were formulated to reflect the research questions arising from the study. Having identified the key questions posed by the study, the investigator refined the initial outline of questions for the Canadian study (as well as for parts of the Nigerian study) through insights obtained from examining a major validated study on integrated healthcare conducted in the United States. The investigator formulated research questions that were unique to the Nigerian context, such as the questions related to IP protection. The survey questions were also developed by the investigator. The author formulated each question to reflect the perceived problems in healthcare delivery in the relevant communities and as theorized in this study. The survey questions in totality capture the main issues – access and equity, other types of evidence, IP, and governance – discussed in relation to the three primary barriers to integrated healthcare identified in this work.

A total number of 300 questionnaires were distributed at university campuses, markets and shopping centres, public squares and in biomedical and indigenous healthcare centres. The survey was extended to both biomedical and indigenous healthcare centres to account for any professional or philosophical biases that might arise among participants (who included healthcare professionals, staff and healthcare consumers) in these centres. The survey was anonymous, voluntary, and inclusive. It was generally designed for respondents who had utilized either biomedicine or indigenous medicine. While 300 questionnaires were distributed, 220 questionnaires were returned. Data entry for both questions and responses was done through coding, using consecutive numbers for the questions and alphabetical ciphers for the responses. The outcomes were calculated in percentages based on computations of the relevant

119 M.H. Cohen, M. Ruggie, and M.S. Micozzi, *The Practice of Integrative Medicine: A Legal and Operational Guide* (Springer, 2006). The authors’ research was based on interviews with over twenty healthcare providers and facilities practicing integrated medicine.
alphabetical codes representing the specific research questions to be addressed. The results of the questionnaire survey are reproduced in chapters three and four.

The research outcomes collectively provide statistical support for the contentions in this work. However, it is important to issue a caveat that this is a small-scale study focusing only on four and two locations in Nigeria and Canada respectively. As such, in the absence of large-scale studies in these communities, the findings of this research should be interpreted as reflecting the situation in only some segments of the Nigerian community and the Canadian integrated healthcare community. While many nations in the South may share many of the experiences and outcomes described in this study, the outcomes of this research are not employed to recommend reforms in other nations. As expatiated in the rest of this chapter, the research data and outcomes address key issues discussed in the chapters of this work as they relate to the Nigerian and Canadian communities under study. These issues include the disparity in access to biomedical and indigenous care, the necessity for comprehensive evidence and a broader research paradigm for the regulation of indigenous medicines, and the need for patent reform to protect NHPs as well as to facilitate medical integration. Lastly, and most importantly, by identifying prevalent practices in the clinical setting that complement trends in consumer healthcare behaviour, and by highlighting the disparity between these practices and extant law and policy frameworks, the research outcomes substantiate the underlying thesis of this study – that this disparity represents a failure of governance. The research outcomes further support the contention that health governance must be reconceived to reflect the experiences of healthcare consumers and produce functional institutions that can address the needs of society members.

1.3.3.2. Theoretical Methodology

The choice of a fitting theory for analyzing the research questions in this study was closely linked to the hypothesis of the study. Given that the study is itself a challenge to existing healthcare laws and institutions, it was necessary to adopt a differing thesis on how health systems should be governed, that is, how health laws, institutions, and administrative practices should be framed if they are to produce the best outcomes for legal subjects. Thus, as outlined in chapter two, the study employs the interactional theory of law as developed by Lon L. Fuller and functional jurisprudence as enunciated by Felix Cohen because these theories recognize the
intercomplementarity of law and society which underlies the postulations of this study. This study draws upon Fuller’s treatise that promulgated laws must exhibit the cohesive relationship that ought to exist between law and the dynamics of societal norms, and on Cohen’s hermeneutical theory that law is meaningful only in the context of its application to real events (which he captures as ‘law-in-action’) to advocate for a new approach to health governance. It is, perhaps, necessary at this point to provide a further explanation, not so much of the choice of these theories but of the reasons for not adopting a related (for lack of a more apposite word) theoretical approach, such as the interpretive principles offered by Ronald Dworkin. \(^{120}\)

While Dworkin’s treatment of law as an ‘interpretive concept’ and his moral perspective of law and of the ideal judicial approach in hard cases certainly illumines some of the interpretive questions raised in this work, it was necessary to avoid theoretical conflicts between the propositions advanced in this study and Dworkin’s attempted distinction between a judge’s responsibility when individual rights are violated and (their ‘lack’ of responsibility) when the disputed issue relates to a matter of public policy. Dworkin’s attempt to draw a notional line between policy and principle is both obscured and contested by the subject of medical integration. In fact, the individual rights that consumers of integrated healthcare contend are violated by the law are also policy-based issues that test the boundaries of where a judge’s responsibility to creatively intervene in an alleged rights-violation claim begins and ends. And, because these issues also evoke both minoritarian and majoritarian policy questions, they further complicate any attempt to apply Dworkin’s thesis in the same manner in which Fuller’s and Cohen’s have been employed here.

### 1.4. Health Governance and Medical Integration

Health governance involves the management or administration of health systems and population health through the design and implementation of laws and policies to achieve specific health outcomes. \(^{121}\) Thus, the state’s approach to health systems management necessarily influences

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the type of healthcare institutions that are established within a given society. This implies that health laws and policies, which are the administrative tools of the state, are crucial to producing the desired institutions. The relationship between health governance and medical integration is, therefore, evident in the power of states, through the legal process, to put in place the right legal mechanisms for the creation of an integrated medical system.

In this regard, a proposal for medical integration would most certainly fail in a political and legal setting skewed to delegitimize non-biomedical health systems. In the current politico-legal framework, healthcare laws and policies as well as the organization of roles and powers within the healthcare system entrench the biomedical paradigm. This framework creates an insidious hierarchy between biomedical and indigenous medical systems. It also creates a risk of legal liability for practitioners who engage in integrated or indigenous medical practice. This politico-legal framework further entrenches the erroneous view – itself supported by the extant healthcare decision-making processes in Canada and Nigeria – that health governance is solely the business of the biomedical class. This state of affairs has led some scholars to conclude that physicians are agents of the state.122

This study contests this approach to health systems governance. This approach to governance is analogous to the stewardship concept of governance, in which the state is considered an agent of the citizenry, and assumes primary responsibility for the regulation and delivery of healthcare through its biomedical class of decision-makers.123 This system of health governance discounts the input of a broad category of unconventional actors in the healthcare system, and often lacks the fiscal resources to sustain an equitable healthcare system. This study also rejects theories of governance at the opposite end of the spectrum, such as the micro-governance theory, which espouse the management of healthcare through private or non-state actors based on the imperfections and failings of the modern state.124 Private actors lack the institutional power of the state to maintain healthcare standards. Furthermore, this approach to governance might produce laws, such as the much-critiqued TRIPS Agreement, whose creation

123 Saltman and Ferroussier-Davis, supra note 121.
124 Burris, “Microgovernance”, supra note 121 at 336.
was influenced by powerful private actors and lobbyists. Against these pervasive concepts of governance, this study contends that medical integration would require a broad-based approach to governance, one which embraces diverse actors and hitherto marginalized practitioners.

In furtherance of this proposition, this study inquires into how health systems could be organized or structured to achieve the desired goal of integration. Contending that extant theories of governance have failed to produce the necessary institutional reform, this work proposes that the theory of governance that undergirds the management of a health system must be grounded on the lived experiences of legal subjects. Simply, this implies that theories must reflect “reason informed by experience”. Contending that the experiences of most Southern countries depict a pluralistic nature of healthcare usage and delivery founded on unique socio-economic, political, geographic, and historical landscapes, this work posits that the realization of health equity in the South and in underserved Northern populations is dependent on a new approach to governance sustained by a reformed legal framework in which policies and attitudes to governance reflect the needs and experiences of the populations. This assertion is supported by a historical analysis of the advent of biomedicine and the development of healthcare laws in formerly colonized territories. The lack of congruence between the World Bank and International Monetary Fund’s (IMF) neoliberal health policies for Africa on the one hand and the continent’s socio-economic and cultural worldviews on the other hand, which resulted in the failures of the health initiatives in the 1990’s, provides further support for the proposition.

In order to avoid a repetition of past and ongoing failures in the attempt to establish a sustainable health system, this study proposes a system of Integral Governance—denoted in this study as a theory of Integrated Governance—as a suitable approach to health systems governance. ‘Integrated governance’ is first a theory of law—an of the design of laws that embody the empirical realities of legal subjects. It is also an administrative theory—a theory of democratic governance which recognizes the interdependence of the state, healthcare professionals of the different healthcare systems, healthcare consumers, and relevant non-state

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125 Seidman and Seidman, supra note 39 at 64.
126 Ibid.
actors in the enterprise of health systems management. This study proposes that the integrated approach to governance provides the right political and legal framework to support medical integration. It is noteworthy that while the concepts of medical pluralism and medical dominance (that is, the ascendancy of a given medical system over others) as will be argued are dependent on the historical milieu and the political factors that influence the rules within a given society, the achievement of an ideal integrated health system cannot be left to the vagaries of politics and desultory evolution. Thus, the integrated approach to governance represents a deliberate design – from an existing political will to achieve medical integration to orchestrated legal and institutional reforms at each of the six levels of the healthcare system – the policy, healthcare practitioners, healthcare clinics, healthcare institutions, healthcare organizations, and consumer levels.

As discussed in chapter five, integrated healthcare facilitated at each of these six levels represents a “systemic” model of integration outlined by Douglas Tataryn and Marja Verhoef. Tataryn and Verhoef’s brilliant exposition of systemic integration depicts this system as both the ideal model of integration and the ideal healthcare system. However, while Tataryn and Verhoef have clearly outlined the nature of the systemic model of integration – that is, as a healthcare system that incorporates both biomedical and alternative healthcare at each of the above levels of the health system – it remains important to address the role of law in fostering integrated medicine at each of these levels considering that interactions between consumers, professionals, and institutions at each level are governed by law. Integrated governance offers a theory for resolving at least some of the legal complications implicated at each of these levels.

1.5. Integrated Governance and Medical Integration

The proposal for an integrated approach to governance draws its foundation in part from the comprehensive nature of integrated medicine. This study envisions an integrated health system that involves non-hierarchical inter-professional collaboration, and is holistic, comprehensive, and geographically and financially accessible. Integrated governance, which is geared towards

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128 See Tataryn and Verhoef, supra note 1 at VII.102-105, where the authors set out the systemic model of integration and the changes necessary at each of the six healthcare levels. See chapter five, infra for a summary discussion of the systemic model of integration.
achieving these healthcare objectives, eschews historical inequities in health systems governance and incorporates the socio-economic, geo-cultural, political, and historical experiences of healthcare consumers into its policies. While this conception of governance is fully discussed in chapter six, chapter two provides a background discussion of why such a new concept of governance is necessary.

Chapter two connects the debate on the legal status of indigenous medical systems with the colonial encounter between the South and the North. With some focus on colonial Africa, the thesis asserts that the advent of biomedicine to African territories as a tool of colonialism marked the decline of legitimacy for indigenous medical systems. Beyond the adoption of the institutional framework of biomedicine, the Westphalian state, which was inherited by colonized territories, also adopted the governance regime that defined the biomedical system. This regime was, and continues to be, dominated by health policymakers who are biomedical professionals and features the adoption of the Common Law, such as the tort of negligence for governing medical malpractice, and other regulations governing biomedical practice in the West to manage the new healthcare institution in the newly independent states. The governance regime also embraced a global capitalist approach to healthcare delivery in which healthcare came to be available to those who could afford its costs. As observed in chapter two, African states further adopted a capitalist model of healthcare delivery when, in exchange for foreign aid and financial assistance, they accepted proposals of the World Bank and the International Monetary Fund, which were founded on the neo-liberal ideology that the private sector could best deliver healthcare to the populace.129

Chapter two further discusses the problems and historical failure of these transplanted norms and ideologies. While the transplanted institution of biomedicine and some of its laws, such as the tort of medical negligence, could have universal application, the application of these laws in an African or Southern state which is primarily dependent on indigenous healthcare approaches and which lacks the necessary economic and technological resources to sustain the new system was certain to produce poor outcomes. Chapter two identifies how this new system and approach to governance has left indigenous medical systems in a legal void where the practice of indigenous medicine is not directly outlawed, but at the same time not fully

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129 Freedman et al., supra note 127; see generally Colleen O’Manique, Neoliberalism and AIDS Crisis in Sub-Saharan Africa: Globalization’s Pandemic (New York: Palgrave Macmillan, 2004).
accounted for. The implication of this is that there are no applicable legal rules to govern the unique practice of indigenous medicine.

Rather, the prevailing norm as evident in decided cases on indigenous medicine is the application of legal rules formulated from biomedical standards to legal questions on indigenous and alternative medical practice. This situation evinces a conflict between extant health governance regimes and the experiences and behaviour of legal subjects. The chapter proposes that since the state is composed of legal rules and official action, governance reform would necessarily involve institutional and legislative reform, as well as creative judicial interpretation of current laws. Applying insights from Lon Fuller and Felix Cohen’s Interactional theory of law and Functional jurisprudence respectively, the chapter suggests that a functional and contextual interpretation of relevant laws and policies in which legal interpretation reflects the interconnectedness of healthcare, socio-cultural, economic and political norms is instrumental to reform.

Situating this analysis within critical legal theory, the proposal to replace the current positivistic interpretation of healthcare laws in the context of indigenous medicine with a contextual interpretation reflects the theoretical disparities between legal positivism and the interactional theory of law – a derivative of Lon Fuller’s natural law theory. The relevance of these theoretical approaches is evident in the judicial opinions of Canadian judges in cases involving consumers’ entitlement to the medical expense tax credit (METC) under the Canadian Income Tax Act for their use of indigenous and alternative medicines. Section 118.2 of the Canadian Income Tax Act, which is the most contested provision on this subject under Canadian law, fails to include indigenous and alternative medicines within the types of medical expenses that can be claimed under the METC. The court judgments closely follow positivism’s prescriptive approach to legal interpretation, as well as its preference for observable and quantifiable forms of evidence. The judges have almost consistently held themselves bound by the texts of the law – supported by a contestable argument suggesting that parliament considered some scientific evidence before drafting the medical expense provisions.

Chapter three situates Canadian court judgments on the METC and on consumers’ entitlement to reimbursement for expenses on CAM in the context of the influence of the

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131 *Ibid, section 118.2(2).*
‘evidence-based medicine’ paradigm on health law and policymaking.\textsuperscript{132} The Evidence-based Medicine (EBM) paradigm prioritizes the systematic reviews of Randomized Controlled Trials (RCT) over other forms of evidence for medical decision-making. In what is evidently an adoption of the EBM approach, the courts’ interpretation has followed the plain provisions of the Act on the argument that no liberal interpretation of the law could produce a favourable outcome for litigants.\textsuperscript{133} While highlighting the need for policymakers to embrace a broader paradigm of evidence beyond that proffered by the RCT, the chapter highlights several problems with the policymaking process – problems that are further complicated by a positivistic attitude on the part of the courts. Observing that the decision-making process in Ontario, Canada (as well as at the Federal level in Nigeria) is dominated by physicians whose decisions narrowly focus on evidence of medical efficacy and cross-provincial uniformity,\textsuperscript{134} the chapter discusses the need for an open and participatory health policymaking process, which takes into consideration consumers’ healthcare values and interests. It also argues for a more critical judicial stance on the inequity inherent in a decision-making process that excludes consumers’ values and healthcare behaviour, and the considerable body of evidence that can assist in confirming the validity of these values and healthcare behaviour.

In this regard, the chapter examines a range of evidence critical to decisions affecting population health. It contends that a decision whether or not to regulate a healthcare paradigm utilized by a significant number of healthcare consumers or to exclude indigenous medicines from coverage under reimbursement provisions necessitates the consideration of other important types of evidence beyond that of scientific efficacy and safety. These other types of evidence, which Canadian health policymakers have failed to incorporate into their decision on the METC, include evidence of cost-effectiveness, cost-minimization and cost-utility of indigenous medicines, socioeconomic data, statistics on the accessibility of human and material resources, geographical disparities in healthcare access, consumers’ healthcare behaviour and values, and the availability of biomedical options. Analysis of data from a research conducted among a sample of 220 respondents in Nigeria reveals the importance of some of these factors

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\textsuperscript{132} Evidence-based medicine (EBM) involves the use of current best evidence in making healthcare decisions: David Sackett et al., "Evidence-Based Medicine: What It is and What It Isn’t" (1996) 312 Br Med J at 71.
\end{footnotesize}
to consumer’s access to healthcare. For example, in connecting evidence of accessibility of healthcare services to the need to legitimize indigenous healthcare systems, the chapter compares research outcomes on wait-times in biomedical clinics vis-à-vis indigenous healthcare centres in three rural communities and a city in Nigeria. The responses of healthcare consumers to the proposals for medical integration, insurance coverage for indigenous medicines and the inclusion of IMPs into community healthcare delivery provide further insights into the needs of consumers, and reveal how these proposals might address financial and geographical inequities in access to healthcare in these localities.

Chapter four addresses other impediments to the regulation of indigenous and alternative medicines, and to their integration into national health systems. Building on the argument for a broader evidential paradigm beyond the RCT model set out in chapter three, chapter four examines how the insistence on the RCT model of regulation and the absence of an intellectual property law regime to protect natural health products validated under the RCT model constitute a barrier to the regulation and standardization of NHPs in Nigeria and Canada. In Canada, CAM practitioners have resisted the regulation of NHPs as drugs under the *Food and Drugs Act* because of concerns regarding the power of pharmaceutical corporations to monopolize the production of NHPs through patents obtained after huge expenditures on the RCT process. Further, there are concerns that this scientific process fails to recognize the unique holistic nature of NHPs and indigenous medical practice, which renders the RCT an imperfect standard for testing NHPs.

In the Nigerian context, practitioners wary of the state’s relationship with multinational pharmaceutical corporations have expressed disinterest in the regulation of NHPs by the National Agency for Food and Drug Administration and Control. This attitude is based on concerns that pharmaceutical corporations may appropriate their medicinal knowledge of herbal plants considering the absence of intellectual property protection for NHPs. The Nigerian *Patents and Designs Act*, in conformity with the TRIPS Agreement, restricts the grant of patents to products that are deemed novel, inventive, and capable of industrial application. Chapter four contends that these requirements arise from within a fixed definition of ‘science’. The chapter analyzes how science – narrowly and culturally defined – is employed to determine

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the type of innovations that merit juridical status under the Intellectual Property Law regime (IPL) represented by the TRIPS Agreement. While observing (through an analysis of the requirements for patentability under the *Nigerian Patents and Designs Act*\(^{136}\)) that states have adopted the scientific definition of innovation and patentable property which governs the IPL regime at the international level, the chapter traces the linkages between this definition of property and the associated IPL regime, and the narratives that facilitated colonialism. These narratives depict a vertical relationship between the North and the South in which (post)colonial regions sign on to unfair Agreements that delegitimize certain types of knowledge that are classified as public domain and freely appropriable resources.

The chapter challenges these popular narratives about the nature of indigenous medicine through research conducted in Nigeria and Canada. The research involved the use of questionnaires and structured and semi-structured interview sessions with indigenous and integrated healthcare providers in both countries to examine respondents’ knowledge of indigenous medicines. The questions were designed to investigate the popular assumption that indigenous medicinal knowledge is a transgenerational and non-inventive resource existing in the public domain. Based on the outcomes of the research, chapter four contends that most of the notions about the nature of indigenous medicine that circulate in the scholarship are contrary to the realities of respondents in at least a city and three rural communities in Nigeria. While observing that the spread of capitalism, the growth of the urban society and the lures of a market economy among other factors in some indigenous societies, like Nigeria, have had an impact on the transgenerational nature of indigenous knowledge, the chapter argues that indigenous medical practice is an intricate, specialized field of knowledge practiced by a closed group of professionals. The chapter concludes with an examination of different proposals for protecting indigenous medicinal knowledge, noting the difficulty with proposals for a new intellectual property framework for the South. Arguing that Southern nations can amend national patent laws to suit the needs of their communities, the chapter proffers suggestions on provisions that could be included in an amended patent Act in Nigeria. The proposal for an amended patent law draws from the theory that laws need to reflect the needs of the communities that they are designed to serve.

\(^{136}\) *Patents and Designs Act*, *supra* note 84.
Having addressed the above impediments to medical integration, chapter five provides a precursory analysis of the processes necessary for medical integration and the relevance of theorizing governance towards attaining the goal of integration. While recapitulating the imperatives for institutional and legislative reform the details of which are set out in chapter six, chapter five provides a précis of three key reform initiatives – dialogue and negotiation between the state and IMPs as well as between IMPs on central issues pertinent to integrated medicine, and contestation, which involves the legal challenge of laws that are considered unfair or prejudicial to the interests of patrons and practitioners of indigenous medicine. Each of these initiatives – dialogue, negotiation and contestation – is further developed in chapter six. While alternative medical practitioners are responsible in part for initiating these processes, the responsibility for structuring governance to accommodate the evolution in healthcare patronage and delivery rests primarily on the state. This study contends that the state must structure governance on a feasible theory that emerges from information and knowledge about a peoples’ resources, experiences and needs. Chapter five discusses the significance of a theory of governance to the process of integration, and compares current theories of health governance, such as the micro- and stewardship governance theories, against proposed models of integrations.

Three models of integration that may be identified in the scholarship include co-optation (or co-option), parallel integration (or co-existence) and systematic integration. The chapter argues that models of integration are not separable from the institutional setting within which they exist. This implies that the co-optive and parallel models of integration are products of specific systems of governance, each of which is founded on a given theory of how health systems should be managed. For example, the co-optive model of integration, which involves the delivery of integrated medicine by the biomedical class to the exclusion of IMPs, is a product of a system of health governance – denoted as the ‘stewardship’ model of governance – in which the government is considered the sole provider of healthcare goods and services based on standards established by the allopathic healthcare profession. Similarly, parallel integration – which involves the co-existence of biomedicine and indigenous medicine as an independent,

138 See generally, Tataryn and Verhoef, supra note 1.
(un)regulated and politically unaffiliated medical system – fits within a model of micro-governance involving the privatization of healthcare and its management by private or non-state actors. The chapter contends that the chosen theory or approach in any given society must be that which effectively incorporates the realities and expectations in the specific society.

Given the conceptual and practical limitations of both micro-governance and the stewardship model of governance and their disutility to the concept of medical integration, chapter six proffers the Integrated Governance or Integral Health Governance theory. The integral approach to health governance encapsulates a representative system of governance or decision-making by a broader category of actors and envisions the replacement of the current ahistorical health policy framework with a legal framework that recognizes the complex relations of socio-economic, geographical, political and cultural influences on the health and healthcare behaviour of legal subjects. Integrated governance provides an avenue for comprehensive healthcare reform. As expatiated in chapter six, integrated governance necessitates specific legal and institutional changes at each level of the health system. For example, at the health policy or system level, the chapter argues for the formulation of laws and policies to facilitate medical integration. The chapter emphasizes the importance of the state in this regard. The state possesses the necessary institutional resources to establish an integrated healthcare system. It is noteworthy that this position does not ignore its past failings and ongoing difficulties, especially in Southern regions. Rather, the proposal focuses on the strengths of the state institution in the areas of lawmaking and enforcement, quality control, and institutional access to important local and international organizations, such as the World Health Organization (WHO), which can influence health systems management.

Chapter six also makes the case for an amendment of current laws and policies in the area of medical practice and healthcare delivery. Within this area, the chapter addresses emerging constitutional debates about the place of indigenous medicines within national healthcare systems, and the right of healthcare consumers to be reimbursed for medical expenses on indigenous and alternative healthcare services and products. There has been an increase in constitutional litigation by healthcare consumers in Canada and the United States over their right to access and be reimbursed for expenses on complementary and alternative medicines (CAM). The emerging case law reveals two categories of constitutional questions. The first question relates to whether consumers have a constitutional right to access and be reimbursed
for alternative therapies, which are not covered through Medicare.\footnote{Medicare is the unofficial designation for the publicly funded Canadian Universal Health Insurance Program.} Under this category, there are a growing number of constitutional challenges against the exclusion of alternative therapies from eligibility under the medical expense tax credit (METC).\footnote{Davar v. The Queen, supra note 133; Franklin D. Tall v. The Queen, 2009 DTC 1036; 2008 TCC 677; Noddin v. The Queen, 2004 D.T.C. 3577; 2004 TCC 687 (NB); Chevalier v. Canada, [2008] T.C.J. No. 5. (‗Chevalier‘) (QB); Ali v. Canada [2006] T.C.J. No. 213, 2006 TCC 287 (ON); Bannan v. The Queen, [2001] 2 C.T.C. 2111 (SK); Melnychuk v. Canada, [2002] T.C.J. No. 84 (AB); Roy v. The Queen, 2006 DTC 2888; Bissonnette v. Canada, [2002] T.C.J. No. 94 (BC).} Litigants often claim that the non-inclusion of alternative medicine within the list of medical expenses that can be claimed within a given tax year constitutes an act of discrimination against minority groups that dependent on CAM. The second component of the constitutional debate addresses the integration of indigenous medicine into national health systems. This aspect of the debate questions the constitutionality of integrated medicine in countries with secular constitutions that prohibit governments from adopting a state religion. In this case, the argument is that indigenous medicine is intertwined with religion, and by implication, its integration into national health systems with secular constitutions would constitute a violation of the law.

Next, chapter six focuses on reform at the practitioner level. The chapter examines the prospects of integration under medical negligence law. While focusing on malpractice law, including the restrictive rules on scope of practice set by state medical disciplinary boards, the chapter reads medical negligence law as a barrier to medical integration. Beyond incurring liability in tort for malpractice, physicians who practice alternative medicine often face professional disciplinary procedures under state medical practice laws for an alleged deviation from ‘conventional’ or biomedical standards. Current medical malpractice and regulatory laws are built upon the Western biomedical conception of disease.\footnote{See generally Cohen, Beyond Complementary Medicine, supra note 91.} For example, the law of medical negligence as presently constituted effectively places non-conventional medical practices within the definition of malpractice. Medical negligence occurs when a physician deviates from the biomedical standard of care and that deviation causes the patient injury. By the very definition of indigenous and alternative medicine as unconventional therapies “which fall outside biomedical standards”, the practice of indigenous medicine constitutes a classic case of malpractice.\footnote{Ibid at 24.} This state of the law, while aiming to protect patients from harm, imposes
limitations on the practice of indigenous or integrated medicine and drives the need for legal reform. The study examines how these rules might be reformed to accommodate integrated medical practice.

A related issue at the healthcare practitioner level (discussed as part of the standard of care analysis under malpractice law) involves the allocation of roles between healthcare professionals. Presently, while there is some agreement that an alternative medical provider can employ alternative medical standards in the course of treatment, the Canadian court often rejects the suggestion that there should be a dual standard of care as between biomedicine and alternative medicine in the area of diagnosis. Thus, medical providers who employ a non-biomedical method of diagnosis in Canada might face liability for medical negligence. Law reform in this area might assist in a non-hierarchical apportionment of tasks as regards who diagnoses, prescribes or treats, and in a manner that reflects the strengths of each profession as well as the needs of patients. This study argues for the adoption of a new standard of care in diagnosis and utilizes data on the processes of treatment and diagnosis in seven Integrated Health Centres (IHCs) in Canada and Nigeria to support the proposed standard.

At the consumer level, chapter six argues for an extension of the legal concept of informed consent to reflect consumers’ interest in and utilization of indigenous therapies. At the level of the healthcare clinic and the institution, the chapter examines the types of liability that might arise from referral between biomedical and alternative healthcare providers within the seven integrated clinic organizations surveyed in Canada and Nigeria. The chapter also analyzes the types of liability that might arise from the organization of responsibilities within the clinical setting (that is, with respect to diagnosis, treatment, and prescription) and from the structure of the clinic itself. This part of the chapter also applies data collected from the seven Canadian and Nigerian IHCs in which interviews were conducted. Finally, at the level of the healthcare organization, the chapter summarily discusses state medical practice laws governing the practice of medicine. These laws often place legal restrictions on medical practice by non-biomedical providers and on the scope or nature of medical practice by physicians. These issues are similar to those discussed under the practitioner level.

Chapter seven synthesizes the research outcomes in the previous chapters and applies the conclusions towards mapping out a theoretic and diagrammatic framework of Integrated
Governance as a legal theory designed to facilitate the establishment of an integrated healthcare system.
CHAPTER 2. INDIGENOUS MEDICINE, LEGAL AND INSTITUTIONAL TRANSPLANTS AND THE LEGITIMACY CRISIS

So long as biomedicine remained integral to colonialism’s political concerns, its intents and cultural preoccupations…ceased to be merely a matter of scientific interest.

Osaak Olumwullah, Dis-Ease in the Colonial State.¹

2.1. Introduction

Indigenous and alternative medical systems face a crisis of legitimacy. The systems exist in a predominantly ungoverned social space within which the prevailing practices and norms are shaped by mercantilist principles.² In many jurisdictions of the North and South, states have no policies governing the regulation of these systems of medicine.³ In some other jurisdictions, such as Canada, the systems are selectively regulated in different provinces.⁴ While the healthcare laws in WHO Member States⁵ endorse and stipulate the requirements for the practice of biomedicine, some of these laws may not expressly prohibit the practice of indigenous or alternative medicine. The laws may simply stipulate prohibited acts, which are restricted to physicians. Thus, while indigenous medicine can co-exist with the biomedical system since it is not expressly outlawed in such regions, it is also not accounted for within the boundaries of state law. The problem with this unlegislated status is that the practice of controlled medical acts by indigenous medical practitioners (IMPs) or of integrated medicine

¹ Osaak Olumwullah, Dis-Ease in the Colonial State (Westport, CT: Greenwood Press, 2002) at 286.
² Today, most indigenous, alternative or integrated medical enterprises operate on market-based principles; cost of products and services are unregulated, there is high-level competition between centres, and clever marketing strategies are adopted to keep the businesses afloat.
³ See the WHO Congress on Traditional Medicine, 7-9 November 2008, Beijing, China, online: World Health Organization <http://www.who.int/medicines/areas/traditional/congress/en/>; calling for national regulation of indigenous medicines and practices in Member States. The WHO reports that only twenty-five of a hundred and ninety one World Health Organization member states have national policies on indigenous medicine: Gerard Bodeker and Fredi Kronenberg, “A Public Health Agenda for Traditional, Complementary and Alternative Medicine” (2002) 92:10 American Journal of Public Health 1582 [‘Bodeker and Kronenberg’].
by physicians can result in tortious or criminal liability. There are also statutory barriers involved in the financing of indigenous medicine. In some countries such as Canada, the courts have denied insurance reimbursement and tax credits to consumers for their medical expenses on alternative medicine. In many African jurisdictions, such as Nigeria, where indigenous medical systems (IMS) or specific therapeutic systems are recognized through a promulgated statute, there are no provisions for insurance coverage, tax relief, or research funding. The users and providers of indigenous medicine in these jurisdictions operate outside the legal protection and benefits conferred by law on mainstream biomedicine.

Part of the objectives of this chapter is to discuss the historical, as well as the present economic, ethical, legal and jurisprudential issues, implicated in this state of affairs. However, this important exposition must necessarily be guided by the knowledge that the detrimental impact of the legal void in which IMS exist is often discounted in the maze of legal rhetoric that accompanies the discourse. The case of *Herzig v. R.*, which is further discussed in section 2.4.1 *infra*, represents a classic example of the impact of the legal status of IMS on healthcare consumers. In that case, the appellant’s wife had terminal cancer and spent $46,266.00 on alternative medical treatment. Although the treatment significantly reduced her pain and kept her alive for another four years, the Minister of National Revenue disallowed $30,963.77 of the claim. The Minister’s decision was based on the provisions of the Canadian *Income Tax Act*, which disallows expenses based on medical products that are not prescribed by a physician or recorded by a pharmacist. While the patient’s use of the alternative healthcare products was based on the recommendations of two physicians, the purchase of the products was not ‘recorded by a pharmacist’.

The *Herzig* case is one of a growing number of cases in which patients who require and use non-biomedical medicines or consult non-biomedical experts have been denied tax benefits because their claims are not recognized by law. In most of the global South where

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there are no insurance schemes for indigenous medicine, the experience is often far worse than the *Herzig* case depicts. The typical case involves a consumer who uses indigenous medicine and pays for the services or the products out of pocket, or by installment over a long period. The sums expended are neither subject to tax benefits nor are they reimbursed through health insurance. Individuals and families bear the full burden of the cost of therapy. While payment by installment is sometimes available for low-income earners,\(^\text{10}\) the payment procedure places a financial burden on families and individuals in the long run.

Although some alternative therapies are regulated in some countries,\(^\text{11}\) there is still considerable disparity in the law’s treatment of biomedicine and indigenous medicine in these jurisdictions. A historical survey reveals the affinity between biomedicine and the state. This enduring relationship is manifest today in the non-recognition of many indigenous healthcare providers as healthcare professionals, as well as in the legal exclusion of indigenous/alternative medical services and therapies from state medical insurance schemes. As the *Herzig* case reveals, the state’s exclusion of non-biomedical therapies and services from the ambit of governance has often resulted in hardship to consumers who find relief from the use of these modalities. These everyday cases reveal the incongruence between the law as it is on one hand and the expectations and experiences of health consumers on the other hand.

This chapter examines the disparity between the state of the law and present realities and expectations in the use and practice of indigenous medicine. The chapter investigates the imperial origin of this state of affairs with some focus on colonial Africa, while highlighting related themes in discourses on medicine, value systems and knowledge ownership in Asia and North America. The chapter links the historical to the present in explaining the absence of governance in the area of indigenous and alternative medical practice (AMS). The historical overview of the role of imperialism in the structure of healthcare laws outlined in this chapter is crucial to understanding the spatial and temporal specificity of biomedical laws. To invoke Foucauldian philosophy, such historical overview is indispensable to the task of unmasking and understanding the structures of extant legal orders and the shifting boundaries of

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\(^{11}\) For example, Canadian provinces regulate IMS selectively. Only a few alternative health services are regulated in the provinces.
legitimacy. It is also central to comprehending why healthcare in most countries of the South remains in a nascent state.

The chapter contends that the advent of Western biomedicine as an instrument of governance in colonized territories marked the decline of state legitimacy for indigenous healthcare systems. While indigenous medicine has cultural legitimacy for the over 80% of its users in the South, the legacy of extant colonial biomedical laws continues to relegate indigenous medicine to the fringes of the law – often an unlegislated space where the practice of indigenous medicine is not governed by regulatory policies and laws or where the practice of certain restricted medical procedures by indigenous and alternative medical practitioners may attract civil and criminal sanctions. Beyond highlighting the non-progressive state of existing laws governing healthcare and biomedical practice, the historical analysis provided here foregrounds the theoretical (and functional) question of whether laws should be interpreted in accordance with textual provisions or by reference to the implicit objective of law to ensure fairness and justice in human relations. This question arises because of the legislative barriers to the mainstreaming of IMS and AMS and the consequential interpretive difficulties that arise in court cases on the subject.

In addressing this question, the chapter discusses the Interactional and Functional Jurisprudential Schools of Thought – both derivatives of the Natural and Realist schools of legal philosophy respectively. There are diaphanous philosophical lines between the Interactional and Functional legal schools. This chapter draws upon the shared meanings of legal validity between these schools and applies insights gained from the postulations of both schools towards outlining the problems of extant approaches to health governance. The shared meanings extrapolated from both schools are represented within the concept of ‘legal reciprocity’ – which denotes a relationship of dependency between law and its subjects. The concept of reciprocity is further developed as mandating, where necessary, the contextualization of norms and institutions in any given society. This reading of reciprocity is employed in the rest of this study to determine how a feasible theory of governance may be constructed to support the paradigm of integrated medicine within a medically pluralistic society.

12 See generally Michel Foucault, The Birth of the Clinic: An Archaeology of Medical Perception (Vintage Books, 1975) at xix (preface) ['Foucault, The Birth of the Clinic'].

The chapter begins with an introduction to the nature of indigenous medicine. Following this introduction, it proffers a definition of indigenous medicine that captures the essential nature or elements of this medical system. This first section discusses and juxtaposes indigenous medical systems and biomedicine while identifying the intricate and multilayered elements that distinguish the former from the latter. The philosophical commonalities and differences between both systems provide insights into why indigenous medicine has survived the incursion of expansionism and imperialist philosophies in Africa, Asia, South America and the indigenous communities of North America. In section two, the chapter discusses the concept of medical pluralism while highlighting the political, temporal, and economic factors that determine medical dominance in any society with multiple healthcare systems. Within the framework of this discussion, section three examines the relationship between the state and Western biomedicine, and discusses the postcolonial society’s adoption of the Westphalian state, its laws and standards of medical practice. Today, these standards remain largely unmodified versions of colonial biomedical laws. Section four outlines how the modeling of healthcare institutions and laws after Western frameworks has left indigenous medical systems in a legal void. The section discusses this legal vacuum as an outcome of the historical neglect of indigenous medicine by the state.

Section five examines the theoretical lenses through which the courts might construe the emerging legal issues in the practice of indigenous and integrated medicine. This final section of the chapter proposes that institutional reform and an inventive hermeneutical agenda are crucial to the mainstreaming of indigenous forms of care. In outlining this proposition, the section draws on Lon L. Fuller’s Interactional theory of law and Cohen’s Functional Jurisprudence as theoretical frameworks for understanding and addressing the dissonance between law and societal expectations. The social and legal problems that arise in a schism between law and society are aptly captured by the conflict between governance frameworks and consumer healthcare behaviour in the area of indigenous or integrated medicine. The derivative concepts of “legal reciprocity” and “functional interpretation”, as evident in Fuller’s and Cohen’s Interactional and Functional Jurisprudence respectively, will frame the analysis of the legal void that presently constitutes the greatest barrier to medical integration.

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13 I will refer to these theoretical approaches as the discussion progresses in the following chapters.
2.2. The Nature of Indigenous Medical Systems (IMS)

The popular theme in early Western anthropological and historical comparisons of indigenous medical cultures with Western biomedicine is a bifurcated rhetoric of natural/supernatural, scientific/unscientific, modern/primitive, and civilized/uncivilized. These terms were not mere heuristic devices to facilitate understanding of the different medical cultures of colonized and non-Western peoples. Rather, they were part of a linear agenda, which itself was entrenched in imperialism, geared towards ‘establishing’ the supremacy of Western ideologies over the worldviews of the colonized.14

While anthropologists captured what was assumed to be “exotic” and “prescientific” healthcare practices related to sorcery and magic in indigenous communities, historians drew comparisons between the “reconstructed records” of primeval healthcare practices in the West, which existed before the dawn of scientific medicine, and those from present day nation-states of the global South now commonly referred to as “less-developed”, ‘developing’ or ‘Third World’ societies.15 This comparison is the foundation of accounts of indigenous medical systems (IMS) as transitory systems which are in a “static, precontact phase”.16 These accounts foresee the demise of indigenous medical systems on the assumption that they will be supplanted eventually by the ideologies of the scientific age, especially as embodied within biomedicine.17

The persistence of indigenous medicine contradicts this enduring Western worldview of indigenous health systems. Although some scholars, like David Fidler, argue that the survival and increasing importance of indigenous health systems have more to do with “the failure of national and international health policy to improve conditions along Western models”18 than any other factor, an objective analysis of indigenous medicine reveals the multifaceted factors that have ensured its survival through the ages. These factors include the intricate disease etiologies of indigenous medicine, the world-views and cultural values embodied in IMS,

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16 Ibid.
17 Ibid.
18 D.P. Fidler, “Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World” (1999) 7 Indiana Journal of Global Legal Studies 191 at 218, see also note 106 [‘Fidler’].
popular beliefs about their efficacy and safety, the availability and accessibility of these systems, and the flexibility of payment for treatment or services rendered within these systems. These factors contradict the view that the lifespan of indigenous medicine is subject to “a delayed, but inevitable, generational change”.  

The survival of indigenous medicine may also be cast as a “response to Western aggression – an alternative understanding of health and illness that partially borrows from the colonizer” without entirely discarding the fundamental values of indigenous belief systems.  

Indigenous medicine has also benefited from the common knowledge that Western science has limitations in its efficacy against the range of medical conditions that afflict humanity. Some of these factors are presently influencing the incursion of indigenous healthcare philosophies into Western societies. The growing patronage of complementary and alternative medicine (CAM) in the US, Canada, and the UK as well as in other European nations captures consumers’ attraction to non-Western philosophies of health. The above factors, which have ensured the survival of indigenous medical systems over the ages, also constitute the defining elements of indigenous medicine. An examination of these elements illuminates the essence of IMS. The world-views and explanatory theories of disease causation in IMS are arguably the most essential features of these systems and are the appropriate starting point for the discussion in this chapter.

2.2.1. Definition of Indigenous Medicine and Overview of Essential Elements

According to the World Health Organization (WHO), indigenous medicine includes “diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness”. This definition is comprehensive and highlights some of the core aspects of indigenous medicine such as the diversity of techniques and resources employed in indigenous medical practice. However, the definition omits the unique matrix of disease etiologies and

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19 Baronov, supra note 14 at 125. The author attributes this impression to early anthropological and historical writings about African medical cultures.

20 Ibid at 126.

worldviews that characterize and distinguish indigenous medicine from biomedicine. While there is no all-encompassing definition of indigenous medicine, this study proposes a definition that highlights the very important epistemic dichotomy between biomedicine and indigenous medicine.

Accordingly, indigenous medicine comprises the totality of therapeutic knowledge, methods and systems, including the natural, psychosomatic, psychosocial and mystical, employed in maintaining health or preventing, diagnosing and treating illness, which are based on mechanisms and theories that may or may not be explicable through Western biomedical philosophy; the methods and systems typically employ plant, animal and other mineral resources in combination or independently in the therapeutic process.

This definition highlights a constellation of four elements – the natural, supernatural, psychosomatic and psychosocial, and holism – which make up the indigenous medical paradigm. Each of these elements identifies the origin of diseases as conceived within indigenous cosmology. Natural theories identify observable forces and elements within the material world as the cause of diseases and directly link measurable environmental phenomena such as pollution, infection, and contagion, to illness. Within this theory, the indigenous medical practitioner (IMP) relies on physical substances such as medicinal herbs, roots and plants for treatment. Supernatural or mystical theories identify factors and phenomena beyond the natural world as the origin of illness. Within this category, transcendental forces such as ancestral beings and religious deities are believed to be imbued with the power to interfere in human relationships and cause health-related problems. Illnesses linked to the transcendental cannot be rationalized through the “dynamics” of the physical world. They require knowledge of the systems of “interaction” that exist between the natural and supernatural realms.

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23 Ibid.
24 Ibid at 128.
25 Ibid at 129.
26 Ibid at 129.
Psychosomatic explanations link certain illnesses to the influence of mental or emotional factors. This element emphasizes the interrelationship between the body and the mind, and changes or distress in any of the realms of consciousness represented by the body and the mind can result in sickness in the other.\(^\text{28}\) Factors that create psychological changes or disturbances between the mind and the body are diverse and might include experiences in the social world. A related theory to the psychosomatic, therefore, is the psychosocial etiology, which interprets some diseases and illnesses through the social and psychological experiences of the patient. Disharmonious social relationships between the individual and members of the community are deemed to create an imbalance between the body and the mind of the patient, and this can result in illness.

Western medical anthropology conflates IMS into the natural and the supernatural spheres. In this categorization, the psychosomatic, psychosocial and supernatural theories are conflated as a single theory; thus, phenomena that address social relationships are often classified as supernatural.\(^\text{29}\) The broad categories of ‘natural’ and ‘supernatural’ are treated as distinct categories of a “premodern” medical system.\(^\text{30}\) These contrived categories mischaracterize the nature of indigenous medicine. Contrary to the perspective depicted by Western anthropologists, the four elements of indigenous medicine identified above are seldom exclusive. They often overlap to emphasize the importance of a harmonious relationship between the body, mind, community, and metaphysical forces to an individual’s health and general well-being.

The overlap and interdependence between the first three basic elements of indigenous medicine underscores the fourth element or principle – ‘holism’ – which is a “core organizing principle” of indigenous medicine.\(^\text{31}\) Holism in indigenous medicine represents the interrelatedness and conceptual inseparability of the natural, transcendental, psychosomatic and psychosocial elements in medical diagnosis and treatment.\(^\text{32}\) This holistic framework complicates any attempt to isolate the natural theories of illness from the broader cosmology

\(^{29}\) Baronov, supra note 14 at 128.
\(^{30}\) Ibid.
\(^{31}\) Ibid at 130.
\(^{32}\) Ibid, see generally pgs. 130-147. See chapter three (subsection 3.3.1.7.) infra, where holism is further discussed.
of indigenous medicine as is the case with biomedicine. In fact, the exclusion of any essential element in a specific case often undermines the wholeness of an indigenous therapy and strips indigenous medicine of its uniqueness as a distinct healthcare paradigm.

Beyond the above elements, other defining features of indigenous medicine include the empiricism in the search for causes and cures within the natural, psychosomatic and psychosocial theories of illness, the social and yet capitalist nature of indigenous medical practice, and of course the “receptive” and pragmatic attitude which indigenous healthcare practitioners have adopted towards biomedicine. Most indigenous healthcare systems, including African and Asian systems of medicine, recognize the interrelationship between medical systems and the importance of integrating the best of different medical cultures. According to Baronov, the pragmatism of African pluralistic medical systems “extends to the acceptance and incorporation of biomedicine as a duly respected, alternative medical system”. In this case, the flexibility and evolution of practices within indigenous African medicine does not approximate to the “wholesale replacement of one medical system for another based upon the ethnocentric Western premise of inherent incompatibility”.

The combinatory elements of indigenous medicine, while differing from one society to another in different degrees, mark the paradigmatic difference between indigenous medicine and biomedicine. On the one hand, while both systems are similar in terms of the empiricism in research, diagnosis and treatment of illnesses associated with natural theories, yet the interdependence of the elements of indigenous medicine signify a system of medical care that cannot be reduced to a substrate of biomedicine as is the case with attempts to exclude the non-observable aspects of indigenous medicine in scientific research.

As will be later argued, biomedicine itself embodies a specific paradigm of disease, which differs from the indigenous in its exclusion of non-specific, non-observable and socio-

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33 However, see chapter three, infra, where I discuss other biomedical schools of thought whose conceptions of ‘medicine’ challenge the view—conventionally advanced by EBM advocates, that medicine (supposedly a pure science) is a fixed field of knowledge largely unconcerned with the social determinants of health.
34 Baronov suggests that there is empiricism even in the mystical etiology of disease, which involves the identification of specific physical objects introduced into the body (by spiritual means) as the causes of illness in a given patient.
35 Baronov, supra note 14 at 130.
36 Ibid at 131.
37 Ibid.
38 See chapter three, infra.
transcendental elements from its conception of illness. This narrow worldview of disease consigns Western biomedicine to its own geo-cultural realm. While biomedicine is today a universal phenomenon having been accepted by virtually every medical culture in the world, yet it remains an alternative medical phenomenon traceable to a specific geographical, cultural and philosophical milieu simply denoted as the ‘West’. This discussion as it relates to the scientific validity of IMS continues in Chapter 3 where I examine in some detail and juxtapose the natural, transcendental, psychosocial and holistic elements of indigenous medicine with the monolithic disease paradigm of biomedicine.

2.3. Medical Pluralism

2.3.1. Defining Medical Pluralism

Medical pluralism has been defined in multiple ways. Each definition highlights the fundamental fact that biomedicine is only one of several paradigms for diagnosing and treating disease and illness. World cultures historically have employed diverse preventive and curative methods against illness and disease. Within these methods are combinations of philosophies and paradigms, including natural, psychosomatic and psychosocial theories of disease, each of which represents a specific worldview. The combination of these operative elements distinguishes other healthcare paradigms from biomedicine. The arrival of biomedicine in the 19th century as an integral part of the “capitalist world-system” and its subsequent transportation to other world systems did not obliterate other healthcare systems though it displaced many of them politically and legally. The term ‘medical pluralism’ denotes the co-existence of these “differently conceived and designed” healthcare paradigms within a given society. It involves the utilization of “a wide range of sources of medical care” within a society. The phenomenon of medical pluralism is common to every society, whether or not laws exist to suppress the non-conventional system(s) in a given society. However, why and

39 Baronov, supra note 14 at 33.
41 Obi Aginam, “From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World” (2002) 3:1 Chicago Journal of International Law 102, also online: Social Science Research Network <http://ssrn.com/abstract=319162> at 10 [‘Aginam’].
42 David Phillips, Health Care in the Third World (New York: Youngman, 1990) at 75 [‘Phillips’].
how a given system becomes ‘dominant’ or ‘unconventional’ has as much to do with temporal, economic, and political factors as with the legal norms of a state.

2.3.2. Pluralism and Medical Dominance

The state’s decision to support or restrain the development of a plural medical society is influenced by economic, political, and ideological considerations as well as by historical and geographical factors. The first three factors are instrumental to determining the boundaries of legitimacy within the healthcare context because the state has to maintain equilibrium between itself as a regulator, the needs of a diverse society and the resources available for meeting those needs. Historical and geographical contingencies including but not limited to advances within a given healthcare system, prevailing norms or events, and the spatial availability of healthcare providers might also be influential in delineating the boundaries of legitimacy. These factors also define the relationship between the co-existing medical systems. Within a permissive political and legal environment in which indigenous healthcare practices are recognized as valid healthcare systems, the relationship between biomedicine and indigenous medicine might be complementary and cooperative. In such a milieu, there may simply exist a healthy competitive relationship between both systems. However, medical rivalry often exists where one system of healthcare attracts a faithful consumer followership even though it is deemed illegitimate based on the ethos of the legally dominant medical professional group(s) in the society. This is the case in many societies in the North and South where indigenous and alternative medicine is patronized in spite of the lack of legitimacy.

The prevailing temporal and geo-political setting of a community also influences the nature of the relationship between medical systems and may define the relationship as one of antagonism, dominance or acceptance. In British West Africa in the early 20th century, the existing relationship was one of dominance of biomedicine over indigenous medical systems. Contrary to popular theory, biomedicine’s agenda during this period was not simply to save and enlighten the colonized, agendas which are themselves not innocuous. It was rather an agenda inextricable from economic imperialism, political subjugation and the need for the

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West to salvage the savage mind. Thus, the outlook of colonial biomedical professionals regarding indigenous healthcare systems was necessarily antagonistic. As discussed later, this was generally not the case with indigenous views about biomedicine, and the underlying reason for this is the acceptance within indigenous healthcare theory of the fluidity of medical systems. Prior to the arrival of biomedicine, indigenous African and Asian societies had the natural and the observable as aspects of several etiologies of illness. Thus, biomedicine’s monolithic explanatory paradigm of disease as based on phenomena from the natural world concurred with aspects of the indigenous medical paradigm. Hence, the nature of the relationship – whether antagonistic or accommodative, convivial or dominative – may be different depending on which side (biomedical or indigenous) the issue is assessed.

Given the political, historical and economic factors that govern the dominance or hierarchy of medical systems, it is problematic that some scholarly descriptions of both IMS and biomedicine retain the ‘traditional/modern’ dichotomy, which obscures the heterogeneity and empirical-rationality of indigenous medicine. An objective study of indigenous medicine reveals a different picture from that generated by the traditional/modern dichotomy. While the latter portrays indigenous medicine as a system trapped in a pre-scientific age, other academic accounts have revealed the empirical character of IMS before the arrival of biomedicine and the continuous dynamism of post-colonial IMS. Ralph Schram notes that the “medical care brought out by Europeans or Arabs was only in rare instances scientific. Medical practice during this era included much that was empirical, traditional care, little different from traditional African care”. Michel Foucault makes a similar point in *The Birth of the Clinic* in the context of the French revolution. According to the French philosopher:

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44 See generally Baronov, supra note 14.
45 Ibid.
46 See, for example, David Phillips’ definition of medical pluralism as “a wide range of sources of medical care, traditional and modern, static and evolving”: Phillips, supra note 42 at 75. Emphasis added.
47 For example, see generally L.L. Wall, *Hausa Medicine* (Durham and London: Duke University Press, 1988). Wall’s analysis of indigenous Hausa Medicine in Nigeria is largely represented in less than admirable terms, choosing to find only an occasional sparkle of talent among the practitioners.
48 ‘Scientific’ as used by the author in this context might be understood in terms of the technology-intensive connotation of the word ‘science’ in the present day. This connotation or description may be differentiated from the view expressed by Schram and advocated by the present author that IMS is empirical – the difference between the two expressions, that is, empirical versus scientific, being that indigenous medical systems lack the modern technologies employed in biomedical practice.
The clinic - constantly praised for its empiricism, the modesty of its attention, and the care with which it silently lets things surface to the observing gaze without disturbing them with discourse - owes its real importance to the fact that it is a reorganization in depth, not only of medical discourse, but of the very possibility of a discourse about disease.\textsuperscript{50}

This point, as Cousins and Hussain have noted, reinforces the view that “the empiricism of modern medicine itself was no less founded on \textit{a priori} conceptions than the medicine it superseded”.\textsuperscript{51} Thus, the \textit{new} clinical medicine is, in Foucault’s view, simply a shift in the organization of medical knowledge; it is a \textit{different} kind of medical discourse.

Further, the ‘traditional/modern’ dichotomy ignores the evolutionary nature of medical knowledge. Indigenous medicine, much like biomedicine, has evolved from its early beginnings. This internal evolution has occurred in spite of the legal and institutional factors that have constrained its development. Given that indigenous healthcare systems have always been open to accepting the best of different medical cultures, biomedicine – in the absence of its insalubrious colonial appurtenances - was approached as just another healing system among many, which bore some semblance to extant indigenous medical systems. As David Baronov has noted, indigenous societies have always incorporated other medical systems into their own medical cultures\textsuperscript{52} and this element typifies the non-static and progressive attitude indigenous systems have towards medical practice. Thus, the expression, “traditional and modern”, is not apposite for differentiating indigenous medicine from biomedicine.

Indigenous healthcare systems have developed from a continuing “historical-cultural exchange of values, beliefs and practices” across foreign ethnic landscapes.\textsuperscript{53} Hence, indigenous systems are composed of different elements from different medical cultures.\textsuperscript{54} With particular reference to African medical systems, Baronov observes that prior to the arrival of biomedicine, the major sources of cultural influence in African medical practice were “neighbouring African medical systems and, in certain regions such as East Africa, the regular contact with Arab traders”.\textsuperscript{55} By implication, the empirical-rational character of

\textsuperscript{50} Foucault, \textit{The Birth of the Clinic}, supra note 12.
\textsuperscript{51} Mark Cousins and Athar Hussain, \textit{Michel Foucault} (London: Macmillan, 1984) at 143.
\textsuperscript{52} Baronov, \textit{supra} note 14 at 31.
\textsuperscript{53} \textit{Ibid.}
\textsuperscript{54} \textit{Ibid.}
\textsuperscript{55} \textit{Ibid.}
African medical systems – much as they have come to be influenced by the clinical sciences – is not the product of the colonial-biomedical encounter. Rather, the interplay of diverse philosophies – empirical-natural, cultural and metaphysical – in African medical systems predates biomedicine’s arrival. This history is significant because the academic literature often ignores the natural etiologies of disease causation in IMS. The emphasis more often is on the supernatural in indigenous systems – the supernatural itself being conflated with the psychosomatic and psychosocial.

An objective historiography of indigenous medicine must highlight the fact that prior to biomedicine’s colonial incursion into African societies, indigenous medical systems “already featured many of the fundamental organizing principles of biomedicine”. While the majority of Western anthropological studies depict IMS as anti-scientific and anti-logical, the history of indigenous healthcare systems negates this perception. Baronov’s impression of the medical exchanges between indigenous African societies reveals the pragmatism employed in the process of exchange. Simply, what was and is acceptable as a valid system of medicine to be incorporated in the existing medical cultures are those that are considered the best practices in other cultures. Today, biomedicine co-exists with diverse healthcare traditions in many societies in the North and South. In Canada and the United States, for example, biomedicine co-exists with a range of therapeutic systems, including acupuncture, chiropractic, homeopathy, massage therapy, naturopathy, yoga, meditation, amongst others. In Nigeria, biomedicine thrives alongside a broad range of healthcare systems, some indigenous to the Nigerian society and others incorporated from other cultures. These systems include herbalism, naturopathy, psychotherapy, spinal manipulation, bone-setting, massage therapy, hydrotherapy, heat therapy, homeopathy, orthopedics, acupuncture, chiropractic, amongst others. These systems and practices are selectively regulated in Canada and Nigeria. This prejudicial regulatory approach can be traced to the history of imperialism and the legal, political and socio-cultural transformations it brought in its wake. The next sections examine

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56 Ibid at 30.
how biomedicine was employed as a philosophical and political instrument to legalize extensive institutional changes in colonized territories.

2.4. Imperialism and Indigenous Medical Cultures: The Arrival of Biomedicine

2.4.1. Biomedicine as Ethnomedicine

Nineteenth century colonialism in Africa, South East Asia and the Caribbean established new institutional frameworks in the colonies. In British West Africa, colonialism heralded far-reaching transformations in the laws and institutions of the states. These transformations affected virtually every aspect of the laws and cultures of the peoples. The specific interest here is on the effect of colonialism on healthcare and of colonial laws on medical practice. The analysis of this process of transformation will be based primarily on the experiences in Africa. Colonialism and biomedicine are discussed here as two interlinked and interdependent phenomena. This is because the introduction of biomedicine into Africa served multiple purposes, all of which are traceable to the agenda of subjugation and conquest.

Biomedicine is discussed here as a political, ideological and medical tool that facilitated and later “legalized” the West’s colonial agenda. The term “legalized” is fitting because even though biomedicine’s original objective in Africa in the 19th century was to ameliorate the plight of European soldiers and administrators, it eventually became an ideological weapon that rationalized Europe’s presence in Africa, and a political tool that was effectively used to challenge African belief systems and values.\footnote{See Baronov, supra note 14 at 18.} Biomedicine became conceived, not as the scientific and medical phenomenon it should have been, but as an ideological tool of empire that made Europe’s presence in Africa an absolute necessity. Baronov observes that “alongside the Bible and the gunship”, biomedicine was the “syringe” that facilitated the global rise of Europe.\footnote{Ibid at 17.} Biomedicine soon became an instrument for (re)educating Africans about the supposedly more civil values of the West, which Western biomedicine was said to represent.

However, this was not unexpected. Biomedicine and indigenous medicine each uphold beliefs and values that in some cases counter the other. Biomedicine embodies the West’s cultural perspectives on health and medicine, and these provide insights into Western society’s
collective worldviews.\textsuperscript{60} For example, biomedicine primarily treats disease or illness as a biological process, which requires the isolation and eradication of specific disease causing agents in the body. Biomedicine defines human health or disease as “[a]ny variance from the normal statistical ranges for the specie’s regular physiological functioning…”\textsuperscript{61} Within this perspective:

[T]he human body itself is laid before biomedicine as a soulless, multifunctional machine whose detailed internal structures require precise probing via a sophisticated complement of capital-intensive biotechnology. As such, biomedicine today is unmistakably identified with a range of scientific-material forms (from syringes to CAT scans) that mediate the relationship between physician and disease, between physician as active investigator and patient as passive object, and between the patient (a full person) and his or her body (a mass of biomedical functions and reactions). As a scientific enterprise, objectivity, standardization, and the peer-reviewed rigour of the scientific method provide biomedicine with the only conceivable investigative techniques for its phenomenal forms.\textsuperscript{62}

Thus, the term invokes “the primacy of its epistemological and ontological commitments, which are what is most radically different about this form of medicine”,\textsuperscript{63} and its epistemological and ontological foundations are traceable to the rise of the physical sciences in the $18^{th}$ century.\textsuperscript{64} Hence, biomedicine may be understood as a specific system of medicine embedded within a distinct cultural space, and which gives “concrete form to assumptions about reality drawn from the wider culture”.\textsuperscript{65} However, the term also expresses the “established institutional structure of the dominant profession of medicine in the West”\textsuperscript{66} though biomedicine is “no longer only Western, in its site of practice or in its locus of knowledge production and technological innovation”.\textsuperscript{67}

\begin{footnotesize}
\begin{enumerate}
\item Ibid at 18.
\item Ibid. Baronov, supra note 14 at 34.
\item Ibid at 34-35.
\item Baronov, supra note 14 at 34.
\item Steven Feierman, “Struggles for Control: The Social Roots of Health and Healing in Modern Africa” (1985) 28:2/3 \textit{African Studies Review} 73 at 110 ['Feierman']. Here, Feierman specifically refers to both indigenous African medicine and biomedicine as ethnomedical systems, which are both embedded within a system of social relations.
\item Kleinman (1993), supra note 63 at 16.
\end{enumerate}
\end{footnotesize}
Like biomedicine, which is allegiant to Western worldviews and values, indigenous medical beliefs and practices are reflections of a society’s underlying ideologies. As discussed above, indigenous medical practices combine the belief in the natural origins of illness with the knowledge of the influence of psychological and metaphysical phenomena on the physical body. The indigenous belief in the existence of transcendental beings is also reflected in the diagnostic and curative process. Indeed, medical systems originate from the cultural philosophies of the practicing community. As Fan and Holliday have observed:

Every long-standing medical tradition has developed within a particular culture: its key concepts of disease, illness and health, as particular substantive concepts, have functioned within a net of specific goals granted in that culture, based on its particular evaluative and explanatory assumptions. Accordingly, medicine is best taken to be part of the function of a particular culture. In order to decide what is a suitable medical problem and what is an appropriate medical way to deal with the problem, a distinct group of substantive goals set in a particular culture must be referenced.

Similarly, in The Birth of the Clinic, Foucault recognizes the temporal-situational nature of medical paradigms. He contends that various medical paradigms have progressively contributed valuable systems of knowledge and practices that have enhanced the understanding of the human body. From this perspective, medical knowledge may be viewed

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68 Note, however, that the biophysical and holistic nature of biomedicine and indigenous medicine should be understood as broad categorizations. These broad categories represent the core elements among “distinct health subcultures” (Oguamanam, supra note 22 at 12) as both medical systems – biomedicine and indigenous medicine – are dynamic systems, which are subject to constant evolution (Baronov, supra note 14 at 20). As Helman has noted, “There is really no such thing as uniform Western or scientific medicine” [C.G. Helman, Culture, Health and Illness (Oxford: Butterworth, 2000) at 82].


70 Ruiping Fan and Ian Holliday, “Which Medicine? Whose Standard? Critical Reflections on Medical Integration in China” (2007) 33 Journal of Medical Ethics 454 at 458. See also Baronov, supra note 14 at 34-35, where the author notes that “health beliefs and practices reflect a fundamental understanding of how societies view an individual’s and a community’s place within the world and how societies interpret an individual’s and a community’s relation to the natural, supernatural and social worlds.

71 Foucault, The Birth of the Clinic, supra note 12.

constructively “not simply as a given and objective set of facts but as a belief system shaped through social and political relations”.

Thus, while the incursion of biomedical philosophies into Africa was accepted pragmatically as an alternative system of knowledge, Europe’s use of biomedicine as a tool to challenge the culture of the colonies was a serious source of conflict. Although this conflict was arguably minimized by the colonies’ pragmatic acceptance of biomedicine (and other economic and political developments) as a new system of things, history would later reveal the devastating impact of the imposition of ‘one system of things’ over the established cultures and philosophies of the people. In the establishment and transplantation of laws and policies to legitimize certain institutions (such as the medical system) and prohibit or derecognize other systems or institutions, it failed to be recognized that the “non-legal constraints and resources” in the receiving countries differ widely from that of the exporting country. These factors – a broad range of social, cultural, political, economic, geographical and even historical dynamics – highly influence the success of the new set of norms.

2.4.2. The Role of Biomedicine in Legal and Institutional Transplantation

The arrival and imposition of new norms owed nothing to chance. It was part of an ideological battle designed to place Europe’s capitalism at the world stage. Scholars have noted that biomedicine’s transportation to Africa during the late 19th century and early 20th century period of imperialism, which marked a period of territorial expansion of capitalism, was strategic. According to Baronov, “at the level of the capitalist world-system…. biomedicine in Africa marked a transformation of collective worldviews in concert with participation in the global division of labour and processes of capital accumulation”. For Europe to obtain successfully the raw materials and “coerced labour” that sustained capital accumulation among the advanced nations, biomedicine gilded as ‘tropical medicine’ needed to be introduced. As a branch of biomedicine, tropical medicine is designed to identify and treat

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73 Ibid.
74 A. Seidman and R.B. Seidman, State and Law in the Development Process: Problem-Solving and Institutional Change in the Third World (New York: St. Martin’s Press, 1994) at 46 ['Seidman and Seidman'].
75 Baronov, supra note 14 at 26.
76 Ibid.
77 Ibid at 78.
specific diseases found in the tropics. Narrowly linking diseases to parasitic vectors, Europe through tropical medicine strove to “convince Africans first of the superiority of the European’s medicine and second of the need to treat “medicine” as an ends-driven, purely scientific matter – unrelated to supernatural or interpersonal concerns”.

Notably, in furtherance of European expansion, tropical medicine was employed to serve and place the wellbeing of Europeans in the colonies before that of the colonized. After European soldiers and administrators, the next group of people on the hierarchy of those who needed to be protected from tropical diseases were settlers, civil servants, and labourers who occupied key economic positions. These groups of people had to be kept alive to sustain Europe’s capitalist expansion. While British expeditions to West Africa between 1805 and 1841 had met with a mortality rate of 50%, the same expeditions into the Gold Coast (Ghana) and Nigeria between 1881 and 1887 met with a greatly reduced mortality rate of 5-8%. The golden tool for survival in this latter period was quinine, which was administered to the twenty-five hundred British troops to resist malaria. MacLeod has noted that “European medicine, and its handmaiden, public health, served as ‘tools of empire,’…as images representative of European commitment, variously to conquer, occupy or settle”. The destabilization of indigenous medicine and its ideologies was one result of this commitment. Baronov notes that:

As an expression of social power, tropical medicine in Africa supported and legitimated European colonial rule and persistently marginalized African pluralistic medicine. The benefits of tropical medicine for treating age-old scourges provided a benign rationale for European activities in Africa. At the same time, the “scientific” methods behind tropical medicine were purposely portrayed in a manner to denigrate and belittle African pluralistic medicine.

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78 Ibid at 94.
79 Ibid at 95.
81 Roy MacLeod, “Introduction” in Roy MacLeod and Milton Lewis, eds., Disease, Medicine and Empire: Perspectives on Western Medicine and the Experience of European Expansion (New York: Routledge, 1988) at 7 cited in Baronov, supra note 14 at 95-96 [‘MacLeod’].
82 MacLeod, ibid at x.
83 Baronov, supra note 14 at 95.
This agenda had far-reaching implications. Colonialism, sustained by tropical medicine, drastically “restructured” virtually all of the African continent’s political, economic, and socio-cultural institutions.\(^{84}\) As discussed below, it also radically altered the existing legal order. The destruction of the extant legal order – law being the primary instrument for institutional design – could be argued to be the most devastating of the transformations because the restructuring of the legal order resulted in the alteration of the political, economic, and socio-cultural order. With economic and political domination as a central aspect of Europe’s goals, colonies were transformed into “international economic network(s) in which trade occurred within a single economic unit (such as the British empire) rather than between units (such as between Nigeria and Britain)”.\(^{85}\) Economic prohibitions sought to abolish “industrialization, manufacturing, or the processing of raw materials – involving the manufacturing of a vast range of products, including soap, building materials, iron tools, cloth, pottery, and gold. These were the very activities that had sustained the African community prior to colonialism. Agriculture was also restructured to focus on the production of cash-crops that served the interests of international exports. This trend contrasted the “semisubsistent” lifestyle of the African family, which had allowed Africans very limited contact with the nascent capitalist market economy.\(^{86}\)

While the extant state system was enthroned and African political institutions and “cultural symbols of African authority and power”\(^{87}\) were denigrated and dethroned, the social system was largely restructured as an individualistic worldview replaced the “established communal social orders”.\(^{88}\) The destabilization of beliefs systems led to a loss of faith in the traditional laws that held the African society together.\(^{89}\) Again, it is important to reemphasize the strategic role of biomedicine as a new scientific force in this process. In replacing African institutions with European institutions, the health clinic, as well as the church and centres of education, were employed as tools of propaganda.\(^{90}\) The words of H.C. Trowell, a colonial

\(^{84}\) Ibid at 86.
\(^{85}\) Ibid at 88.
\(^{86}\) Ibid.
\(^{87}\) Crawford Young, The African Colonial State in Comparative Perspective (New Haven, CT: Yale University Press, 1994) at 93.
\(^{88}\) Baronov, supra note 14 at 90.
\(^{90}\) Ibid.
medical officer, confirm the link between the powerful influence of biomedicine, the church, the school and Europe’s politico-economic machinery in the gradual disintegration of the legal, political and economic life of the colonies:

The combined forces of scientific invention, materialistic philosophy, philanthropic humanism, Christianity, education and economic enterprise are breaking down this primitive philosophy, and the greatest of these is the ruthless energy of modern economic enterprise which in every plantation, every market and every wayside stone is throttling out the life breath from the primitive philosophy of magic.\(^{91}\)

In the light of this colonial philosophy, it is logical to conclude as some scholars have asserted that biomedicine was indeed “one of the most powerful weapons for imposing Western cultural values, beliefs, and practices on African peoples and, thereby, for furthering the colonial mission of conquest and economic exploitation”.\(^{92}\) Similarly, Bynum affirms that “if medicine could tame the diseases that were rampant in the tropics, it had undoubted political force as a tool of empire, and the country with the most advanced medical capabilities stood the greatest chance of success in the hostile environments of Africa, Southeast Asia and the Caribbean”.\(^{93}\)

The colonial agenda, bolstered by the ideological and cultural power of biomedicine, also had extensive impact on the health of the people. This impact was particularly evident in the case of malaria and sleeping sickness.\(^{94}\) A number of scholars assert that the “pattern of European colonization” exacerbated the spread of malaria and other insect-borne diseases.\(^{95}\)

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\(^{92}\) Baronov, supra note 14 at 91.


\(^{94}\) Feierman, supra note 65 at 96-99.

The works of these scholars suggest that “the origin and spread of disease was often a direct function of the disruption to settled patterns of social organization and daily life introduced by colonial structures”. The arrival and pattern of colonization took the form of war and ambush, communal destabilization and resettlement, deforestation and ecological disruption and large-scale movements of people. In Tanzania, this led to the rapid spread of epidemics, in the Belgian Congo, it resulted in the rapid spread of sleeping sickness, and in Morocco it caused a serious outbreak of cholera. David Patterson notes that “deforestation allows sunlight to reach pools of water, creating favourable breeding conditions for Anopheles gambiae, the major vector of falciparium malaria”. While clearings and resettlements encouraged contact between “previously separated populations” and exacerbated the spread of previously localized insect-borne diseases, the locals’ intensive labour on the cash-crop farmlands created for the European export business and their focus on cash-crops resulted in “decline in the nutritional status and general well-being of natives”.

2.4.3. Independence, the Alma-Ata Declaration and New Boundaries of Legitimacy

It is important to emphasize that when biomedicine and the specialized branch of tropical medicine were introduced to ensure the survival of the colonial agenda, its benefits were unevenly split between the colonizers and the colonized. While Dar es Salaam had one hospital bed for every ten Europeans which contrasted one bed for every 400 to 500 Africans in the 1920s, “by the 1930s, Nigeria had 12 hospitals for 4,000 Europeans and 52 hospitals for 40 million Africans”. This situation worsened when independence arrived in the 1960s. The

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96 See *ibid*.


99 Turshen, *ibid* at 134.


102 Patterson, *supra* note 95 at 8.

103 Porter, *supra* note 100 at 466. See also Onoge, *supra* note 95 at 225.

sudden return of European medical staff to their homelands left African hospitals seriously understaffed. Africans had been excluded from positions of responsibility while European occupation lasted.\(^{105}\) By the 1970s, healthcare in Africa had evidently deteriorated. And, by 1978, this situation culminated in the “politically charged” Alma Ata international conference.\(^{106}\) The resulting Declaration of the Alma Ata conference affirmed healthcare to be a basic human right,\(^{107}\) and this created an international awareness of the dire healthcare problems that had besieged previously colonized territories. Nevertheless, the lofty objectives of the Alma Ata could not be achieved with the highly limited resources Europe had left behind.\(^{108}\)

The situation was further complicated by the nature of the newly established laws and institutions, which – as expected of any major and radical institutional change – redefined the boundaries of legitimacy within different institutions, including the healthcare institution. Colonial healthcare laws and policies espoused biomedicine while suppressing indigenous medical practices. The new biomedical institution pandered to the capitalist market, in which public health came to be viewed as “a commodity in the market place” available to only those who could afford it.\(^{109}\) This trend replaced the socio-cultural practice of indigenous medicine, which when expedient, was more socialist than capitalist in its economic ideology. In the transplantation of legal norms from the West, there seemed to be no acknowledgement of the fact that the receiving nation had limited technological resources and a unique socio-economic pattern differing from the imposed capitalist system. Take for example the ideology of the Western patent system, which espouses a notion of innovation and knowledge ownership that runs counter to the economic and technological realities of many Southern nations. Medical innovations from the knowledge of peoples of these nations are presently excluded from the protection of the Western (now worldwide) system of patents, which confers patent protection only on ‘innovations’ that are scientifically reducible. Some of the disparities between African and European knowledge systems, and the manner in which each has developed have much to

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\(^{105}\) Baronov, ibid at 118.
\(^{106}\) Ibid.
\(^{107}\) Ibid.
\(^{108}\) Ibid.
\(^{109}\) Onoge, supra note 95 at 229.
do with the availability of the material and technological resources available to Africa. As Onoge clearly explains:

..It is clear that the limitations in the fund of medical knowledge in traditional Africa were not strictly a function of an antiscientific temper. A more plausible explanation will have to be predicated on the level of sophistication of the technological base. A community without microscopes cannot be expected to formulate a germ theory of disease, when germs are invisible to the naked eye…

The appropriate means (beyond Europe’s transplanted patent system) for protecting the indigenous therapeutic innovations of the global South, which is the subject of chapter four, remains a much-contested issue in international law.

The problems of institutional and legal transplantation have persisted from colonial times to the present day, and societies are yet to recover from the drastic change from one communal, socio-economic system of healthcare, which figuratively speaking was available at every street corner, to an essentially capitalist system of healthcare, available to the highest bidder and with a dismally limited number of administrators. Over the years, this institutional transformation has been further entrenched in the post-colonial society by the transposed models of governance that sustain the institution of biomedicine in the West.

2.5. Corollaries of Colonialism: The End(s) of Health Governance

2.5.1. New Ideologies and New Governance

In the years that followed the departure of Europe, Africans began formal training programs in biomedicine. Worboys notes the devastating and enduring effect of the new African state’s focus on a narrow biomedical paradigm:

Paradoxically, as colonial medical institutions gained greater formal autonomy they were drawn into international medical and science networks which meant that rather than setting their own priorities, they were drawn to the priorities of the North and its approach to disease control.  

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110 Ibid at 223.
While colonialism lasted, indigenous medicine (with its emphasis on preventive measures) was effectively pushed to the sidelines. Although some practices, such as herbalism, were generally tolerated because of the heavy reliance of Africans on these therapies, the ideology and practices of indigenous medicine were largely suppressed through various campaigns and laws designed to abolish indigenous health-related practices in the colonies. For example, laws were passed to abolish socio-cultural and health-related practices that were founded on the belief in the supernatural. In many parts of Africa, anti-witchcraft laws were passed to put an end to the belief in the existence and disease-causing power of witchcraft. These laws prohibited any imputations that a person had caused illness in another by the power of witchery or wizardry or similar superstitious means. Chapter 20 of the Nigerian *Criminal Code* retains provisions traceable to pre-colonial times that outlaw charms and the invocation of *juju* in certain cases. In 1917, the British banned the Sopona smallpox cult in Nigeria – a public health institution that had served as a mechanism for protecting the health of Nigerians in the pre-colonial era.

In spite of these laws and policies, indigenous medicine survived in Africa. One reason for its survival could be linked to its role in meeting the deficit in biomedical services. Another relates to its holistic nature, which respects the cultural values of indigenous peoples. It also appears that the British tolerated some aspects of indigenous African medicine because indigenous medical practitioners had political influence among their people. However, while indigenous healthcare systems have remained a significant part of the medical options of indigenous communities, they have never been accorded the same status conferred on biomedicine. It is pertinent to explain that the dominance of biomedicine in cultures with a strong indigenous medical culture has more to do with its political and ideological power than with some of its inherent strengths over indigenous medicine. The colonial message that “scientific invention”, “Christianity”, and “materialistic philosophy” were more noble goals and ideals had certainly infiltrated the previously tight-knit belief systems of the colonized. Scientific biomedicine was at the forefront of the colonial aspiration to ‘stifle’ “the life breath

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113 Baronov, *supra* note 14 notes (at 120) that “it was evident to colonial officials that the position of pluralistic-medical practitioners as interpreters of – and mediators within – the broader African cosmological order granted them considerable power and influence”.
from the primitive philosophy of magic” of the colonized. After the arrival of independence and of a new breed of elite African leaders educated in the West, there was an outward shift towards European values, philosophies, and institutions, which was evident in the new legal and institutional frameworks that replaced the pre-colonial systems.

This shift was emblematic of the aspiration of the post-colonial state to fit into Europe’s internationalized legal order and institutional norms. Ironically, this outward, political interest in modernizing Africa in the likeliness of Europe did not always reflect the internal beliefs of the policymakers. Thus, a significant number of politicians in African states continue to patronize IMPs. Their patronage is withheld (as much as possible) from public knowledge while they publicly adopt and implement European policies and agenda. This interest in adopting “an alternative understanding of health and illness that partially borrows from the colonizer” while maintaining the values of indigenous belief systems explains the somewhat incompatible realities of the survival of indigenous medicine and the difficulties encountered by IMPs in their struggle for recognition. The formal attempts of the elite leaders to develop or integrate indigenous and allopathic medicine in the post-colonial state began only in the 1970s when the WHO began to make calls for the integration of both medical systems. While some African states have attempted to grant recognition to indigenous medicine through “Traditional Medicine Acts,” this initiative has granted very limited legitimacy to indigenous medical systems.

Health governance transcends the mere promulgation of Acts to recognize the existence of indigenous medical practice. It also has a broader role beyond the validation process carried out by food and drug agencies for indigenous medical products, important as this is for consumer protection. The current trend of ‘governance’ involves the restriction of regulatory concerns to issues of safety, non-toxicity and efficacy of products and services, a task easily assigned to the biomedical profession, while substantive governance of indigenous health systems is left to practitioners, private actors and market forces. In many jurisdictions, including Canada and the US, state ‘governance’ of indigenous medical systems begins and ends with the grant of self-governing status to specific indigenous medical professional.

114 Ann Beck, A History of the British Medical Administration of East Africa (Cambridge, MA: Harvard University Press, 1970) at 139. The word used in place of ‘stifle’ in the original quotation was ‘throttling out’.
115 Baronov, supra note 14 at 126.
116 One example of these laws is the Nigerian Traditional Medicine Bill (draft is on file with author).
groups. In some cases, these groups are legislated under their own statutes, and in other cases, are included within broad statutes (such as the Regulated Health Professions Act of Ontario, 1991 or the Nigerian Traditional Medicine Bill) which identify the indigenous medical groups to which they relate as self-governing professions.

Presently, two regulatory approaches emerge from this trend: a co-optation model of regulation in which biomedical providers sanctioned by the state deliver indigenous or non-biomedical therapies, which have been certified to be safe and effective, and a parallel existence or co-existence approach in which certified (or uncertified) indigenous and alternative medical practices exist alongside the biomedical system. In the latter case, the state does not extend to the indigenous or alternative systems its broader responsibility to govern health systems. While it may regulate selected alternative systems, the state’s primary allegiance is to the Western biomedical system to which it owes the comprehensive array of responsibilities that constitute ‘governance’: regulation, research and development, financing (including insurance coverage), educational training through state-approved institutions, continuing education for healthcare professionals, knowledge transfer between the professions, and more importantly, integration of indigenous modalities into national healthcare delivery. Governance, therefore, transcends the simple validation of indigenous and alternative health systems through evidence-based research on safety, efficacy and cost-effectiveness of the products and practices. As explained in chapter three, while there is need for a comprehensive research paradigm to confirm the safety and effectiveness of the therapies utilized by healthcare consumers, state governance of indigenous and alternative medical systems must address the broader issues that form part of a governance regime.

A significant consequence of the modern state’s minimal interest in indigenous medical systems is that there are either no directly applicable laws or policies to determine the relevant

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117 See for example, the Ontario Regulated Health Professions Act, S.O. 1991, c.18. This law, without more, recognizes the regulatory colleges of some alternative medical professions, such as chiropractic and massage therapy, and two transitional councils representing the colleges of traditional Chinese medicine and acupuncture, and Naturopathy. Even in provinces where some alternative medical professions are statutorily recognized, there is usually no provision for financing, itself an aspect of ‘governance’; the norm is selective or zero Medicare coverage of alternative medicine.

118 See ibid, Regulated Health Professions Act, S.O. 1991, c.18.

119 Nigerian Traditional Medicine Bill (on file with author).

standards in indigenous medical practice in some countries like Nigeria, or existing medical and other relevant laws pertaining to health consumption are skewed to recognize only the biomedical form of healthcare. Statutes established to grant official state recognition to indigenous medicine (such as Traditional Medicine Acts) are of no use in everyday medical practice. Although Traditional Medicine Acts grant formal recognition and legitimacy in limited cases to indigenous medical systems, the adjudication of substantive medical issues (including but not limited to malpractice, funding-related and reimbursement claims, as well as constitutional claims based on a supposed right of access to specific therapies) are often based on legal rules, which recognize biomedicine as the dominant healthcare system. For example, the charge of malpractice against a healthcare provider who administers non-biomedical therapies is often adjudicated on the principles of tort law – principles drawn wholesale from biomedical practice standards.

To put it plainly, the tort of medical negligence has no inherent source for the legal rules that it establishes. The source of its legal rules in practice is biomedicine; the precepts of biomedical practice implicitly determine what standards are legally acceptable. As Michael Jones has noted, while “it is the tort of negligence that provides the bottom line: minimum standard of acceptable professional conduct”, in actual practice “medical negligence is a failure to live up to proper medical standards, and those standards are set, not by lawyers, but by doctors”.121 This position was laid out by the English Court in Sidaway v. Board of Governors of the Bethlem Royal Hospital,122 where Lord Scarman stated that “the law imposes the duty of care: but the standard of care is a matter of medical judgement”.123 Thus, where a legal issue arises in the context of indigenous medical practice, indigenous medicine is placed in a grey space, where the questions include: should biomedical rules apply to the indigenous medical practitioner whose medical standards of practice (i.e. methods of treatment and diagnosis) differ from that of the biomedical practitioner? In the case of an adverse reaction from the administration of a specific indigenous therapy, what standard has the practitioner (being either a biomedical or indigenous practitioner) contravened? Healthcare laws in many

122 Sidaway v. Board of Governors of the Bethlem Royal Hospital, [1985] AC 871.
123 Ibid at 881. Lord Scarman made this point while referring to the problematic Bolam principle (Bolam v. Friern Hospital Management Committee, [1957] 1 WLR 582) in English medical law jurisprudence.
countries of the North and South, including Canada and Nigeria, have no clear answers to these questions.

A number of judicial examples illustrate the legal problem here. In the Canadian case of \textit{Ter Neuzen v. Korn},\textsuperscript{124} the court’s dicta suggests that once a practice is established as generally accepted within \textit{a profession}, then the courts will defer to the expertise of the profession as a whole in determining the applicable standards of care. Of course, this begs the question of what constitutes a profession.\textsuperscript{125} In the US case of \textit{Rosenberg v. Cahill},\textsuperscript{126} a chiropractor who failed to see the patient’s tumours on an x-ray misdiagnosed the medical condition and prescribed manipulation therapy. At trial, the chiropractor contended that a medical doctor could not testify as to the standard of care required of chiropractors. The court had to decide whether a biomedical practitioner could provide the required expert testimony based on the chiropractor’s use of a biomedical tool of diagnosis. Evidently, there was professional overlap between two medical paradigms. By crossing from one paradigm to another in the course of practice, the chiropractor fell outside the general rule that only members of the same profession can provide expert evidence of the standards of practice.\textsuperscript{127}

The Canadian cases of \textit{Gibbons v. Harris},\textsuperscript{128} and \textit{Penner v. Theobald},\textsuperscript{129} provide further examples of the unsettled nature of the law on alternative or integrated medical practice. In \textit{Gibbons}, the Alberta Appellate Court rejected the notion that a physician could not testify as to the correctness of a chiropractor’s diagnosis on the ground that “there cannot be any question of different schools of opinion” when the diagnosis of a certain practitioner is called into question.\textsuperscript{130} However, the Manitoba Court of Appeal in \textit{Penner} rejected this earlier position. Allowing evidence of the form of diagnosis peculiar to chiropractic, the court held that “types of diagnosis may vary with different systems of health care; the type of diagnosis is naturally founded on the basic principles of each particular system. For that reason diagnosis by a

\textsuperscript{125} This issue is discussed in chapter 6, \textit{infra}. For a discussion of what constitutes a healthcare profession, see Colin Feasby, “Determining Standard of Care in Alternative Contexts” (1997) \textit{5 Health L.J.} 45-65.
\textsuperscript{126} \textit{Rosenberg v. Cahill}, 492 A 2d 271 (NJ 1985).
\textsuperscript{127} This general rule is known as the ‘same school rule’. Having noted the overlap of two schools of practice in the chiropractor’s use of an x-ray in diagnosis, the court held that the facts of the case constituted an exception to the same school rule. See chapter 6, \textit{infra}, for a full discussion of this rule.
\textsuperscript{128} \textit{Gibbons v. Harris} (1924), 1 DLR 923 (Alta SC App. Div.).
\textsuperscript{129} \textit{Penner v. Theobald} (1962), 35 DLR (2d) 700 (CA) [‘Penner v. Theobald’].
\textsuperscript{130} \textit{Ibid} at 925. The court stated that the general rule preventing medical practitioners from assessing a chiropractor’s standards of care “can only apply where the diagnosis has been correct” (at 928).
medical doctor or an osteopath or a chiropractor may differ in some respects …". Interestingly, the Ontario Court of Justice in the more recent case of Barber v. Wilson followed the earlier decision in Gibbons.

These are a few of the many cases that exemplify the uncertainties in the law on integrated and alternative medical practice. Thus, whether we are considering the legal landscape in the United States where there are more promising legislative developments in this area or Canada with more conservative laws on the subject, there are no preset legal principles for determining the applicable standards in integrated and alternative medical practice. The healthcare laws of these countries – like in many postcolonial states in the South – have their roots in biomedicine.

2.5.2. Ideology, Capitalism and Health Equity
The attainment of independence has not removed many of the vestiges of colonial rule. Laws governing medical practice in many postcolonial states are virtual replicas of imperial laws. For example, the English Common Law, the doctrines of equity and the statutes of general application effective in England as at January 1, 1900 are generally in force in Nigeria, except where a local statute expressly makes provisions over the subject matter of a particular statute. Thus, the rules of tort law as part of the inherited Common Law tradition apply to negligence in medical practice in the country. The Medical Practitioners and Dentists Act, which was established in 1958 to regulate the ‘new’ medical and dental profession in Nigeria was also modelled after its British counterpart to regulate the new institution of

131 Penner v. Theobald, ibid at 222.
133 Precedents from different areas of law including property, contracts, commercial, banking, and insurance laws are often directly applied in receiving states: see generally Seidman and Seidman, supra note 71. However, exceptions are created in some areas, such as in matters concerning land tenure, succession and inheritance, marriage and family, and chieftaincy cases to which Nigerian customary law shares some jurisdiction with British law: T.O. Elias, Nigeria: The Development of Its Laws and Constitutions (London: Stevens and Sons, 1967) at 310 [‘Elias’]. Even where a local law or custom is deemed applicable to a matter, the Nigerian courts are enjoined to ensure that such custom is not “repugnant to natural justice, equity and good conscience, nor incompatible either directly or by implication with any law for the time being in force” (ibid). The rules of natural justice, equity and good conscience, however defined, are usually construed based on what is acceptable under the British legal system: for details of how this situation may be held accountable for underdevelopment in Africa, see generally Seidman and Seidman, supra note 74.
This Act was repealed and replaced by the *Medical and Dental Practitioners Act of 1963*. The new Act set out to “rationalise the basis of medical and dental education and, in consequence, to make new provision for the registration, discipline and other matters relating to the medical and dental professions”. The Act established the Nigerian Medical Council, part of whose duty was to determine the “standards of knowledge and skill to be attained by persons seeking to become members of the medical or dental profession and the raising of those standards from time to time”.

Evident from the objectives of the law and the organization and practice of the biomedical profession in Nigeria are clear attempts to streamline Nigerian biomedical practice along the frameworks established by the progenitors of biomedicine. Today, this framework is more clearly represented by an international capitalist model of healthcare delivery. From the myriad private-for-profit healthcare clinics proliferating and concentrated in the major cities to the state’s subordination to global biomedical actors (including pharmaceutical and biotechnology companies, funding agencies for biomedical research, the World Bank and the International Monetary Fund), what is operative is a global biomedical institution that recognizes and privileges biomedicine (and its ethno-Western ideology of health) over all other medical systems, that considers biomedicine a commodity like any other to be bought and sold based on the dictates of market principles, and that assumes neoliberal policies can be effectively applied to govern the healthcare system. On this note, Baronov observes that:

> A…sphere of global actors – a collection of influential foundations and governmental and nongovernmental organizations (NGOs) – has emerged to expedite this expansion of biomedicine via the provision of “foreign aid” in the form of humanitarian medical assistance. Not unlike officials from the World Bank and International Monetary fund who link financial assistance to neoliberal policies (for example, structural readjustment), these avowedly humanitarian organizations largely adhere to the cultural and economic norms of Western biomedicine when designing aid and promoting market-based medicine.

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134 *Medical Practitioners and Dentists Act*, CAP 116 LFN 1958. The Act came into effect on November 22, 1934. The Act established a Board of Medical Examiners part of whose responsibility was to grant certificates to medical assistants who had graduated from the then Nigerian Medical School at Yaba Higher College. The board’s responsibilities ended in 1957 when the University College Hospital, Ibadan, began to grant degrees to fully qualified doctors.


136 Elias, *supra* note 133 at 397-398.

137 *Ibid* at 398.


139 Baronov, *supra* note 14 at 191.
This argument resonates in the writings of a number of scholars. According to this argument, the unrealized promises in the healthcare systems of African nations are the outcomes of the illusory proposals of the World Bank and the IMF, which proffered solutions to Sub-Saharan African healthcare systems on the assumption that the privatization of healthcare was the most effective means of achieving efficiency and equity.\textsuperscript{140} The World Bank’s \textit{World Development Report}\textsuperscript{141} published in 1993 introduced a “new orthodoxy” in health policy: “drawing on the neo-liberal ideology that framed policies of the international financial institutions in other sectors, the core of the new orthodoxy was the view that the private sector could most efficiently meet most healthcare needs and should be allowed…to do so.”\textsuperscript{142} Within this arrangement, the public sector was relegated to the reactive role of intervening when there was market failure and providing a range of “cost-effective services”.\textsuperscript{143} O’Manique contends that:

\begin{quote}
The World Bank’s health strategy was one instrument for bringing global health policy into line with the neo-liberal canon that ascribed health mainly to the private domain, through the introduction of market forces into the health sector and the allocation of public resources according to the criteria of technical efficiency and cost-effectiveness.\textsuperscript{144}
\end{quote}

However, the reality of the healthcare situation in Sub-Saharan Africa sharply counters the bilateral public-private picture generated by the World Bank’s Report. The situation in most medically pluralistic countries in the South can be more appropriately divided into “organized” and “non-organized” categories.\textsuperscript{145} According to the Freedman \textit{et al.}:

\begin{quote}
\textsuperscript{142} Freedman \textit{et al.}, supra note 140 at 39.
\textsuperscript{143} \textit{Ibid}.
\textsuperscript{144} O’Manique, supra note 140 at 53.
\end{quote}
The choice that people confront is not between a private healthcare system that charges for a broad menu of high-quality services and a public system that offers essential services at no or low cost. Instead, all users, rich and poor alike, are confronted with a bewildering array of sources for healthcare, from medicine peddlers to traditional healers to highly trained specialist physicians to civil servants setting up private practices of wildly uneven quality...As Bloom and Standing point out, the weakening of government supervision systems, is “an important factor contributing to the de facto marketization of health services.”

The Nigerian healthcare system exemplifies such a pluralistic and implicitly chaotic healthcare situation. Healthcare consumers are confronted with an array of costly services in a system where government control has since colonial times been predisposed towards a biomedical and capitalist approach. Biomedicine remains the central focus of health governance in many Southern countries – a situation bolstered by the delivery of humanitarian biomedicine through foreign aid initiatives.

The pluralistic nature of healthcare in most countries of the North and South makes the monolithic governance of healthcare through the neoliberal ideologies of biomedicine a less than efficient way of governing healthcare. Within the cohort of medical systems and methods that exist in these societies are a complex combination of differing medical philosophies and socio-cultural worldviews, as well as diverse approaches to patient care, healthcare delivery, and financing. This multifarious combination of systems and procedures requires a governance model engineered to address its unique form. However, WHO Member States are yet to recognize the importance of governance reform in this respect. Propelled by a global market where Western biomedical and pharmaceutical firms unilaterally (or bilaterally depending on the influence of powerful funding agencies) dictate local trends by reifying the colonial ideology of biomedicine as the only dependable system, state governance of IMS has remained in infancy. The continuity between the colonial past and the colonial present is pervasive in the present system of governance: foreign organizations “adhere to the cultural and economic norms of Western biomedicine when designing aid and promoting market-based

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146 Freedman et al., supra note 140 citing Gerry Bloom and Hilary Standing, Pluralism and Marketization in the Health Sector, ibid.
147 Iyioha, In Search of Law’s Residence, supra note 138 at 270.
148 However, there are some recent changes in the Nigerian healthcare system. See the next section where these changes are discussed.
149 See Baronov, supra note 14 at 191.
medicine”¹⁵⁰ for Southern nations. Further, “just as the colonial powers of the past introduced tropical medicine to reap the benefits of a healthy workforce, today Western biomedical firms continue to profit from providing healthcare to Africans”.¹⁵¹

Fundamentally, what has happened in postcolonial Africa and indeed, in many societies in the South, is a near total replacement of local laws and institutions with a set of foreign laws and institutions, which were themselves designed to apply to a different people and a different set of circumstances. The legal order, as the primary tool for institutional change, was instrumental to the wholesale adoption of the West’s monolithic healthcare structure with its accompanying medical laws. The new legal order sanctioned and facilitated the establishment and practice of biomedicine and signalled the disenfranchisement of indigenous health professions. The blanket adoption of biomedicine, and the consequential lack of governance of indigenous medicine, has failed to save African¹⁵² and Southern healthcare systems generally. Decades after biomedicine’s adoption and the attempts by African governments to streamline healthcare policies alongside the European model, Africa still has a weak healthcare system that has failed to sustain its population.

2.5.3. Healthcare Affordability, Financing Models and State Governance: Imperatives for Institutional Change

Whether in the specific area of medical practice or in the fields of law, economics or politics, the transplantation of the institutions and/or the legal system of one country to another has not been successful. In fact, Seidman and Seidman assert that “legal transplants” have failed universally.¹⁵³ This is because:

Inevitably, people chose how to behave, not only in response to the law, but also to social, economic, political, physical and subjective factors arising in their own countries from custom, geography, history, technology and other, non-legal circumstances.¹⁵⁴

¹⁵⁰ Ibid.
¹⁵¹ Ibid at 192.
¹⁵² Ibid at 118-119. According to the author (at 118), in spite of all the “impressive developments in the area of biomedical services in these decades, long-standing colonial policies based on racial exclusion proved highly destructive during the decade of independence in the 1960s”.
¹⁵³ Seidman and Seidman, supra note 74 at 44.
¹⁵⁴ Ibid at 45.
Stated differently, while the new laws and institutions demand or expect particular outcomes, the cultural, social, and economic realities (including the availability of key human and technological resources and their impact on the spatial or geographical distribution of healthcare resources) prevent those outcomes from taking shape. Take for example the realities – broadly stated – in the Nigerian state. As already briefly discussed above, the Nigerian healthcare situation is pluralistic. The diverse sources of healthcare services and products outside the biomedical institution are not unrelated to the limited availability of technological and human resources in healthcare. While since independence the country has attempted to trail the path of capitalist nations in many of its institutions including its healthcare sector, the independent Nigerian state has emerged from a past that could be rightly described as a social economy.

The Nigerian social economy – as exemplified by its pre-colonial indigenous healthcare system amongst other institutions – is founded on values of cooperation, sharing, and mutual obligation.\textsuperscript{155} The indigenous healthcare establishment as a socio-economic institution placed the consumer’s ability to finance healthcare services at the forefront of considerations factored into payment schemes. Today, most practitioners continue to maintain a variable fee structure.\textsuperscript{156} Fees may be charged on the basis of the economic power of the patient; the more wealthy members of society are charged higher medical costs than are the poor. A diverse range of payment methods are adopted to cater to the interests of different healthcare consumers. For example, practitioners may adopt an “outcome-contingent” payment scheme, in which payment is made only after the treatment is successful.\textsuperscript{157} Such a payment method might be employed for an indigent patient or in a situation where the practitioner suspects the medical condition may be better suited for referral to a biomedical practitioner or a colleague specialized in the area of the medical condition. In this case, the indigenous practitioner is interested in seeing that the patient pays for effective care. In other cases, an indigenous practitioner may offer free services or simply ask the patient to express gratitude in some other


\textsuperscript{156} Data obtained from Nigeria drawn from the International Research on Usage, Financing and Governance of Indigenous and Integrated Medicine (2009) [‘Iyioha, International Research’] on which this work is founded (on file with author). See chapter three, infra, for research outcomes on payment methods for indigenous medicines.

non-monetary method. This method may be by way of complimentary services rendered to the indigenous medical practitioner. In some other situations, payment for health services may be either waived or postponed to an (un)specified future time when the patient is able to afford it.\textsuperscript{158}

However, it is important to introduce a caveat here: indigenous medical services and products are not in themselves ‘cheap’. The scholarship on indigenous medicine often describes these systems of healthcare as cheap and affordable; the assumption is that indigenous medicine is more affordable than allopathic medicine. This supposition often provides some form of justification for why citizens of Southern nations continue to patronize IMS in spite of its supposedly unscientific nature. Other scholars have affirmed the more accurate account that the services of indigenous healers are often expensive, and in many cases, indigenous medicine is “the more expensive option” among different alternatives.\textsuperscript{159} Thus, “[w]hile many Western observers have assumed that healers charged less, (often in a face-saving context of trying to explain why indigenous medicine retained so many patients)”, the more correct observation, as Anne Digby notes of South African indigenous medical practice, is that many do not charge low fees.\textsuperscript{160} Another scholar observes that routine biomedical care is often less expensive than the care of indigenous medical practitioners in Africa.\textsuperscript{161} However, to sum up the different accounts of the cost of indigenous medicine, when payment for indigenous medical care is made on the basis of contractual agreements between practitioner and patient in which payment is based on a negotiated formula, it can be a more affordable form of care than biomedical care.

The range of methods developed by IMPs to ensure the affordability of indigenous medicine places indigenous medicine apart from its biomedical counterpart: while in its form and content, the financing approach within indigenous medical systems resembles the Welfare system aptly captured by the social health insurance scheme, its diversity of approaches transcends the features of the Welfare system. These financing models are still in practice in some communities. Respondents in the research conducted in Nigeria affirmed and approved

\textsuperscript{158} Iyioha, International Research, supra note 156; Muela et al., ibid.
\textsuperscript{160} Digby, ibid at 12.
\textsuperscript{161} Baronov, supra note 14 at 32.
the existence of these approaches. In contradistinction to this flexible payment scheme, healthcare consumers in the country are usually unable to access healthcare services in biomedical health centres without expensive down payments.\textsuperscript{162} Years of purchasing expensive biomedical healthcare out-of-pocket has caused immeasurable hardship to the country’s citizens.

Recently, Nigeria established the Social Health Insurance Scheme (SHIS), which provides insurance coverage for a limited range of biomedical products and services.\textsuperscript{163} Again, in line with the historical trend, the Scheme does not cover indigenous medical services and products. It is also noteworthy that the Scheme’s benefit package excludes a number of chronic medical conditions from coverage. While the list of biomedical services and products excluded from the Scheme could be said to be a primary reason for its limited impact on healthcare inequity in Nigeria, it must be emphasized that the SHIS is not immune to the human resources in health crisis and other governance problems that have besieged the healthcare system. The SHIS is designed to cater primarily to one aspect of the healthcare problem – the financial. It does not attempt to tackle the human resources in health crisis in the country and contains no provisions whatsoever on the issue. Thus, it is not surprising that dependency on indigenous medical systems has remained very high in the country even though governance is yet to match the level of interest in these therapies.

It is in light of this situation that the concept of medical integration surfaces to the forefront of discourses on health inequity in the South. As Mburu has aptly noted, biomedicine is a “poor competitor” to indigenous medicine in terms of human resources and access to care.\textsuperscript{164} It is expedient to take advantage of both systems through integration such that both systems become “vehicles of change”.\textsuperscript{165} The non-governance of indigenous medical systems equates with “banishing” indigenous medicine to “its natural self-propagating cocoon where it is further entrenched to the detriment of the health improvement…of indigenous populations”.\textsuperscript{166} Given the impressive impact of the “feldsher” in Russia and the “barefoot

\textsuperscript{162} Iyioha, \textit{International Research, supra} note 156.
\textsuperscript{163} See the Nigerian National Health Insurance Scheme, online: <http://www.nhis.gov.ng/about.asp>.
\textsuperscript{165} Ibid.
\textsuperscript{166} Ibid.
doctor” in China in reducing mortality and morbidity, scholars have rightly argued that the “gradual melding” of the indigenous healthcare provider and the biomedical healthcare worker will prove very efficient in meeting the needs of population health.167

The feldshers are healthcare workers with some training in medical and health professional schools who deliver mostly primary and preventive healthcare in rural areas in Russia. While they may deliver healthcare in the area of intensive care, they usually refer critical cases to advanced professionals. The barefoot doctors in China, which were influenced by the Russian feldshers, were farmers who had basic medical and paramedical training to deliver healthcare in rural areas. Biomedical professionals refuse to set up medical practice in these areas. The barefoot doctors programme was integrated into national policy in 1968 and quickly diminished the dominance of China’s health ministry. Before this period, Western trained physicians had dominated the ministry. As part of the Rural Cooperative Medical Systems (RCMS), the barefoot doctors initiative had the objective of integrating community participation with the rural provision of health services.168

The creation and success of a new system that integrates the best of medical cultures into rural and national healthcare delivery is dependent on the restructuring of health governance through an approach that avoids the political errors inherent in the wholesale transposition of European medical institutions and norms to Africa. The events leading to the end of China’s barefoot doctor programme, and the subsequent domination of its health ministry by Western trained physicians, bears some similarity to the political mistakes involved in Africa’s adoption of the West’s approach to health governance. The barefoot doctors initiative was abolished in 1981 following the end of China’s collectivist agricultural cooperatives.169 China’s new economic policy promoted a shift from collectivism to individualized production, which led to a privatization of healthcare, and subsequently to the ousting of the barefoot doctors.170 Based on new standards established by the new system, such as the condition requiring barefoot doctors to take and pass formal examinations to become ‘village doctors’ as

167 Westermeyer, supra note 159 at 106.
170 Ibid.
opposed to ‘village health aides’, the barefoot doctors privatized their medical services\textsuperscript{171} and shifted their interest to chronic medical conditions rather preventive medicine.\textsuperscript{172} This course of events, much like the history of colonialism and healthcare development in Africa, holds lessons critical to health systems governance.

Governance embodies the application of state authority and power to engineering societal relations. This power can be applied to reforming, creating and structuring institutions that serve the interests of society. The modern state in the South – itself a transplanted European political structure in the strict terms of its territorial and structural design – has been greatly problematized in legal and political discourses sympathetic to the South’s experiences. The charge against the post-colonial state has been its failure to rise to the expectations and needs of communities, which in pre-colonial times had well-established geographical, economic and cultural identities. The imperial conflation of colonized states, without due regard to “geographical, economic or historically shaped cultural realities”\textsuperscript{173} has been blamed for the dysfunction and developmental problems of the South. While this work espouses this \textit{bona fide} sentiment, the argument proffered in this study for a state-engineered institutional reform is based on the reality that the post-colonial state has come to stay. It is the new reality of governance in the South, and it is, therefore, the institution (including its parastatals\textsuperscript{174}) that this work targets for reform.

The state, being merely a concept in abstraction, is operational in promulgated laws and the institutions created by those laws.\textsuperscript{175} State action is embodied within the specific norm-generating power of law. Law, therefore, serves as a tool for reform. However, in achieving its mandates, the legal order must be cognizant of the \textit{history} (political and economic), \textit{resources} (human, material, technological), \textit{values} (culture and tradition), \textit{lifestyle} (choices) and general situation of legal subjects, social actors or “role-occupants”\textsuperscript{176} to which it applies. This

\textsuperscript{171} \textit{Ibid}.
\textsuperscript{172} Zhang and Unschuld, supra note 168.
\textsuperscript{173} Seidman and Seidman, supra note 74 at 5.
\textsuperscript{174} This includes all health-related ministries and offices carrying out the state’s policies on healthcare.
\textsuperscript{175} Theodore J. Lowi, “The State in Politics: the Relation between Policy and Administration” in Seymour Haregot, \textit{Law Making and Development, Vol. II} (Washington, D.C.: International Law Institute, 1987) cited in Seidman and Seidman, \textit{supra} note 74 at 41, noting that “one can look in vain for the state. What one generally sees are rules… The most important and formal rules are called by many names, such as laws, statutes, decrees, regulations. Most recently, the general category is referred to as policies, or public policy”.
\textsuperscript{176} This term is used by sociologists: see Seidman and Seidman, \textit{Ibid} at 40.
cognizance is imperative if its mandates are to take root and generate the changes necessary for institutional reform. As Seidman and Seidman have rightly noted, social actors and their interactions constitute institutions.\textsuperscript{177} For the law to successfully create a positive impact in the institutions of a given society, its mandates – while attempting to guide the actions of legal subjects and redirect conduct towards new patterns of behaviour – must also accord with the collective psycho-social behaviour and economic realities of legal subjects.\textsuperscript{178} Notably, Seidman and Seidman in their impressive work on institutional change in the “Third World”\textsuperscript{179} suggest that the resolution of social problems requires understanding, “\textit{not individuals’ idiosyncratic behaviours}, but their \textit{repetitive patterns of behaviour} in their relevant social roles”.\textsuperscript{180} While the authors’ postulation is accurate considering that repetitive patterns of behaviour are predictable and are, therefore, useful for policymaking, their argument should not detract from the fact that critical information about a people’s needs and expectations are deducible from the \textit{collective psyche} or what might be called \textit{collective idiosyncrasies} of a people. This argument is made here because while repetitive patterns of behaviour might reveal social problems and societal needs, they can also conceal or misrepresent the underlying reasons for the subject’s behaviour. The persistence of indigenous medicine in Africa can be used to illustrate this point.

As a starting point, the importance of factoring psycho-social attitudes into policymaking in the post-colonial state is underscored by the presence of \textit{new} institutions and the conflicting maze of \textit{new} and old rules which formerly colonized peoples live by. Thus, while it is often argued, and indeed expected, that most formerly colonized peoples have adapted to the new institutions and rules, the reality in most former colonies often consists of a conflicting set of norms and values. When “extrinsic political and economic forces prey upon local idioms to infiltrate the consciousness of people”, the consequence is often the destruction of “coherent pictures of reality…, de-centering of collective life, and the dissolution of

\begin{footnotesize}  
\textsuperscript{177} \textit{Ibid} at 41.  
\textsuperscript{178} See Seidman and Seidman, \textit{ibid} who contend (at 40) that: “to unravel social problems requires understanding, \textit{not individuals’ idiosyncratic behaviours}, but their \textit{repetitive patterns of behaviour} in their relevant social roles”.  
\textsuperscript{179} A. Seidman and R.B. Seidman, \textit{State and Law in the Development Process: Problem-Solving and Institutional Change in the Third World}, supra note 74.  
\textsuperscript{180} \textit{Ibid} at 40.  
\end{footnotesize}
common and shared meanings‖. Hence, it is important to identify whether within the conflicting realities there exist specific patterns or resilient belief systems that have stood the imperial invasion, and on which we can ground new or amended set of laws. In the case of indigenous medicine, such patterns exist.

The psycho-social behaviour of social actors collectively is manifest in their healthcare choices overtime. Distinct patterns of behaviour are identifiable from the actions of these actors. Though citizens are faced with a maze of regulated and unregulated healthcare choices, the patterns are evident in the continuous patronage of indigenous medicine by wealthy social actors who can afford high-tech biomedicine but choose indigenous medicine. The patterns are visible in the behaviour of indigent social actors who still seek out expensive indigenous health services and products even where there exists cheaper biomedical alternatives, or the African mother whose chronically ailing child might receive cheaper healthcare from a public biomedical healthcare facility, but opts for the indigenous healthcare centre. Also manifesting the collective idiosyncrasy is the case of the biomedically trained orthopaedic surgeon who ‘quietly’ refers his patients to the bone-setter in a rural community or remote village, or the biomedical health professional who abandons conventional care in a leading national orthopaedic hospital only to submit to the care of the bone-setter who sometimes operates with minimal, locally-made surgical instruments. These examples are part of the collective narratives about the high patronage of indigenous medicine in different societies, including societies with advanced medical systems, such as Canada and the US, and those with limited financial and geographical access to healthcare. These repetitive patterns of behaviour, to borrow the phrase employed by Seidman and Seidman, are in the context of the present discourse bona fide proof of a collective psychology that has survived overtime the destructive ideology of colonialism.

These repetitive patterns of usage could easily be simplistically interpreted, as David Fidler has done, as manifestations of a people’s failure to attain technological development in healthcare delivery. Yet, while the limited resources available to a people, as well as the inadequacies of the allopathic health system are part of the reasons for the growing interest in

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182 See Fidler, supra note 18, linking the popularity of indigenous medicine to “the failure of national and international health policy to improve conditions along Western models”.

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indigenous medicine, a superficial focus on repetitive patterns of behaviour might obscure the existence of deeper socio-cultural reasons underlying a given social behaviour. Consequentially, it might reduce the deduced explanations to economic reasons alone. Thus, health policymakers must look to other indicia – culture or tradition, history, values and belief systems – in order to make effective decisions on governance. By examining the collective idiosyncrasies of those who patronize indigenous medicine (whether in the North or South) as manifested in their healthcare behaviour, states would most certainly arrive at the factors that have perpetuated indigenous medicine in the medical history of the world’s peoples. These factors should be incorporated into the policymaking process, as they are just as important as the economic reasons that underlie the patronage of indigenous medicine. In the context of health systems governance, the law’s reflection of the psycho-social and economic realities of legal subjects implies that the transplanted legal order must be reconstructed and realigned to recognize favourable patterns of practitioner-consumer healthcare behaviour and legitimize new institutional frameworks that directly attempt to ameliorate economic realities that hinder healthcare equity.

To achieve this, the state requires, not only the instrument of the legal order, but also the support of the officials of its several institutions or parastatals – healthcare officials and other relevant ministerial officials, the courts, educators, amongst others, and the active collaboration of its private subjects. The actions of these groups, bolstered by a legal order that reflects the needs of its society, are critical for institutional reform. The combination of a legal order that grows from within the society to which it applies and institutional or official action reflects aspects of the philosophies of the Interactional theory of law (as enunciated by Lon L. Fuller) and the Functional Jurisprudential school of legal thought (as articulated by Felix Cohen). Drawing on the logic of these theories as they relate to the reciprocal nature of law and society, the next section outlines a theoretical viewpoint that highlights the problems of institutional and legal transplants, while delineating how this viewpoint serves as a guidepost for state-law reform.

The section builds on the above discussion of the conflict between the institutionalization of a transposed system of health governance in formerly colonized states

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183 See Seidman and Seidman, supra note 74 (at 41) where the authors state that “the state comprises, not only the rules of law, but also the behaviours of “all the officials who formulate and implement them”.

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on the one hand, and the socio-economic realities of life in those regions on the other hand. The section grounds the need for health governance reform in a theoretical framework that recognizes the intercomplimentarity of law and society.

2.6. Theories of Change: Legal Transplants and the Indigenous Medico-Legal Order

2.6.1. Positivism and the Problem of Legal Transplants

In the area of legal philosophy, almost every critical narrative begins with what might be termed the “story of orthodoxy”. The story of orthodoxy reflects the “inflexibility and closure of positive law”. It originates from the theory of positivism, which envisages law as “an autonomous system of legal concepts, rules and arguments”, and as an amoral datum with a “settled meaning”. Orthodox or traditional jurisprudence locates this system of rules within the institutional and conceptual walls of the nation-state. Orthodox legal theory conceives the promulgated laws of the state as immune to notions of what ought to be law in the light of extant or changing societal expectations. In this context, transplanted norms – once promulgated into law – must be applied according to the texts of the given law. Thus, rules promulgated in a given temporal milieu are subject, not to changes in societal experiences, but to the written prescriptions of a new and/or superior decree.

It is pertinent to note that in the determination of acceptable societal expectations to legislate upon, the state more often than not utilizes the “presumed rationality” of science. As Santos has observed, the “circulation of meaning between science and law” is one of the principal features of regulation. The relationship between the state and science, as evident in the state’s espousal of science in rule making, is intertwined with the history of marginalization of alternative knowledge systems whether in the area of healthcare or within other domains. Scholars contend that the state has “legitimated decisions based on scientific

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184 Iyioha, “In Search of Law’s Residence”, supra note 138 at 257.
185 Ibid.
188 Iyioha, “In Search of Law’s Residence”, supra note 138 at 257.
189 Ibid.
190 Boaventura de Sousa Santos, Toward a New Legal Common Sense: Law, Globalization and Emancipation 2d (London: Butterworths, 2002) at 7 [“Santos”].
191 See generally Iyioha, In Search of Law’s Residence, supra note 138.
judgments”,¹⁹² and in these cases, “scientific judgments glide into normative judgments”.¹⁹³ These institutionalized norms help define the biomedical system “in terms that entrench orthodoxy and criminalize alternative practice”.¹⁹⁴

Operating on the logic of the supremacy of the written law whose precepts reflect the dialectics between law and science (‘science’ at least as defined by Western philosophy), non-conformist systems (such as IMS and other alternative medical paradigms) existing outside the prescriptions of the written law are largely excluded from the protection the law confers on recognized norms. Given the history of the post-colonial state’s legitimization of transplanted norms or its codification of norms established by ‘Western science’, post-colonial medical laws may be perceived as upholding systems of rules founded on the orthodoxy of Western positive law, which in many cases have little correlation to societal changes and the realities of legal subjects in receiving nations.

Beyond the obvious case of the application of biomedical standards of care within the tort of negligence to alternative medical practice highlighted above, there are several other examples operative in the laws governing healthcare in different countries. An example is the new Nigerian Health Bill. In a country where more than eighty percent of the population depend on non-biomedical forms of healthcare, the Bill fails to include indigenous services and pharmacopoeia within patient’s right to be informed of “the range of diagnostic procedures and treatment options generally available”.¹⁹⁵ We can extrapolate that the treatment of ‘informed consent’ in the Act is premised on the biomedical origin of the concept, which recognizes only biomedical therapies as legally valid medical options. This state of the law can result in malpractice liability for biomedical providers who refer patients to indigenous healthcare providers since the latter are not recognized by the relevant provision of the law. Another example inheres in the Nigerian National Health Insurance Scheme Act.¹⁹⁶

¹⁹² Ibid at 258.
¹⁹⁵ The Nigerian National Health Bill, 2008 (SB.50), section 23 (1) (b), on file with author.
¹⁹⁶ National Health Insurance Scheme Act, CAP 35 LFN 1999.
Granted that the Scheme is in its early stages, yet it is worthy of note that no indigenous therapy is included on the list of covered services and products.\textsuperscript{197}

Other examples may be found in Western nations, such as Canada and the US, where consumers face legal barriers in accessing complementary and alternative medical providers or in obtaining reimbursement for non-conventional therapies when they are able to access an alternative provider.\textsuperscript{198} Specific examples include the cases of the \textit{Medical Act}\textsuperscript{199} the Professional Code\textsuperscript{200} and the Code of Ethics of Physicians of Quebec, which distinguish between legal and illegal medical practice while restricting medical practice to biomedical professionals.\textsuperscript{201} The case of \textit{Herzig v. R.}\textsuperscript{202} provides further evidence of the burdens imposed by the absence of progressive legislation in this area of healthcare. In \textit{Herzig v. R.},\textsuperscript{203} the wife of the appellant suffered from a fatal metastatic breast cancer. The patient had found homeopathic medicine, herbal supplements and nutrients helpful in ameliorating the conditions and manifestations of the disease. In his testimony, Herzig reported that the oncologist had given his wife six months to live. With the use of the homeopathic medicines and herbal supplements prescribed by two physicians, his wife lived for another four years, and died in 1993. Although these medicines were prescribed by a medical doctor, Herzig was denied the medical expense tax credit for the cost of the homeopathic medicine and the other non-biomedical products used by his wife. While Herzig’s total claim was $46,266.00, Canada Customs and Revenue Agency disallowed $30,963.77.\textsuperscript{204}

The Minister of National Revenue contended that the services and products were not recorded by a pharmacist and hence the expenses could not be claimed. Based on a narrow interpretation of the statute, the court upheld the Minister’s decision on the ground that the medicines and supplements did not come within the list of statutorily recognized products and

\textsuperscript{197} The Nigerian National Health Insurance Scheme, online: <http://www.nhis.gov.ng/about.asp>.
\textsuperscript{202} \textit{Herzig v. R}, supra note 8.
\textsuperscript{203} \textit{Ibid.}
\textsuperscript{204} Note that Herzig later amended his claim to $32,762.02 at trial on the account that some products had been purchased in the United States in U.S. dollars. See \textit{Herzig, ibid} at para. 3.
services that are entitled to tax relief under s.118.2(2) of the *Canadian Income Tax Act*.\(^{205}\)

Section 11.8.2(2)(n) of the Act restricts medical expenses to drugs, medicaments or other preparations or substances “manufactured, sold or represented for use in the diagnosis, treatment or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof or in restoring, correcting or modifying an organic function, purchased for use by the patient as prescribed by a medical practitioner or dentist and as recorded by a pharmacist”.\(^{206}\)

Thus, the primary requirements that must be met for medicines or other curative substances to qualify for the medical expense tax credit are that the said product or substance must be prescribed by a medical practitioner and recorded by a pharmacist.\(^{207}\) The court “regretfully”\(^{208}\) upheld the decision of the Minister, dismissing Herzig’s appeal. Associate Chief Justice Bowman (as he then was) noted that this was “a most deserving case”\(^{209}\) in which a patient ought to have been entitled to tax relief for medical expenses.

A related case, which captures the detrimental impact of the impugned provisions of the *Income Tax Act*, is that of *Pagnotta v. Canada*,\(^{210}\) where the Minister of National Revenue denied the appellant taxpayer’s tax claims for her use of alternative therapies. The specific claims were denied on the ground that they did not qualify as ‘medical’ expenses pursuant to paragraph 118.2(2)(n) of the Act. It is noteworthy that in some of these cases, such as in *Herzig v. R.* and *Davar v. The Queen*,\(^{211}\) the court was convinced that the alternative therapies used by the patients/applicants had been effective in ameliorating their pain and illness or for prolonging their lives.\(^{212}\) The courts’ conviction was grounded on the affirmative testimonies of the biomedical practitioners who prescribed the therapies and the patients who used the therapies.

A further example of the disparity between law’s treatment of biomedicine and indigenous or alternative forms of healthcare may be found in the provisions of specific laws governing medical practice in Canada. For example, while the Ontario *Regulated Health*
Professions Act, 1991 (RHPA) recognizes and is accommodative of a broad class of practitioners, including a few alternative practitioners, the RHPA creates differential standards in diagnosis. The RHPA permits only practitioners of five professions to ‘diagnose’. These professions are medicine, dentistry, chiropractic, optometry and psychology; every other profession, whether regulated or unregulated, can only “assess” a patient’s medical condition. Amongst these five professions, the standard of diagnosis is different as doctors are granted the broadest freedom to diagnose. The law further entrenches double standards between biomedicine and other medical paradigms in the divisions it creates within the area of diagnosis. For example, diagnosis in chiropractic practice is restricted to “dysfunctions or disorders arising from the structures of functions of the spine (or joints) and the effects of those on the nervous system”. Furthermore, the mere existence of the Canadian universal health insurance scheme for biomedicine – with only a scattering of indigenous therapies in some provincial plans – creates yet another level of legitimacy and authority for biomedicine above indigenous and alternative systems. The Ontario Health Insurance Plan grants a host of privileges, including hospital-admitting privileges, to physicians. These privileges further confirm “scientific medicine’s dominant position”. A similar pattern of dominance exists in other Western jurisdictions, and in post-colonial states, where transplanted laws uphold biomedicine over other cultural systems of medicine utilized by a significant number of healthcare consumers.

In fact, a close examination of judicial pronouncements and decisions on patients’ claim for tax credit on complementary and alternative medical expenses in Canada reveals the ambivalence (for lack of an apposite word) of the court where they are compelled by law to reject the applicant/appellant’s claim. The language of the court has often revealed the court’s

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214 See ibid; see also section 27(2) for a list of controlled acts.
215 Ibid.
216 Ibid.
217 Ibid.
221 Haigh, supra note 194 at 155.
knowledge of the disparity between law and social trends and the need for legislative reform. For example, in Davar v. The Queen, Justice Miller stated with considerable empathy:

The Appellant understands that there is no authorizing legislation in New Brunswick for such practices. The Davars have even written a letter to the Government of New Brunswick seeking change. They are frustrated, and as Ms. Davar stated, offended by this. They ask who can they turn to. While this Court has interpreted these laws liberally and compassionately, the Court cannot turn a blind eye to the real and exact meaning of the law, no matter how unfair the taxpayer believes it to be…

Regrettably, we often have to decline these types of expenses. The Act does not yet acknowledge the trend in our healthcare system towards alternative forms of treatment … You must appreciate it is not for me to rewrite the legislation. But by bringing your concerns to this Court, you will, as many others have, make the legislators aware of your concerns regarding alternative treatments. I appreciate your effort in doing this, but I cannot allow your appeal.

I dismiss your appeal, but I do wish you both well.

Bound by the rules of the written law, the court has often reached the decision in what appears to be allegiance to the tradition of positivism – albeit with some hesitation – that the texts of the law must prevail.

This legal and institutional ordering may be critiqued from different theoretical perspectives. Critical legal jurisprudence, through a variety of schools, challenges the administration of state law in ways that fail to recognize the everyday realities of the legal subject. The interactional theory of law, as enunciated by Lon Fuller, problematizes the transplantation of foreign norms into communities where lived experiences run counter to transplanted norms. This school of thought, also denoted as the reciprocal theory of law, critiques the non-progressive interpretation of laws in spite of social transformations which provide legitimate and compelling reasons for a new approach to governance. The next subsection examines this school of thought.


Fuller’s postulation on the reciprocal or interactional relationship between law and society critically challenges the positivistic trend of legal interpretation, which the body of case law on

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222 Davar, supra note 7.
223 Ibid at paras. 6, 7, 9, and 10. Emphasis added.
complementary and alternative medicine exemplifies. Generally, Fuller’s work on law and legal validity posits that law has an *internal* authority comprising eight procedural requirements for legal validity and the substantive requirement that it embodies accepted social norms. Both of these requirements confer on law “the competency it claims.” This study focuses on the latter aspect of the theory – the substantive requirement that promulgated laws must exhibit the cohesive relationship that ought to exist between law and the dynamics of societal norms. In this sense, law is valid when it reflects the shared or interacting norms of legal subjects.

Fuller’s reciprocal theory of law is clearly enunciated in his treatise, “Human Interaction and the Law.” The treatise captures the evolutionary nature of the (common) law, which was reshaped through judicial pronouncements at different periods to suit those to whom it applied. According to this theory:

The phenomenon called customary law can best be described as a language of interaction. To interact meaningfully, men require a social setting in which the moves of the participating players will fall generally within some predictable pattern…The virtue of the common law is that, proceeding case by case, it can *fit* and *refit* its prescriptions to the configurations of life as they reveal themselves in litigation. What the common law lacks in the way of clear advance formulation, it may more than make up for by its capacity to *reshape* and *reword* its rules in the light of the actual situations that offer themselves for decision.

Implicit in all…this…is the view that law and its social environment stand in reciprocal influence; any given form of law will not only act upon but be influenced and shaped by the established forms of interaction that constitute its social milieu. *This means that for a given social context one form of law may be more appropriate than another, and that the attempt to force a form of law upon a social environment uncongenial to it may miscarry with damaging results.*

Fuller’s treatise on law and societal interaction establishes the interdependent relationship between law and its social milieu. While, affirming the importance of shared meanings

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224 These requirements, which are constitutive elements of the ‘Rule of Law’ include the generality or existence of rules, promulgation of laws, clarity of laws, non-retroactivity of legislation, the enactment of non-contradictory rules, the enactment of rules requiring only the possible, constancy in the rules, and congruence between the rules as announced and their administration: L.L. Fuller, *The Morality of Law*, Rev. Ed., (Yale University Press, 1964) 33-94 at 39 [‘Fuller, *The Morality of Law*’].


between social actors to lawmaking, his thesis effectively defines the foundations of a valid law. As a starting point, Fuller’s thesis (parts of which are reproduced above) underscores the discussions in the previous sections on the dangers inherent in a unidirectional application of norms from one legal environment or social milieu to another. Fuller’s observation regarding the problem associated with the transplantation of norms and institutions that are unsuitable to their new legal environment is buttressed by the fact that “laws and institutions can be both barriers and facilitators” to progress. This is because “while law can be a powerful force, entrenching values and protecting entitlements”, it can also constitute an impediment to reform if it fails to keep up with changing expectations and healthcare needs.

Although certain transplanted rules, such as the principles of the tort of negligence, may seem neutral on the surface, however, such rules remain problematic because societal expectations vary temporally and spatially, irrespective of the neutrality of the rules. Similarly, although colonial biomedical laws may be neutral in their application to the practice of allopathic medicine, yet the laws are often inapplicable to non-biomedical systems. In this situation, the CAM or indigenous healthcare consumer is the party most often affected by the problems of the legal void. Ironically, the imported laws (whether statutory or common law, the latter being itself “a complex amalgam of law making forms”) historically have been subjected to amendments and reinterpretations to ensure a conformity with the realities of the day in the originating societies. The rules and standards of the common law, for example, were

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229 Colleen Flood, ed., Just Medicare: What’s in, What’s Out, How We Decide (Toronto: University of Toronto Press, 2006) at 35 [‘Flood, Just Medicare’].
232 See chapter three, infra for a discussion of judicial precedents depicting the practical difficulties faced by many consumers in their attempt to obtain reimbursement for utilizing alternative medicine.
233 Fuller, “Human Interaction”, supra note 226.
at different stages sculpted to fit human interactions in European societies. As one scholar has noted:

Rules, standards and principles of law are said to reflect justice not only because they are compatible with the social life, moral principles and ethical standards, but also if they are founded on the realities of life at a particular time. Legal rules, standards, and principles should, therefore, be flexible variables in the constant search for social ideals and justice.

This principle, commonsensical as it appears, needs to be applied to health governance in today’s changing society where millions of people worldwide rely on indigenous medicine for their general healthcare needs (as is the case in many countries of the South) or for specific chronic and terminal medical conditions (as is often the case in the North). As part of a broad-based institutional and legislative reform agenda, changes in extant attitudes to health systems governance will necessarily require a contextual and inventive interpretation of law in the courtroom. Inventiveness and contextualization in legal interpretation reflect the core needs of legal subjects in a given factual situation. Notably, there is a diaphanous line between these elements—which are a core aspect of Fuller’s theory, and the concept of ‘functionalism’, a concept more usually associated with legal realists. ‘Functional jurisprudence’ provides insights into the nature of inventive legal interpretation.

Functional jurisprudence, like the interactional theory of law, promotes practicality and flexibility in the pursuit of legal meaning. Both theories locate legal validity and justice within the purposes or social function of law. Felix Cohen, an exponent of the functional school, advances a theory of law, which conceives law as meaningful only in the context of its application to real events. Within this postulation, law that fails to meet societal expectations

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234 Mubirumusoke, supra note 231 at 155.
235 Ibid.
237 The choice of the functional school, itself arguably a variant of the much-critiqued Realist school, is based on the strengths of this school in its identification of the interconnectedness of law and society. Rather than dwell on the limitations in the Realist’s conception of law as solely the predictions of judges, I choose to expatiate aspects of the Realist’s jurisprudence relevant to the discourse here because law and society will benefit from studying the “role” which Realists assign to legal rules within the normative society: see T.W. Bechtler, ed., “American Legal Realism Revaluated” in Law in a Social Context: Liber Amicorum Honouring Professor Lon L. Fuller (The Netherlands: Kluwer, 1977) at 20.
is questionable. Cohen describes law that reflects the needs of society as “law-in-action”.\(^{238}\) Law-in-action describes the “inter-relationships between judicial decisions and all the other events of the social scene. The meaning of law depends…on all the social facts that give law-observance…their human significance”.\(^{239}\) In Cohen’s words:

In writing the life-history of a legal rule, one does not reach the end of the story when the rule is obeyed or disobeyed. There remains to be told the meaning of obedience or disobedience, in terms of social institutions and customs, in terms of the material things over which law gives control, in terms of human habits, modes of thought, fears, hopes, pleasures and pains.\(^{240}\)

In defining law in terms of its social function in society, one finds in the works of Fuller and Cohen the foundations of a functional theory of law that embodies the interconnectivity between law’s validity and its social purposes. This functional theory of law strengthens the thesis articulated in this work, that it is imperative for state medical laws to accommodate the evolution in consumer healthcare behaviour.

This proposition is important in today’s health systems for many reasons. Apart from the cost-saving advantage that scholars have identified as an outcome of medical integration, migration and the growing multiculturalism of Canada and the United States also mandate a consensus on how the healthcare and medical preferences of new members of these societies may be adequately addressed. As already noted, medicine is value-laden. Medical care in different societies is built on an ideological and “cultural construct”\(^ {241}\) that is designed to meet the needs of specific societies. A functional conception of law conceives societal ideologies and cultural factors as crucial to the validity or meaning of a piece of legislation. The poor state of healthcare delivery in most countries of the South, the increasing desperation of patients (especially women) with cancer and other serious medical conditions denied of tax relief and reimbursement for their medical expenses on CAM, and the growing consumer movement in support of CAM need to be factored into the making and interpretation of healthcare laws. For, if legal validity lies within the law’s reflection of accepted norms as we have extrapolated from a functional analysis of law, then state law must respond to the


\(^{239}\) *Ibid.*


\(^{241}\) Haigh, *supra* note 194 at 173, 158.
emerging consumer movements and increasing reliance of society on safe and efficacious indigenous therapies for both common and terminal diseases. The Canadian court has affirmed this as a valid point. In Davar v. The Queen, Justice Miller echoed the sentiment that:

There is no doubt in my mind that pain and suffering can be relieved by alternative medicine. Sometimes the law leads society in a certain direction, but often times societal behaviour leads the law…it is a matter of the law eventually catching up…and I am hopeful the legislators will do that…they…are not there yet regarding the types of alternative treatment expenses you seek.

Justice Miller’s words highlight the need for legislative reform. Although Miller, J. opined that the texts of the law gave little room for judicial manoeuvring, a liberal and creative interpretive agenda for healthcare laws that inhibit access to indigenous/alternative healthcare is not impossible. A functional and reciprocal concept of law meets the need for such an agenda. The term “reciprocity” as used in this theoretical analysis denotes an “interactional” relationship between law and the society that it serves. Dominant societal norms are the substance of the law; in other words, law is or ought to be a reflection or the embodiment of rules that conform to the lived experiences of the citizenry. As these norms evolve, law is expected to be malleable, and to reflect the changes in societal expectations. In this context, law serves a critical purpose in ensuring that it acts upon popularly accepted and progressive societal trends as well as redirecting future conduct towards conformity with prescribed norms. Thus, law as Justice Miller has implicitly noted, should recognize emerging conceptions of health and treatment, and legitimize safe and efficacious alternative therapies, where these are crucial to health equity as between different members of society.

As further argued in chapter three, court judgments on patients’ right to access indigenous medicine and CAM in themselves must reflect an understanding of both the injustice in the laws and the mounting frustration of consumers. Increased frustration among legal subjects affects their commitment to institutionalized norms and can compromise support for public policies. An oppositional relationship between law and its subjects negatives the tenets of reciprocal

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242 Davar, supra note 7.
243 Ibid at paras. 7-8. Emphasis added.
244 See C.M. Flood, M. Stabile, and C. Tuohy, “What Is In and Out of Medicare? Who Decides?” in Flood, Just Medicare, supra note 229 at 26 writing about the Ontario Health Service and Review Board, which reviews appeals against the government’s decision not to fund particular treatments and services.
justice. Thus, ‘reciprocal justice’ as used in this study simply represents fairness in the promulgation and application of legal norms. Fairness, in these contexts (‘promulgation’ and ‘application’ of legal norms), denotes the imperatives for legal validity in terms of the constitutive elements of law\textsuperscript{245} and its conformity with shared social values, and in terms of its interpretation and application to the actions of legal subjects. As implicit in the analysis above, fairness in the application of laws to the actions of legal subjects necessarily implicates flexibility in legal interpretation.

The reciprocal theory recognizes law, not simply as an instrument employed by state officials in the legitimization and execution of policies, but also as a symbol of authority, capable of generating new patterns of behaviour – especially where old attitudes run counter to societal development and progress. As the Grundnorm, the law gives a stamp of authority and approval to those societal norms or new patterns of behaviour that it converts into rules. Suffice it to be stated that for law to be meaningful in this regard, these new patterns of behaviour must not be so oppositional to the actual realities on ground as to become unachievable or detrimental to societal cohesion. Thus, while law can both create and be created by society, the instrumental use of law as in the former case to redirect the course of events in a given societal milieu must be geared towards (re)creating new institutions or patterns of behaviour that do not complicate pre-existing problems of the given society. This is the lesson from the imposition of foreign institutions and laws on colonized territories, and it is simply that the instrumental use of Western colonial laws to create new societies and socio-economic institutions in most of the countries now commonly regarded as the ‘Third World’ has in many cases created more problems than it solved.

A reciprocal and functional theory of law mandates law’s reflection of societal diversity. Diversity in healthcare choices is prevalent in multicultural societies, such as Canada and the United States. A conception of law through functional lenses necessitates an amendment of state laws that currently fail to recognize indigenous/alternative healthcare models that constitute the staple healthcare system for millions of Canadian and US immigrants. Michael Cohen advances this view when he affirms that:

\textsuperscript{245} As noted above, the elements of a valid law include the generality or existence of rules, promulgation of laws, clarity of laws, non-retroactivity of legislation, the enactment of non-contradictory rules, the enactment of rules requiring only the possible, constancy in the rules, and congruence between the rules as announced and their administration: Fuller, \textit{The Morality of Law}, see note 224, \textit{supra}.
Legal process ideally respects the patient’s search for health as a process at the juncture of social, political, economic, and personal events. The legal view of disease and wellness must embrace a broader understanding of healing than is reflected in biomedical orthodoxy. Legal rules reflect essential social values and culturally accepted models of health care. As these values and models continue to unfold, legal rules, too, will evolve to embrace a more expansive and empowering vision of health care and the healing process.\(^{246}\)

In the context of this study, the reciprocal theory of law encapsulates the need for state law to legitimate evidence-based\(^{247}\) indigenous modalities which form a major part of the medicine cabinet for millions of health consumers. The failure of states to engage actively in the governance of this area of medicine deprives consumers of the benefits that come with law’s approval: the assurance of safety and efficacy, insurance and funding benefits, and importantly, increased access to a broader range of treatment options. Since members of society are able to take full advantage of the benefits of positive, pre-existing norms/behavioural patterns when the norms or behaviours are protected by law, what one finds is a ‘give and take’ relationship, a mutual dependency between law and society, which is clearly evident in an interactional relationship between law and society.

A functional theory of law and societal development, as it applies to the arguments for health governance reform, conceives law as “a penetrable system of rules, percolable by society’s changing norms. As a reflection of the society within which it exists, law cannot exist outside itself”.\(^{248}\) Thus, law may be viewed as “validated by the very societal values within which it exists, while it gives a stamp of authority to those same values. The legal order can, therefore, be understood as a system of interdependence or reciprocity between law and society, a system in which law rewards the pluralistic society which gives it its validity, by being a reflection of the changing values of that society and helping to crystallize those values – through its force of authority – in its disavowal or renewal of the old and acceptance or rejection of new norms”.\(^{249}\)


\(^{247}\) The term ‘evidence-based’ is often used technically to denote the “conscientious, explicit, and judicious use of current best evidence” in decision-making: David Sackett et al., “Evidence-Based Medicine: What It is and What It Isn’t” (1996) 312 British Medical Journal 71. The meaning of the term in the context of medical research and practice is part of the subject of chapter three, infra.

\(^{248}\) Iyioha, “From Form to Freedom”, supra note 236.

\(^{249}\) Ibid.
The institution of the state has a critical role in this process of reciprocation and change. Santos clarifies the role of the state in ensuring a reciprocal relationship between law and society when he contends that modern state law is flexible, and can be “brought in” to serve a broad range of interests.\textsuperscript{250} It is noteworthy that Santos’s thesis stands in contrast – albeit in a nuanced manner – to critical legal schools, which reject the centrality of the state. Santos’s stance on the debate regarding whether states should have a more or less dominant role in social ordering is that:

Under current conditions the centrality of the state lies to a significant extent in the way the state organizes its own decentring, as is well illustrated by the state-sponsored back-to-the-community or community-revival policies. The distinction between the state and the non-state is thereby called into question.\textsuperscript{251}

Santos’ claim is that state law is inherently malleable and can be configured to achieve a variety of societal goals. This view further affirms the foregoing exposition on the power of law, as the primary administrative instrument of the state, to create new institutions. These new institutions – for example, a new national health council that features representatives of the alternative medical professional bodies – can diffuse the concentration of governance in the state system alone.

To sum up the above discussion, the analyses and proposals in this work are premised on two interconnected theories: one, that a functional conception of law is necessary for health governance reform (whether in the area of lawmaking or policy implementation) and two, that modern state law is flexible and can be adapted to accommodate changes in societal healthcare behaviour. In this regard, the study proposes that legal contestation of state biomedical laws – which the plasticity of modern state law makes possible – is a necessary tool for reform. These propositions are applied to the subsequent chapters, especially chapters three and six, where regulation and governance are discussed in depth. The chapters make the case for creative interpretation of existing legal principles to reflect society’s changing preferences in medical care. The process of remodelling modern state law to embrace a broader concept of healthcare should typically involve legislative and institutional reforms and legal or judicial creativity. In fact, legislative and institutional reforms are arguably the ideal pathways to medical

\textsuperscript{250} Santos, \textit{supra} note 190 at 94.
\textsuperscript{251} \textit{Ibid.}
integration. However, while legislative and institutional reforms remain pending, patients will continue to look upon the courts for justice. Inventive legal reasoning has a definite role to play in ensuring justice for healthcare consumers.

Since the state legal order is comprised of both rules of law and the behaviour of state officials, the reform of health governance for the purpose of medical integration needs to be implemented at all levels of the healthcare system: from the levels of law/policymaking, implementation and interpretation (legislatures, states and judiciaries) to the levels of healthcare practitioners, healthcare clinics, institutions, and organizations (the healthcare professions), and to the level of the healthcare consumer (society). This proposal broadly captures the integrated system of health governance proposed in subsequent chapters. *Integrated health governance*, which of itself proffers an approach for health systems management, involves a systemic partnership between indigenous and Western medicine reflected at every level of the health system. Integrated governance, as the analyses in the chapters will reveal, embodies the core tenets of a functional and reciprocal conception of law and society. Chapter six, which sets out the theory of *Integrated Governance*, examines the prospect of regulation at the different levels of the healthcare system identified above. The chapter also examines the problematic texts of the law, to which creative legal reasoning may be applied. In order to address the nuances of the regulation debate in chapter six substantially, the next chapter examines the role of scientific evidence in legal validity, while chapter four addresses the barriers to regulation and integration posed by the role of science in the absence of intellectual property protection for indigenous therapeutic products.
CHAPTER 3. SCIENCE, EVIDENCE-BASED MEDICINE AND HEALTH POLICYMAKING IN BIOMEDICAL AND ALTERNATIVE CONTEXTS

…While successive governments grapple with the policy decisions which will affect the future of complementary medicine, we shall all be reminded that medicine is an intensely political activity…

Stone and Mathews (1996)\(^1\)

At this stage in the evolution of Canada’s medical practice, alternative treatments are just starting to gain some recognition as justified, well-researched medical treatments. I believe case law over the next few years will expand our understanding of what can legitimately be considered medical services.

Justice Miller, *Bissonnette v. Canada*\(^2\)

3.1. Introduction

The legal prohibition of the unlicensed practice of medicine is often directed at protecting the public’s health from untested or substandard medical interventions. This is also invoked as the operative rationale for the state’s exclusion of alternative medicines from some federal statutes that provide financial relief for out-of-pocket medical expenses.\(^3\) Judicial opinions in medical malpractice cases where a physician is indicted for practicing alternative medicine or in cases in which consumers have challenged the state’s denial of funding for alternative medicines attempt to link the impugned laws to the legislative interest in ensuring the public has access to only healthcare that is safe and effective. Indeed, policy debates about healthcare regulation often centre on the safety and efficacy of the products and services sought to be regulated. This chapter examines the discourse and dissents regarding the centrality of ‘scientific’ evidence to the validation and regulation of indigenous and alternative medicines. Scientific validation through standards and paradigms established by the scientific community is often argued to be the key criterion for indigenous medical systems (IMS) to become recognized professions.

Healthcare consumers expect policymakers to incorporate experiential evidence to determine which medical services and products provide the best outcomes for their conditions.


\(^3\) An example of such statutes is the Nigerian *National Health Insurance Scheme Act*, CAP 35 LFN 1999 and the Canadian *Income Tax Act*, R.S. 1989, c. 217.
With the growth of the ‘evidence-based’ paradigm, states are increasingly exercising their power to make policy decisions and guarantee societal expectations in accordance with the best evidence available. In the healthcare domain, there is increasing focus on evidence-based healthcare delivery, which involves the utilization of the presumed rationality of science in healthcare management and professional regulation. There is evidently a “circulation of meaning” between science and state law, and this trend has been described as a central feature of modern regulation. Commentators suggest that the state has legitimated decisions based on scientific judgments; in these cases, “scientific judgments glide into normative judgments”. Thus, it is not surprising that many policy decisions are increasingly being founded on scientific evidence, especially when the decision to be made concerns clinical practice guidelines that focus on specific individual treatments. The ‘evidence-based’ paradigm has also been at the core of debates regarding the legitimization of new or pre-existing health systems. In the regulation of indigenous systems of medicine, the state must decide between competing accounts of reality – the scientific (constructed by a biomedically-based Randomized Clinical Trial (RCT)) and the clinical (created through diverse bio- and non-biomedical methods) and reported by ardent health consumers.

However, while there are advantages to having the methods of scientific enquiry directed at addressing the type of medical benefits that governments should fund, the utility of the ‘evidence-based’ paradigm in population health policies might be limited. Evidence of the quality of some healthcare modalities and their impact on specific individuals may not be

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5 Boaventura de Sousa Santos, Toward a New Legal Common Sense: Law, Globalization and Emancipation 2d ed (London: Butterworths, 2002) at 5 ['Santos'].
7 Santos, supra note 5.
9 Greschner, supra note 6 at 47.
11 Ibid.
beneficial in making policies designed to reduce health inequities. The evidence required in the design of policies to address disparities in population health is complex and varies widely. For example, as discussed in sections 3.4 and 3.5 of this chapter, the decision to regulate a given modality for the benefit of the public might require RCT evidence of medical efficacy and safety as well as a broader category of evidence including the availability of biomedical options, financial and geographical access to healthcare facilities, cost-utility and cost-effectiveness, and comparative effectiveness and cost of the modality vis-à-vis the available alternatives. However, these other types of evidence have not been part of the considerations employed by policymakers in decisions on the regulation (and funding) of indigenous and alternative medicine.

In accordance with the trend towards evidence-based policymaking, the regulation of indigenous and alternative medicines is premised on the availability of positive scientific results showing that a given alternative approach is safe and effective. The prohibition of medical practice by non-medical personnel is intended to guarantee that medical care is delivered by qualified persons. A similar logic permeates the case law on the financing of complementary and alternative medicine (CAM) in Canada. The judicial interpretation of the rights of CAM consumers under legislative provisions on the medical expense tax credit (METC) follows a positivistic philosophy in which the relevant provisions of the law are given their literal meaning irrespective of the resultant injustice on the assumption that the impugned provisions evince governmental preference for medicine that is medically and economically expedient.

In the majority of cases, the courts have favoured a rigid, ‘science-based’ analysis of the impugned provisions without considering the range of issues critical to a debate of this nature. These issues, which include but are not limited to the availability of alternative medical options, economic, social and cultural demographics of consumers, and the choices and

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14 There are several cases where patients turn to the alternative option when all else has failed. This was evident in the case of Herzig v. R. [2004] 3 C.T.C. 2496 discussed in chapter 2.
15 It is safe to state that many CAM consumers in Canada are immigrants from communities that have utilized the CAM therapy for which tax relief is sought for thousands of years. These therapies, most of which are regulated in their originating communities, are often the only healthcare options for these groups of consumers.
“values” of healthcare consumers, are the other types of evidence that are not accessible through the conventional scientific framing of the ‘evidenced-based’ paradigm. Further, the courts have largely failed to consider the need to influence legislative and policy changes through a critical interpretation of the impugned provisions. Although it is commendable that some decisions (especially as would be seen in Miller, J.’s judgments) often acknowledge the hardships and frustrations encountered by patients who are denied financial relief based on exclusionary legislative provisions, the courts generally have insisted on a plain meaning interpretation of relevant provisions on the reasoning that no “liberal interpretation” of the law could produce the positive outcome sought by litigants.

This chapter analyzes this judicial attitude as suboptimal given its narrow rule-based approach to the issues. The chapter contends that rather than adopt a ‘science-is-law’ approach to the interpretation of the relevant laws, the courts can employ law ‘instrumentally’ to advocate for the creation of policies that would incorporate both scientific evidence and other relevant evidence (such as socioeconomic data, statistics on the accessibility of human and material resources, geographical disparities in healthcare facilities, consumers’ choices and values, etc) into the decision-making process. While the former judicial approach limits the power of law to engender policy reform, the latter proposal recognizes the inherent ability of law to ensure fairness and equity in law and policymaking. It is acknowledged that the idea that courts can adjudicate actively to the extent that they influence institutional reform is highly controversial. This chapter summarily addresses the controversy while placing the proposal for a more definitive role for the courts in the context of the court’s obligation to ensure justice in human relations – specifically as between government and citizen in the present context. The chapter suggests that the instrumental use of law also embodies law’s ability to mediate between government and citizen in a way that ensures the participation of the citizenry in the processes that produce policies and rules that affect their lives.

Generally, the chapter analyzes two different methodologies for testing IMS – science-based (statutory) regulation on the one hand, and plural investigative methods, which incorporate the best of the RCT with perspectives from other fields, such as anthropology, on

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the other. The chapter specifically discusses anthropological research methods for validating indigenous and alternative medicines. This methodology emphasizes the non-reducible and philosophical aspects of indigenous medicines rather than the pathophysiological. Adopting ethnography as an evidential tool, anthropological research on indigenous medicines emphasizes qualitative data collection techniques, focus group strategies and observation of patient-practitioner interactions. It is important to note from the outset that the objective of this comparative analysis is not to discount the utility of scientific regulation, but to highlight its limits and support comprehensive proposals through which the law can generate the needed evidence to support the regulation of indigenous therapies, particularly those that are not easily amenable to the RCT methodology.

The analyses begin in section two with an examination of the ‘evidence-based medicine’ (EBM) paradigm and its influence in healthcare regulation. The section examines the determinative role ‘science’—narrowly defined—plays in health policymaking with a specific focus on its exclusionary role in regulating IMS. An associated issue discussed in the section is the use of the concept of the placebo as a comparator for measuring the validity of indigenous and alternative medicines. Section three examines the controversy regarding the evidence base of IMS. It begins with an analysis of the indigenous etiology of disease. This analysis sets out the distinguishing features of IMS. These features complicate the problem of the appropriate method for validating indigenous medicines. The features, which are set within the theory of holism, constitute the major barriers to the use of the RCT in validating IMS. Next, the section discusses the limitations in the use of the RCT to evaluate medical interventions, and then focuses on the structure and mechanism of the RCT. As part of the comparative analysis of the RCT vis-à-vis the anthropological research method, the section provides an overview of the historical evidence on the impact of a science-based regulatory framework on the development of some statutorily regulated indigenous modalities, such as osteopathy and chiropractic.

History has shown that statutory regulation (sometimes described as the medical model of regulation), which espouses science as the definitive mode for validating medicine, could have a significant impact on the development and practice of indigenous medicine. The statutory model of regulation necessarily involves the institutionalization of medical practice standards which do not often correlate with those operative in indigenous medical practice. In fact, a temporal examination of legal regulation reveals that indigenous modalities whose underlying
mechanisms of action are amenable to scientific enquiry have achieved state recognition. The implication of this affinity between the indigenous modality and science is reflected in the limitations imposed by statute on the practitioners of the modality. Based on the above discussion, section two contends that the RCT’s limitations in investigating non-biomedical and subjective experiences can lead to the restructuring of non-biomedical healthcare systems, which would have evolved to be unique and well-defined systems that are intrinsically different from biomedicine. The effect of an application of a methodology designed for a specific kind of research on another entirely different set of medical enquiry can be the loss of key aspects of the latter system.

On the strength of the foregoing discussions, the chapter contends that given the limitations in the RCT method, exclusive adherence to the RCT in the regulation of indigenous medicines will have multiple impacts on the status of these systems of medicine. While one of these will predictably be a beneficial impact in its emphasis on outcomes rather than explanations, an outcome that will elevate IMS to the status of an accepted healthcare option, this same benefit interpreted in a historical context will constitute a drawback for the development of some indigenous modalities. Beyond imposing a narrower scope of practice on indigenous medical practitioners (IMPs) and mandating the abandonment of several distinctive notions that distinguish IMS from biomedicine, the use of science as an exclusionary tool for therapies that are not amenable to the RCT might result in the gradual effacing of IMS and its equation with biomedicine. This will hardly be in the best interest of consumers, especially those who are attracted to the indigenous medical paradigm because of its holistic and patient-centred approach to healthcare. Thus, the chapter sues for a regulatory scheme that is accommodative of different evidential paradigms. It suggests that the acceptable evidence must be that which takes into cognizance the unique nature of IMS, and advocates for a modified methodological framework, which accepts the belief systems and values inherent in indigenous medicines as part of the therapeutic process itself.

Section four examines the arguments of medical anthropologists who have questioned the objectivity of scientific forms of evidence through differently constructed evidential paradigms.

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which are reputedly better suited to interpreting the unique features of IMS. The section summarily discusses medical and public health scholarship that promote an understanding of medicine that challenges the now conventional notion of medicine as pure ‘science’ – at least as championed by the advocates of the EBM paradigm. Within this discussion, the section summarily highlights the emerging ‘whole systems research’ methodology which focuses on establishing both the internal and external validity of medical interventions. Based on the inherent limitations in each of the above models of research, section five addresses the need for a composite evidential paradigm for indigenous and alternative medical systems.

Section six discusses healthcare litigation in the alternative medicine context. This discussion, which precedes a further examination of the subject in chapter six, addresses judicial application of the tenets of evidence-based medicine to legal challenges against the METC provisions of the Canadian *Income Tax Act*. While highlighting the weaknesses in the policymaking process that produced the impugned provisions, the section sues for a less conservative role for the courts in the determination of the validity of the contested provisions.

Section seven examines the limitations of the evidence-based paradigm (as framed by the scientific community) in the area of population health policies and specifically in the context of a policy on integrated healthcare delivery. The section examines different types of evidence for health policymaking based on cost-identification, cost-effectiveness, cost-utility, and cost-minimization trials conducted on IMS in different countries including Canada, Israel, Italy and Amsterdam. The section also analyzes research data on healthcare financing, geographical access to healthcare institutions, and availability of human resources in healthcare in an urban town and three rural communities in Nigeria. Section eight draws on Wayne B. Jonas’ work on the subject to outline an integrated approach to health systems research.

Finally, applying research outcomes to the foregoing discussion on the need for a broader definition of what constitutes evidence as well as the categories of relevant evidence, section nine discusses the importance of comprehensive evidence to the courts’ decision in cases involving access to or use of indigenous medicine. In the context of this discussion, the section addresses the responsibility of the courts to ensure fairness and public participation in health policymaking. Drawing from the discussion on functional legal interpretation in chapter two,

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this final section concludes that the courts must look to and beyond the limiting emphasis on one form of scientific evidence for regulating and integrating IMS, and facilitate a (re)direction of policy towards examining a broad range of evidence to investigate the merits of consumers’ interests in these therapies.

3.2. The Evidence-Based Medicine Paradigm and Healthcare Regulation

3.2.1. Evidence-Based Medicine and the Randomized Controlled Trial: An Introduction

The discourse on state regulation of indigenous medical systems (IMS) has often centred on the need for indigenous medicine to be evidenced-based. This implies that indigenous medicine must be amenable to scientific patterns of evidence. Indeed, some commentators have often critically compared indigenous medicine to the placebo, arguing that regulation must be based on scientific evidence of efficacy and safety. This is not a surprising inquiry since healthcare policymakers are increasingly interested in “developing and implementing evidence-based decision-making”. Evidence-based Medicine (‘EBM’) has been defined as the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”. It also denotes the integration of “individual clinical expertise with the best available external clinical evidence from systematic research”. Within the EBM paradigm, the Systematic Reviews of Randomized Controlled Trials (‘SRRCT’) sits at the highest level of the hierarchy of evidence. Below the SSRCT, other evidential paradigms in descending order include Randomized Controlled Trials (RCT), Nonrandomized Controlled Trials and Observational Studies, case series, case studies, surveys, qualitative research, and anecdotes. The importance of approval through the SSRCT method is manifest in its influence in judicial, economic and policy-making circles. For health professions to obtain recognition by the dominant political, economic and judicial structures, they must demonstrate commitment to

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20 Greschner, supra note 6 at 42.
22 Ibid.
23 Greschner, supra note 6 at 46.
the public welfare and be associated with or supported by science.\textsuperscript{25} According to Casey and Picherack, some conventional health professional organizations and commentators have taken the position that alternative medicines should not be recognized by the state through the grant of self-regulatory status unless and until they can demonstrate that their therapies or practices are evidence-based.\textsuperscript{26} Thus, the concept of evidence-based medicine looms largely at the centre of discrediting indigenous medicine, and it is, therefore, fundamental in the barriers to the recognition of this form of medicine.\textsuperscript{27}

The RCT is specially designed to validate categories of medical interventions that are observable and measurable. There are dissenting opinions on the role of the RCT in determining which interventions are effective. Some of the arguments have sought to highlight the structural incompatibility between the RCT, which was designed for biomedical research, and indigenous medicine, which primarily comprises therapeutic philosophies that transcend the biomedical. Other arguments have simply drawn attention to problems inherent in the RCT methodology itself, which render it a less than perfect methodology for researching many therapies, whether biomedical or indigenous. In the former case, the argument is that the very nature of indigenous medicine disqualifies the RCT as a suitable research methodology for validating IMS.

As discussed in chapter two, indigenous medicine constitutes a broad range of holistic and integrated etiologies of illness and healing that incorporate “complex causal networks” and unconventional concepts such as “bioenergetic homeostatis, repressed memories, spiritual disturbances” amongst others.\textsuperscript{28} Indigenous medical practice is based on “complex” and “personalized”\textsuperscript{29} episodes between practitioner and client, in which the treatment regimen is specifically tailored to suit the particular interests of the client. These treatment regimes can differ considerably from one client to another, “both in the substance of their contents and in their methods of application”.\textsuperscript{30} This may lead to varying individual responses, “possibly even for the same person”, though at different treatment episodes.\textsuperscript{31} Furthermore, in chronic disease

\begin{flushleft}
\textsuperscript{26} Ibid.
\textsuperscript{27} Ibid.
\textsuperscript{28} Giarelli, \textit{supra} note 24 at 63-64.
\textsuperscript{29} Ibid at 63.
\textsuperscript{30} Ibid.
\textsuperscript{31} Ibid.
\end{flushleft}
and prevention cases, indigenous medicine is usually administered over reasonably long periods, \(^3^2\) and this may not fit with the methods of conventional research.

### 3.2.2. Indigenous Medicine and the Placebo

The high patronage of IMS in Nigeria (and indeed in most countries of the world) and the rise in constitutional claims to tax relief and reimbursement for expenses on indigenous medicine in Canada and the United States have influenced debates about regulation and cost-effectiveness of alternative therapies. A significant number of indigenous and alternative medical approaches are proscribed by healthcare legislation in different national jurisdictions. In some cases, the law selectively regulates some alternative therapeutic systems while limiting medical practice to stipulated healthcare professions. In Nigeria, section 17 of the *Medical and Dental Practitioners Act* \(^3^3\) makes it an offence for persons who are not registered medical practitioners to practice medicine. Although sub-section 6 exempts communally recognized IMPs from the provisions of section 17, sub-section 7 stipulates that the medical acts that can be performed under the exemption created by sub-section 6 do not extend to “any activity involving an incision in human tissue or to administering, supplying or recommending the use of any dangerous drugs”. \(^3^4\)

In the Canadian context, the provinces regulate selected alternative healthcare systems. For example, the Ontario *Regulated Health Professions Act* regulates chiropractic, massage therapy, naturopathy (‘drugless practitioners’), and traditional Chinese medicine and acupuncture. \(^3^5\) Sub-sections 27(1) and (2) of the Act prohibit a person who is not authorized by a health profession Act from performing any of fourteen controlled acts, including diagnosis, treatment, and drug prescription. However, section 35 exempts aboriginal healers and midwives from the provisions of the Act. \(^3^6\) British Columbia regulates chiropractic, \(^3^7\) massage therapy, \(^3^8\)

\(^3^2\) Ibid.

\(^3^3\) *Medical and Dental Practitioners Act*, CAP M8 LFN 2004.

\(^3^4\) Ibid, section 17(7).


\(^3^6\) Section 35(1), (2) and (3), *ibid.*
naturopathic medicine, \(^3\) \(^9\) and traditional Chinese medicine and acupuncture\(^4\) \(^0\) through the \textit{Health Professions Act} \(^4\) \(^1\) and the \textit{Health Professions Designation Regulation}. \(^4\) \(^1\) These four medical systems are also regulated through the bylaws of the Colleges governing each profession. \(^4\) \(^2\) These indigenous medical professions are permitted to perform the medical procedures stipulated under the relevant regulatory bylaws. Besides these four alternative healthcare professions (and other regulated conventional health professions), no other person or group may practice medicine in British Columbia without a license. Section 13 of the \textit{Health Professions Act} \(^4\) \(^3\) limits the practice of medicine to the designated health professions. In spite of the provisions of section 13 and similar provisions in other state and national jurisdictions, there is a broad category of unregulated alternative healthcare providers who provide healthcare while striving to comply with the prohibition against the practice of medicine by unregistered professionals. While these providers often refrain from ‘diagnosing’ or ‘treating’, they continue to attract numerous patrons based on their message of holistic healthcare.

Generally, debates surrounding the regulation of these systems often question the safety, efficacy and cost-effectiveness of the therapies. Similarly, debates about whether a state should cover regulated alternative modalities also invoke the issues of safety, efficacy and cost-effectiveness as standards indigenous and alternative medicines must satisfy. Cost effectiveness analysis is an index that has emerged as a crucial determinant of which indigenous healthcare modality should obtain state funding. \(^4\) \(^4\) In the debate on the cost-effectiveness of indigenous medicine and on the utility of the RCT in non-biomedical therapies, commentators have called


\(^{39}\) \textit{Naturopathic Physicians Regulation}, B.C. Reg. 282/2008 (M242/2008); Bylaws of the College of Naturopathic Physicians, online: B.C. Ministry of Health Services and Professional Regulation <http://www.cnptbc.bc.ca/rules.html>

\(^{40}\) \textit{Traditional Chinese Medicine Practitioners and Acupuncturists Regulation}, online: B.C. Reg. 290/2008 (M250/2008); College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia Bylaws, online: B.C. Ministry of Health Services and Professional Regulation <http://www.ctcma.bc.ca/upload/091228%20Amended%20CTCMA%20bylaw%20without%20Schedules.pdf>


\(^{42}\) See footnotes 37 to 40, supra.

\(^{43}\) B.C. \textit{Health Professions Act}, supra note 41.

upon IMPs to provide evidence of the superiority of their therapies over the placebo. A related issue to this is whether pre-trial beliefs and consumers’ philosophies – which are assumed to produce a placebo effect – should be factored into the clinical trial process.

The term ‘placebo’ pervades most discussions of the therapeutic effects of indigenous medicine. In fact, the subject of indigenous medicine appears inseparable from that of the ‘Placebo Effect’ (PE). Although there is substantial literature on the precise medical definition of the term, yet there is significant disagreement among physicians, clinicians, psychiatrists and philosophers of science on what constitutes a placebo effect. It is usually agreed to be a non-specific substance, with no specific curative effect, given to satisfy the psychophysiological needs of a patient. As a substance of operant conditioning, the placebo is also “used on a control group in experimental design to further test the efficacy of an active substance or drug”. The placebo effect has been defined as “the bodily change due to symbolic effect of a treatment or treatment situation and not its pharmacologic or physiologic properties”. This definition accommodates a PE achieved by other causes outside the pharmacologic properties of the drug. Such a broad definition of the PE creates room for some indigenous modalities such as mind-body healing and meditation.

While exponents of indigenous medicine may raise the question of scientific efficacy as a matter of genuine scientific curiosity, some commentators devoted to this enquiry have argued that indigenous medicine should not be exempt from rigorous testing and should be examined using the same methods used to test conventional therapies. Brody, in a discussion of the placebo effect in complementary and alternative medicine, asserts that the chasm between CAM

49 Tyler, supra note 47 at 79. See also Iyioha, Deregulation, supra note 4; Iyioha, “Law’s Dilemma”, supra note 4.
50 Brody, supra note 46 at 75.
51 Ibid; see also Iyioha, Deregulation, supra note 4; Iyioha, “Law’s Dilemma”, supra note 4.
52 Ibid.
and biomedicine – insofar as scientific efficacy goes - may be much narrower than advocates of biomedicine would like to believe.\textsuperscript{54} Indeed, some scholars contend that some complementary therapies are so close to orthodox medicine that they can conveniently be regulated along the same frameworks.\textsuperscript{55} However, given the esoteric nature of some indigenous interventions, it has been argued that the therapeutic approach of holistic therapies must take into account the possibility of emotional and psychological harm, which must be considered in the choice of a regulatory scheme.\textsuperscript{56} While notions of harm have been heavily influenced by legal and biomedical rules,\textsuperscript{57} legal regulation of indigenous medicine faces hurdles because the legal and biomedical professions, much like the RCT methodology, lack guidelines to exercise hegemony over notions of harm “beyond the quantifiable, measurable notion of harm”.\textsuperscript{58}

It is noteworthy that indigenous medical practice is common in degenerative medical conditions and those where behavioural, emotional or spiritual factors play a major role; in these areas, the introduction of scientific logic into medicine has not produced “noticeable improvements, and [have] in fact led to deterioration”.\textsuperscript{59} Thus, in considering the RCT as a research tool, the amenability of such cases (especially indigenous therapies that profess to heal the emotional facet of disease) to the RCT need to be factored into the choice of a research methodology.

3.3. The Randomized Control Trial (RCT) and the Etiology of Indigenous Medicine

The Systematic Review of Randomized Controlled Trials sits at the apex of the evidence paradigm in the validation of a new medical intervention. The Randomized Control Trial (RCT) itself is constructed around a given philosophy – the philosophy of science. The scientific philosophy embodies a belief in natural phenomena that are observable and measurable and that can be objectively interpreted. Science, therefore, is designed to disregard all symptoms or forms of evidence that do not fit within this given category. The philosophy of biomedical science is the RCT’s frame of reference. The RCT methodology by design focuses not on

\textsuperscript{54} Brody, \textit{supra} note 46 at 74.
\textsuperscript{55} See generally Stone and Mathews, \textit{supra} note 1.
\textsuperscript{56} Ibid.
\textsuperscript{57} Ibid at 96-97.
\textsuperscript{58} Ibid at 97.
subjective experiences, but on ‘pure’, measurable, clinical responses. On the other hand, the etiology and regimen of indigenous medicine involves a complex permutation of objective and subjective phenomena and therapeutic courses, which vary depending on the symptoms presented by the patient. The etiology involves the natural, psychosomatic, psychosocial and the metaphysical elements. This philosophical disparity between the biomedically-based RCT and indigenous medical philosophy sits at the root of the controversy regarding which evidential paradigm is appropriate for the regulation of indigenous medicine.

This (as well as the next) section explores this debate. The discussion begins with an analysis of the etiology of indigenous medicine. This analysis is a necessary precursor to the discussion of anthropological research methods in the next section because it elucidates the contentions of the anthropological school. The discussion also provides evidence to debunk the assumption that indigenous medicine is anti-science. Next, the section examines the RCT, its mode of operation, and the limitations in its use as a research methodology. Following this discussion, the anthropological research paradigm is examined in the context of the philosophies of indigenous medicine. The discussion concludes with the need for pluralism in the choice of research methodologies.

3.3.1. The Etiology of Indigenous Medicine

3.3.1.1. Natural Etiology of Illness: The Biomedical in Indigenous Medicine

The nexus between natural or physiological phenomena and illness is one of the defining characteristics of indigenous medicine. Theories of natural causation are scientific accounts which explain illness as “a physiological consequence” of some experience of the patient. Within this theory are several factors that can trigger illness. The first of five factors identified by George Murdock is the infection theory, which links illness to the body’s exposure to pathogens or germs. This account matches the biomedical conception of disease, which emphasizes a physical connection between patient symptoms and disease-producing agents such as viruses, bacteria, or other microorganisms. Murdock’s second factor is stress, which relates to the patient’s experience with physical or psychological strain. The physiological effects of aging constitute the third category. The fourth factor is accident, which involves

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61 Ibid.
bodily or mental injury resulting from the body’s encounter with environmental elements. Murdock’s final factor is physical injury, which is an outcome of deliberate physical assault.

Each of these factors is well represented in indigenous medical worldview. For example, IMPs in Tanzania “regard the patient as a complicated ‘machine’ that can get out of order for many external reasons”; and one such reason highlighted in a research on IMS in Tanzania is that too much intake of fat and sugar can result in heart disease. The metaphor of the machine is evocative of biomedicine’s Cartesian scientific materialism, which conceives the human body as comparable to a machine possessing separate serviceable parts. Natural explanations of illness within IMS seek to identify the biological and environmental factors that lead to adverse health conditions. A medical condition may be linked to an infection, environmental pollutant, or unhygienic conditions, and this diagnosis becomes the basis of specific herbal prescriptions. As far back as the pre-colonial era, African communities had already identified a connection between malaria and overcrowding, environmental pollution, and mosquitoes. Karen Flint reports that at the time the Europeans first arrived, “Africans in the Zulu Kingdom had, for the most part, minimized health risks by settling outside low-lying malarial areas and requiring multiple dwelling structures for large families”.

The treatment regimen for illnesses such as malaria, common colds, skin infections, fever, airborne diseases, amongst others, which usually includes therapeutic plants and other natural substances, is further evidence of the existence of natural etiologies of disease in indigenous medicine. From Tanzania, Mali, Cameroon, Nigeria to Iran, India, and

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63 See, for example, Marlene Reid, “Patient/Healer Interactions in Sukama Medicine” in P. S. Yoder, *African Health and Healing Systems: Proceedings of a Symposium* (Los Angeles: Crossroads Press) 121-158, where the author reports that the Sukama in Tanzania attributes widespread contamination in the entire community to environmental pollution or contamination.


China, knowledge of the connection between the physical and the pathological translates into empirical practices, and this knowledge dictates the nature of the advice rendered and treatment administered by the practitioners. While these specific examples are cited to counter popular perceptions which assume IMPs possess little knowledge of the link between natural phenomena and illness, yet the citation of isolated examples is problematic because they may easily be construed by skeptics as the few exceptions to the popular theory. The fact, if it may be so described, is that the natural etiology of illness is prevalent in indigenous medicine across non-Western cultures.

3.3.1.2. Empiricism and the Quest for Scientific Truth

Ethnographies of indigenous cultures, as noted above, largely depict indigenous medicine as anti-scientific. A similar uncritical assumption underlies some legal and scientific scholarship on complementary and alternative medicine in North America. For example, Caulfield and Feasby describe complementary and alternative medicine as “anti-scientific”. Implicit in such assumptions is an attempt to place medical systems within contrived regiments in which Western biomedicine is always “governed by objective and rational rules of proof” and indigenous medical systems remain “beliefs and choices of lay persons”. This insular view of the world is based, as Aginam observes, on the Western belief that the non-allopathic healer belongs to “one single and indivisible…compartment devoid of methodological or analytical

72 Note also that the natural etiology of disease is as dominant in indigenous medical practice as are the metaphysical etiologies. In fact, it is often the case that some indigenous providers who have had higher university degrees in medical practice adhere to the existence and/or unity of the natural and supernatural.
74 Ibid.
75 Ibid.
scientific investigation”. The accurate account, which is consistently suppressed or granted perfunctory mention in Western scholarship, is that methodical observation and experimentation, logical and objective reasoning, and “hypothetical prediction” are central elements of indigenous medical practice.

In the application of natural theories to medical diagnosis and treatment, the IMS practitioner employs a pattern of observation, experimentation, and prediction. The selection of herbs for treating a particular illness reflects such a pattern. The expertise of the IMP in these areas has often been indispensable to the bioprospecting operations of pharmaceutical companies. Further, while Western scholarship primarily depicts indigenous medicine and practices as “mindless concoctions and senseless superstition”, a closer study reveals the rigour involved in the study and practice of indigenous medicine and in the professional training of indigenous practitioners. As David Westerlund has noted, African medical systems involve “an open search for effective methods”, in which there abound “abundant empiricism and experimentation”.

While there are endless debates regarding whether indigenous medicine is itself scientific medicine in a relatively unmodified and natural form, it can be asserted, as Ralph Schram does regarding the indigenous systems of medicine in Nigeria, that some indigenous medical systems were “unconsciously a part of the overall empirical, traditional medicine of the world, from which most certainly much of our modern scientific medicine has evolved”. A brief examination of diagnosis and some methods and techniques applied in indigenous medicine throws further light on the conceptual similarities between indigenous medicine and biomedicine.

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76 Obi Aginam, “From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World” (2002) 3 Chicago Journal of International Law 102, online: Social Science Research Network <http://ssrn.com/abstract=319162> at 9 [‘Aginam’].
78 *Ibid* at 131.
3.3.1.3. Diagnosis

The process of diagnosis often takes the investigative pattern of inquiry, in which the IMP asks questions about the patient’s symptoms and medical history, including where necessary that of his or her family. There is knowledge that the “life history of the patient and that of his immediate parents and family” is important to accurate diagnosis. The process of diagnosis involves extensive consultation with the patient. It is important to note that indigenous medicine has a recognized strength over biomedicine in this regard. The IMP seeks to include the patient in the therapeutic encounter. As Akisanya reports, the indigenous healthcare provider is interested in knowing the symptoms of the patient’s condition, whether the condition is hereditary, the length of time since the manifestation of the symptoms, amongst other relevant information. Where there are uncertainties about a given diagnosis, the practitioner consults a colleague.

It is common knowledge that many IMPs lack the technologies designed to aid healthcare providers in diagnosis, such as ECG for changes in cardiac rhythm, EEG for signals from brain waves, or the simple stethoscope. These instruments aid the physician in reaching accurate diagnosis; the technologies provide precise or near precise graphs and pictures, and changes in the patterns under observation may indicate specific abnormalities in the patient’s physiology. For the IMP, the observation technique which is trusted to reveal abnormalities in a patient has

82 Abayomi Sofowora, Medicinal Plants and Traditional Medicine in Africa (Ibadan: Spectrum Books, 1993) at 29 ['Sofowora']. Sofowora (at 29) suggests that while the practitioner actively listens to the patient’s narratives about his or her condition (in the course of which the practitioner also observes the patient), the conventional physician often “gives the impression of having no time for his patient at all” as he or she is mindful of the queue of patients outside the clinic. According to the author, “the modern doctor is often jokingly described as one who prescribes even before the patient finishes his list of complaints” (at 29). This opinion was confirmed in an interview at the Qi Integrative Health Centre in Vancouver, in which TCM practitioner Kiem Schutter opined that alternative medical practitioners spend more time with their patients than do their biomedical counterparts: Data obtained from Canada drawn from Ireh Iyioha, International Research on Usage, Financing and Governance of Indigenous and Integrated Medicine and the Construction of Intellectual Property Regime for Herbal Medicines (2008-2010) on which this work is based ['Iyioha, International Research'].
83 See Akisanya, supra note 81.
84 See generally John Beattie, “Divination in Bunyoro, Uganda” in John Middleton, Magic, Witchcraft and Curing, ed. (Garden City, NY: The Natural History Press, 1967), where the author’s research on the Ugandan ‘Nyoro’ reveals that the IMP consults a second practitioner to confirm the first diagnosis before embarking on a treatment plan.
85 Sofowora, supra note 82 at 28.
86 Ibid at 29.
often served as a viable diagnostic tool. The practitioner observes the patient for changes or serious abnormality in the patient’s posture or breathing. This technique is most useful in early psychiatric cases, in which the patient’s attitude, gestures and utterances are closely observed. As Tomio Tada has observed, “lacking sophisticated analytical power, these systems have nurtured intuitive diagnostic and healing methods based not on the sub-individual pathology but phenomenological symptomatology at the level of the individual.”

The IMP also employs visual examination, in which case the eyes, skin, and body fluids are examined for abnormalities and/or discolourations as in the case of jaundice or some skin conditions. Further, the indigenous practitioner carries out a clinical examination including “summary of appearance, inspection of moveable parts, palpation”, and pulse examination. Pulse examination is used with a “high degree of perfection” in the Ayurvedic, Unani and Tibetan medical systems; these systems of medicine have successfully established an association between pulse behaviour and humoral imbalance. Another diagnostic method is the analysis of dreams in suspected mental health cases. Sofowora reports the observations of Ademawagun in the latter’s experiences at what appears to be a collaborative psychiatry clinic involving both conventional and indigenous psychiatrists at a rural Nigerian community health project. The project was instituted at the Medical School of the University of Ibadan located in Oyo State of Nigeria. According to Sofowora, Ademawagun observed that the process of diagnosis employed by an IMP is a “[c]omplex of ecological investigations, interview, and consultation, in that it involves the patient’s physical, emotional, and social state”. Ademawagun opined that there was “no doubt that the orthodox practitioner has a lot to learn, particularly from the traditional practitioner’s person-centred diagnostic method”. While these diagnostic methods continue to serve the interests of millions of patients worldwide, yet it is important to emphasize that the limited diagnostic tools available to IMPs in the less

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87 Ibid at 28.
88 Ibid at 29.
89 Tomio Tada, “Towards the Philosophy of CAM: Super-system and Epimedical Sciences” (2004) 1:1 eCAM 5 at 6 [‘Tada’].
90 Sofowora, supra note 82 at 30.
91 Ibid.
92 Sofowora, supra note 82 citing Ademawagun (1973) at 32. Sofowora notes that this process of diagnosis is traceable to indigenous medical systems in other countries beyond Nigeria.
93 Ibid.
technologically-developed societies of the South buttresses the case for collaboration between biomedical and indigenous medical practitioners.

In reproducing Ademuwagun’s observations regarding the pragmatism in the choice of patients at the collaborative psychiatry clinic mentioned above, Sofowora notes that the IMPs were selective in the cases they treated so as to “keep as good a record of successes as possible”. This attitude is said to be influenced by the presence of the medical school at the University of Ibadan about 80 kilometres away. Given the presence of the school and of its activities within the community (in the areas of clinical trials and surveys, and the provision of healthcare), the IMPs accept only cases directly within their areas of expertise. Complicated cases or conditions outside their areas of specialization are usually referred to the teaching school or other conventional hospitals in the neighbourhood. Similarly, Mgbeoji has noted that native healers in Southern Nigeria who are experts in one field often refer patients to another practitioner or a senior colleague who has expertise in the area of medical interest. Beyond providing evidence of specialization within indigenous medical practice, this referral tradition – especially where one provider refers a patient to another provider who dispenses the prescribed medicine – also shows some level of consistency in diagnosis and treatment across providers.

3.3.1.4. Treatment

The nature and formula of many indigenous therapies indicate the presence of rational, evidence-based techniques in indigenous medical practice. The types or methods of treatment within indigenous medicine often reflect the specialized nature of the field. A wide range of methods exist, from the more commonly known naturopathy, massage therapy, psychiatry, acupuncture, chiropractic, osteopathy, psychotherapy, yoga, meditation, faith healing, ayurveda and unani systems to other well-defined methods including hydrotherapy, bone-setting, spinal manipulation, obstetrics and gynaecology, surgery, therapeutic fasting and

94 Ibid.
95 Ibid. Sofowora notes that there is less referral to biomedical practitioners in rural communities where conventional clinics are remotely located.
97 Sofowora, supra note 82 at 33.
dieting. Other systems include the humoral therapy of Latin America, homeopathy, hypnosis, divination and exorcism. With the exception of the faith-based systems, the majority of these medical practices are based on empirical and verifiable principles while being integrated within socio-cultural philosophies about diseases, health and general wellbeing.

Depending on the level of development of the institution, education in the practice of indigenous medicine often covers the subject of anatomy and surgery. The widely acclaimed successes of bonesetters in many African communities lend credence to assertions about the IMP’s understanding of human anatomy. While there is little written on some of the medical achievements within IMS, old testimonials exist such as Robert Felkin’s report on the successful performance of caesarean operations by a Ugandan indigenous surgeon.

The practice of herbalism and the “development of disease classification schemes based on extensive observation” are further evidence of the scientific rationality of indigenous medicine. Having successfully attributed a patient’s condition to a physical cause, the IMP embarks on a logical treatment regimen, consisting of tested and proven herbal remedies. Herbal remedies are prepared and tested on the basis of a logical process of observation over long periods of time. Nigerian herbalists employ a wide variety of medicinal herbs in medical treatment. These herbs are effective for hypertension, ulcers, malaria, convulsions,

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98 This is by no means an exhaustive list. A detailed account of the mechanisms of action and techniques employed in each of these modalities (with the exception of those reliant on the belief or faith of the patient) has been provided in other texts. For this see: Sofowora, supra note 82, chapter 3; Bannerman, et al., supra note 59.
99 See generally Sofowora, supra note 82 and J.I. Durodola, *Scientific Insights into Yoruba Traditional Medicine*, supra note 68.
103 Baronov, supra note 77 at 149.
104 See F.M. Mburu, “The Duality of Traditional and Western Medicine in Africa: Mystics, Myths, and Reality” in Philip Singer, *Traditional Healing: New Science or New Colonialism? (Essays in Critique of Medical Anthropology)* (New York: Conch Magazine, 1977) at 170. Mburu recounts the words of a herbal practitioner who provides the following account of the process of discovering new herbal medicines: “Sometimes it takes me a long time to get what I want… I have to test everything, individual herb by herb, then I mix one by one in varying quantities, tasting it every time… When I have to mix five or so herbs to produce a solution I need, it is neither interesting nor easy to go through the process” (ibid at 170).
hepatitis, fractured bones, among other ailments. Writing on herbal medical practice in Nigeria, Akisanya observes that indigenous medical prescriptions can be grouped into three categories: “(i) that which is made up of plant parts (ii) that which is a combination of plant parts and parts of animals or animal secretions (iii) that which is made up of plant parts, and/or parts of animals in combination with certain incantations”. While some prescriptions may contain one single active ingredient, most herbal medicines are multi-component mixtures. The medicines may be prescribed as liquid (e.g. “decoctions, infusions, oily mixtures, gargles, etc”), solid (e.g. powders, ointments, powdered dried herbs, etc.), semi-solid (“e.g. certain crude balsams, resin, latex) or gaseous (e.g. steam inhalation preparations, fumigations like incense, etc.).

Herbal remedies are often combined with other therapies. Indeed, the treatment procedure is as holistic as the diagnostic process. The indigenous practitioner’s objective is to cure not only the physical manifestations of the disease, but to restore balance in the different aspects of the patient’s life. Other modalities used alongside herbal remedies are chosen based on the practitioner’s diagnosis. These prescriptions could include exercises, relaxation, meditation, sunbaths or making peace with either human or ancestral beings. As noted in chapter one, the wealth of knowledge involved in the use of herbs for treatment by indigenous societies is at the root of the international controversy regarding ownership of pharmaceutical products derived from this knowledge. As Baer et al. have noted, “an estimated 25% to 50% of the pharmacopoeia of indigenous peoples has been demonstrated to be empirically effective by biomedical criteria. Various biomedical drugs, including quinine and digitalis, were

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106 Akisanya, supra note 81 at 237. Incantations, which are often addressed to transcendent forces, identify the interconnectivity between the natural and the supernatural theories. Thus, even while natural theories are relied upon for diagnosis and treatment, the indigenous medical practitioner is concerned with ensuring that the patient is at peace with communal laws that govern the society, deities and other ancestral forces that are believed to protect the society.
107 Sofowora, supra note 82 at 33. Sofowora explains that this is because some of the components are preservatives, while others act as flavouring or colouring agents. This practice is not uncommon as non-medicinal components are often added to preparations in Western pharmaceutical practice (ibid).
108 Ibid.
109 Ibid.
originally derived from indigenous peoples". Today, indigenous peoples contend that the West appropriates their medicinal knowledge with patents for pharmaceuticals derived from their knowledge of herbs.

The narrative of appropriation is captured by the term “biopiracy”. Pharmaceutical companies are alleged to employ the legal power of patents to isolate the pharmacopoeic components of indigenous medicinal knowledge, an attempt that is at best reductionistic and at worst dismissive of the holistic framework of indigenous medical practice. According to Baronov, this “robbery” (of indigenous medicinal knowledge of herbs) derives from “an ongoing relation of exploitation between Africa and the West as well as biomedicine’s proclivity to treat medical care as comprised of discrete elements that exist outside a holistic framework”. Implicit in this comment is an acknowledgement of the unique character of indigenous medicine. While it espouses natural theories of illness, it does not single these out as the only factors that are worthy of attention in medical treatment. The irreducible character of indigenous systems of medicine, as the next sections will show, makes it a system of healthcare that identifies with and yet transcends Western biomedicine.

3.3.1.5. Transcendental Etiologies
Transcendental explanations attribute ill health to “phenomena and forces” that are not explicable through the laws embodied in the Western sciences. Many indigenous societies hold profound beliefs about the existence of a transcendental realm. Among many IMPs, “the reality of the supernatural world is as consequential and as tangible for the lives of individuals as forces in the natural world”. Within this realm are ancestral and religious deities, who are believed to influence human activities. Also within the supernatural category are humans who hold and wield magical powers for good or evil. The role of some IMPs who are skilled in the knowledge of the supernatural is to diagnose whether these forces have inflicted illness on a

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112 Baronov, *supra* note 77 at 137.
113 *Ibid* at 138.
114 *Ibid*. 
patient and avert misfortunes that would otherwise result from the supernatural influence. Hence, even where diagnosis through empirical methods reveals a condition curable by an application of the natural theory of disease, the indigenous practitioner while applying tangible and perceptible cures (herbs, exercises, meditation, etc.) still enquiries about harmony between the individual and the larger community of humans, ancestors and deities.

The belief among many non-Western cultures in the existence of multiple ontological realms has given rise to polarized perspectives in the scholarship. According to Baronov:

> On the one hand, it is argued that such forces contravene the laws of nature and are, therefore, surely nothing more than the fanciful rantings of a preliterate, uneducated, and primitive mind – however respectfully discussed. On the other hand, it is suggested that such forces pertain to a reality not captured by investigations of the natural world (for example, ancestral spirits) and are, therefore, simply beyond the self-imposed ontological limits of the Western natural sciences.¹¹⁵

The former notion – that the transcendental is a contravention of natural scientific theories – is manifest in the terminologies that Western scholarship employs in the description of supernatural phenomena. These terms include sorcery, magic, witchcraft, and superstition. Substantive description of the transcendental or supernatural in indigenous medical practice is complicated by the use of these terminologies. However, what the scholarship seems to have omitted in depicting mysticism in indigenous medicine is that supernatural theories of illness are part of an integral system in which the medical, social, cultural, religious and the legal are fused. This means that many indigenous peoples – especially those who live in non-urban communities largely unspoiled by the forces of globalization or Westernization – are governed by laws that regulate their religious, social and moral lives. A breach of or imbalance in any of these laws (whether it involves a contravention of a religious, cultural or moral norm, or animosity from a failed social relationship) is deemed to have physical or psychological manifestations in an individual.¹¹⁶

¹¹⁶ For example, a diagnosis made in relation to a person afflicted with some disease and who has committed a heinous crime such as murder may indicate that the illness and socio-psychological misfortunes of the patient are traceable to the secret crime of murder. A confession and absolution through rites would be part of other treatment regimen targeted at the biological symptoms of the illness.
This philosophical system, which captures the holistic framework of indigenous medicine, is significant because healthcare among indigenous societies is “a way of life”. Members of the society are cognizant of the interrelationship between communal laws and medical well-being. The IMP, therefore, plays the significant role of ensuring the physical and psychological well-being of his or her patients. Hence, while there is a “covert attribution of irrationality” to indigenous medical beliefs especially as they relate to the transcendental, it would be imprudent to disregard the cultural context and logic which form the basis for these beliefs. There is an interesting example of how what appears to be an unfounded superstition was in fact a public health strategy to avoid widespread smallpox contagion among the Yoruba of Nigeria. Among this tribe, the smallpox was in pre-colonial times symbolized as a deity. While this seemed like an outright misunderstanding of the natural etiology of smallpox, the representation of the disease as a deity was a preventive strategy developed after a long-term observation of those who had survived the disease. Thus, members of the smallpox cult were those who had survived an attack of the disease and who, therefore, had developed a natural immunity to it. These were the only persons allowed to assist in the quarantine and care of infected persons. As Onoge explains:

…it was they only, with their acquired immunity, who were permitted to come into physical contact with anyone afflicted with the disease. When a case of smallpox was suspected, the patient and his belongings were immediately quarantined until the members of the cult could be summoned to remove him for treatment. Under the circumstances, the representation of the disease in religious terms was a mechanism for ensuring strict conformity with the preventive medicine codes.

While the validity of the transcendental realm remains a contested issue in Western and indigenous scholarship, it is more expedient for socio-medical scholarship to focus on the physical and psychological well-being of the patient after his or her encounter with the IMP. Future scholarship should concern itself with how the patient’s belief in these overlapping ontological realms affects the healing process. It is likely that skeptics will classify any

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118 Onoge, supra note 101 at 222.  
119 Ibid.  
121 Onoge, supra note 101 at 223. Emphasis added.
positive physiological response in the patient as placebo. However, since the placebo is itself noted to be capable of generating physiological responses, it calls to question the total dismissal of indigenous medical beliefs as superstitious.122

3.3.1.6. Psychosocial and Psychosomatic Etiologies

The psychosocial theory of disease identifies interpersonal or social relationships as a significant factor in the health of individuals. Events in the social world are believed to have an effect on the emotional and psychological health of individuals. The IMP is not only interested in the empirical, observable causes of the patient’s illness; he or she is also concerned about social stability in the patient’s life. Imbalance in the social world, such as the occurrence of conflicts within a marital relationship, animosity in a patient’s place of work, or a state of depression in the patient resulting from diverse social factors, can be linked to specific medical conditions.

The indigenous concept of unity of the body and mind implies that the psychosomatic condition of the patient may be interpreted as the cause of physical illness.123 Thus, in diagnosis and treatment, the indigenous practitioner does not conceptually separate the body and the mind. Based on the connections made between the interactions in the mind and the body, the treatment regimen involves a “total package comprising complex diagnostic and curative rituals rooted in cultural, religious and psychosocial appeals”.124 All the above elements in combination embody the holistic nature of indigenous medicine.

3.3.1.7. The Concept of Holism

Indigenous medical systems operate within a holistic framework. This implies that the natural, transcendental and psychosocial are construed, more often than not, as integrated factors responsible for a given medical situation. A diagnosis in one of these elements has implications for other elements in this holistic circle.125 The indigenous medical practitioner sees his or her role as that of ensuring balance and harmony in all four aspects of the patient’s

123 Oguamanam, supra note 117 at 113.
124 Ibid.
125 Baronov, supra note 77 at 145.
relationships with the natural and supernatural worlds. Hence, the IMP “must record the physical manifestations of [a patient’s] illness while also placing the person in the broader context of the supernatural and social forces influencing his or her life”. 126

Within this holistic framework, “proper well-being…depends upon an individual’s ability to live in harmonious balance with his surroundings, which include the moral, physical, and spiritual realms”. 127 Health, within this concept, has broader meaning than it is represented to have in biomedicine. For example, the Hausa tribe of Nigeria interprets the concept of health as encompassing the “proper ordering, correct structuring, and general well-being of the social order and the individual’s relations within it, as well as the state of wellness in the human body”. 128 This conception of health or well-being differs from the biomedical. The focus is on the general wellbeing of the individual rather than on the malfunctioning of cells. Hence, the IMP speaks of ‘health’ and ‘order’ rather than disease simpliciter. The Hausa concept of health, lafiya, which literally means ‘health’ connotes the “fundamental, proper order of things, be it a physiological or social equilibrium”. 129 Similarly, “magani, which literally means ‘medicine’, “denotes the means by which disordered states may be returned to their proper order”. 130 Wall notes that the concept of magani or ‘medicine’ in Hausa cosmology is ‘remedy’ in the broadest sense; thus, medicine among the Hausa seeks to restore the “social propriety and balance” as well as treat the “disordered physiology”. 131

A similar concept of health is held among some physicians and indigenous healthcare providers in North America. In an interview conducted at the Qi Integrated Health Centre in Vancouver, the clinical director of the Centre, Dr. Kiem Schutter, R.Ac. expressed the following opinion:

126 Ibid.
128 Ibid at 212.
129 Ibid at 334.
130 Ibid.
131 Ibid.
Health is not an individual thing. Health comes from … community interactions. It is communitarian living, recycling, growing your own food, inviting your neighbour to dinner even though you don’t know them; that creates a healthier place to live for everybody. All of this is related to integrated healthcare because integrated care takes into account your emotional wellbeing, your health in terms of what you eat, …think, and your physical being. And that is different than allopathic medicine has been … where it is simply about division; …either you mentally have a problem or you physically have a problem and the two are not connected. So, in connecting those two, you are connecting a person back with themselves … and …the more you are connected with yourself, the more you connect with other people.  

Beyond this communitarian aspect of holistic healthcare, another arm of the principle of holism is depicted in the rejection to a significant extent of the doctrine of Cartesian materialism that largely operates within biomedicine. Patrons with medical problems that defy the Cartesian logic seek indigenous medicine simply because they want medical solutions that lie outside the philosophical boundaries of biomedicine. Tamio Tada suggests that people are attracted to these systems of medicine because they are searching for answers to their suffering, and these answers do not always exist within biomedicine’s reductionistic and “biased” focus on organs and cells. Essentially, the objective within IMS is to “understand disease by empirical intuitive symptomatology, not reducing it to the abnormalities at subindividual levels”.

Apart from the area of diagnosis, the theme of holism also operates in treatment. The primary objective of therapy in indigenous medicine is “the restoration of the patient to a THERAPEUTIC community”. In administering a modality, the patient is conceived as a “complete whole” and the prescribed treatment is directed to restore balance between and within the competing realms to which the patient belongs. In order to achieve this, individuals are expected to live in accordance with an integral philosophy, involving healthy eating, regular hygiene, maintaining harmonious relationships, and respect for the environment, amongst other philosophies. By virtue of these interrelated elements, indigenous medicine may be regarded as part of everyday living, rather than just as a “discrete,
specialized sphere”. Indeed, the invocation of the causative and punitive powers of spirits and ancestors in illness and wellbeing is fundamentally “a method of drawing attention to the objective disarray in the prevailing network of social relations in which the sick individual is implicated”. Incredible as these invocations are in terms of observable phenomena, the appeal to transcendental forces is aimed at “restating” and restoring ethical norms which “unite the patient and his neighbours” in an integral community. Thus, the use of herbal plants in treatment is to be construed as only one aspect – albeit a significant aspect – of a “complex and holistic regime” of healthcare delivery in its broadest sense.

Evidently, the patronage of IMS bears no sign of regression in the near future. As more patients turn to indigenous and alternative medicines, there is greater need to license practitioners and regulate the therapies. In this regard, the RCT has been touted as the standard that the practices and medicinal therapies must meet for practitioners to be eligible for legal recognition or statutory self-regulatory status. However, as discussed in the following section, the question is whether the conceptual framing of the RCT allows for an objective testing of the multidimensional and holistic paradigm of indigenous medicine.

3.3.2. Evaluating the RCT

The re-emergence of indigenous medicine in spite of the dominance of biomedicine has been attributed to changing conceptions in the nature of health and healing, a phenomenon that is representative of changes in medicine’s institutional authority initiated by a consumer-driven healthcare environment. The increase in the popularity of indigenous medicine has been matched with concerns about its safety and effectiveness. Nigerian and Canadian regulatory agencies, usually at the federal level, have the responsibility to determine the safety and efficacy of medicines, nutritional supplements and herbal medicines. This function is critical to the health and wellbeing of consumers who are unable to assess the safety and quality of health products. Indeed, the healthcare market is described as imperfect because consumers lack the requisite tools to assess the goods on sale since the exercise of their judgment is contingent on

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138 Baronov, supra note 77 at 146.
139 Onoge, supra note 101 at 220.
140 Ibid.
141 Ibid.
factors such as test results, quality assessment and the professional judgment sometimes required before purchase.

Thus, statutory regulation of indigenous medicine is not simply about granting professional recognition to indigenous medical providers; it is first and more importantly about protecting consumers’ health and enabling them to make informed choices. A further objective of regulation is that IMPs will acquire the status necessary to obtain funding/research grants and collaborate with biomedical professionals to ensure the best healthcare that would meet population needs, especially in rural and other underserved communities with a high rate of inequitable healthcare delivery. The recognition conferred by statute raises a specific indigenous modality to an accepted healthcare option. The passing of the Osteopaths Act in 1993 and the Chiropractors Act in 1994 in the United Kingdom have been interpreted as significant landmarks. While many indigenous modalities are voluntarily self-regulated, the passing of similar Acts in other countries has generated a lot of optimism that many indigenous therapies can achieve statutory recognition. However, the process leading up to the grant of statutory legitimacy necessarily requires favourable evidence that the healthcare intervention is effective against the (range of) conditions for which it is directed. In order to establish this evidence, the Randomized Clinical Trial, which is usually controlled and double-blind, is applied to the given data.

The Randomized Controlled Trial is a quantitative study in which people are “allocated at random” to receive one of several clinical interventions. One of these interventions is the standard of comparison or control, and it may be a standard therapy or practice, a placebo, or no intervention at all. When evaluating the results of an RCT, the methodological quality of the design, the conduct of the trial and the influence of pretrial beliefs are important issues to be considered. Hrobjartsson and Brorson have noted that these factors make it imperative to

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144 Willis and White, supra note 18 at 54.
145 Stone and Matthews, supra note 1 at 126.
146 Willis and White report that in Australia, statutory regulation of traditional Chinese medicine was not based on favourable trial results on alternative medicine but on political and social factors external to the health system. See Willis and White, supra note 18 at 58.
147 Giarelli, supra note 24 at 57.
149 Ibid.
interpret RCT results cautiously.\textsuperscript{150} Indeed, where it is likely that a trial has design inadequacies, or when the intervention is based on theories that are not scientifically interpretable, the results of the trial must be viewed with caution.\textsuperscript{151}

Generally, there are a number of limitations to the effectiveness of the RCT in measuring the efficacy of biomedical interventions.\textsuperscript{152} It has been argued that the RCT is not an incontrovertible method for validating indigenous and alternative medicines because the trial will have to confront the same problems inherent in testing biomedical modalities through RCTs.\textsuperscript{153} Howard Brody argues that since the RCT supposedly controls for all “nondrug factors”, it assumes that other possible causative factors are irrelevant to the medical scientist.\textsuperscript{154} As a result, the ‘non-scientific’ elements of indigenous medicine, such as the patient’s belief system and the multifaceted etiologies of disease causation and treatment which produce a placebo effect, are excluded from the trial.\textsuperscript{155} Brody contends that the placebo effect is a significant part of the results of biomedical trials; and as far as this remains the case, the RCT will be an ineffective way of disproving alternative medicine.\textsuperscript{156} It is important to highlight the important point in Brody’s argument in the context of the analysis here. The author’s contention is that the placebo effect remains present in RCTs of biomedical interventions even though the trial is designed to consider all nondrug factors as irrelevant.

Apart from the above problem identified by Brody, a number of other factors could influence the result of a clinical trial. Results could be tainted by inadequate methodological design, bias or chance.\textsuperscript{157} Another factor relates to the attitude or beliefs of the investigators. Scholars have noted that the conduct of a trial by data or outcome interpreters with a high interest in the results of the trial may be a source of bias.\textsuperscript{158} It has been suggested that data or outcome interpreters will need to have ‘genuine intent’ that is unaffected by strong feelings for

\begin{footnotesize}
\begin{enumerate}
\item[151] \textit{Ibid}.
\item[152] Brody, \textit{supra} note 46 at 77.
\item[153] \textit{Ibid} at 79.
\item[154] \textit{Ibid} at 77.
\item[155] \textit{Ibid}.
\item[156] \textit{Ibid} at 79.
\item[157] Hrobjartsson and Brorson, \textit{supra} note 150 at 108.
\item[158] \textit{Ibid} at 111.
\end{enumerate}
\end{footnotesize}
a special result from the trial.\textsuperscript{159} Genuine intent is arguably an abstract term. However, it can be agreed that it implies a lack of interest in any particular trial outcome. It also requires the investigator to exercise a detached assessment of the evidence and trial result(s).

Another set of factors that could influence the result of a trial are the logistical challenges associated with the RCT. A trial must be conducted in accordance with the standards of good clinical (research) practice. This often refers to a process of auditing.\textsuperscript{160} Defective logistical design of a trial can lead to compromised results. Hence, it is not surprising that some systematic reviews of homeopathy trials with poor outcomes have revealed defective methodological designs and a general low trial quality.\textsuperscript{161} In these reviews, the focus was on the logistical design of the trials. Hrobjartsson and Brorson have noted that because quality analyses of RCTs are often based on “analyses of trial reports and not the conduct of the trial”, key aspects of trial methodology or the problems involved may not be identified. In a review of a broad group of trials with binary outcomes, reviewers observed that there was unconcealed allocation and no double-blinding. Thus, trial participants were able to predict the treatment they would receive before the start of the trial.\textsuperscript{162} As Donna Greschner has observed, “the ‘evidence’ in evidence-based decision-making can be collected or interpreted in unfair or biased ways. And if the evidence is biased, so, too, will be the policy or guideline”.\textsuperscript{163}

Finally, it has been shown that the RCT is not designed to accept the metaphysical elements in many indigenous interventions as part of the therapy under trial. Although it can be argued that these elements have no effect beyond that of the placebo, yet their presence in many indigenous therapies is of importance to any scientific trial because the placebo itself has been described as medicinal.\textsuperscript{164} In fact, as Christine Barry has observed, “the phenomenon labelled ‘placebo effect’ in RCTs is recognised as a powerful intrinsic component of alternative healing”.\textsuperscript{165}

\begin{thebibliography}{99}
\bibitem{159} \textit{Ibid} at 112.
\bibitem{160} \textit{Ibid} at 111.
\bibitem{161} \textit{Ibid} at 109.
\bibitem{163} Greschner, \textit{supra} note 6 at 50.
\bibitem{164} See generally the \textit{Report of the Committee on the Healing Arts}, vol. 3 (Toronto: the Queen’s Printer, 1970).
\bibitem{165} C.A. Barry, “The Role of Evidence in Complementary Medicine” (2006) 62 \textit{Social Science and Medicine} 2646 at 2651 ['Barry'].
\end{thebibliography}
The above limitations in the use of the RCT for testing IMS may be summarized through Toke Barfod’s elucidatory account of the relationship between the RCT and different models of healthcare.\textsuperscript{166} Using a general notion which may be denoted as the ‘concept of fragility’, Barfod differentiates between complementary and alternative interventions that are analogous to biomedicine and those that combine both reducible and non-reducible forms of medical knowledge within the therapeutic regimen. While the former include complementary and alternative therapies like herbal medicaments that function (to a significant extent) independently of the patient’s belief system, the latter include interventions founded on theories foreign to biomedical science or that function alongside the belief system of the patient and practitioner.

Barfod places CAM therapies on a spectrum with these two categories of CAM positioned at the two ends of the spectrum. These categories may be classified as the “context/belief-independence” systems and the “context/belief-dependence” systems;\textsuperscript{167} the latter are fragile therapies, while the former constitute non-fragile therapies.\textsuperscript{168} Barford’s argument is that the RCT is an effective way to validate therapies at the non-fragile end of the spectrum. However, as the therapy progresses towards the fragile end of the spectrum, the RCT ceases to be an effective tool for assessment.\textsuperscript{169} The RCT creates an environment foreign to the cultural and philosophical belief context within which the fragile therapies would be most effective.\textsuperscript{170} This argument is similar to that proffered by anthropologists and ethnographers, who assert that the unique nature of indigenous therapies favours an evidential paradigm that is cognizant of the effect of philosophies, culture, and/or belief systems on the efficacy of the treatment.\textsuperscript{171}

While Barford’s thesis might illustrate the arguments of many IMPs and medical anthropologists, the premises of the theory have been challenged. For example, Brody argues that it is fallacious to suppose that RCT results are influenced only by ‘pure pharmacologic drug effect’. Through an example that captures the role of the placebo in a real trial, Brody asserts

\textsuperscript{167} \textit{Ibid}; Brody, \textit{supra} note 46 at 78.
\textsuperscript{168} \textit{Ibid}.
\textsuperscript{169} \textit{Ibid}.
\textsuperscript{170} \textit{Ibid}.
\textsuperscript{171} See generally, Barry, \textit{supra} note 165.
that the placebo can generate an observable difference in the condition of the subject.\textsuperscript{172} According to his argument, while scientists insist that the best result in a trial is that which is wholly based on the pure pharmacologic effects of a drug (or on the pure therapeutic effects of a medical intervention) in which case there is double blinding, yet such an administration does not represent a real clinical setting.\textsuperscript{173} A drug or intervention in everyday clinical settings will usually be administered under an ‘open label’ condition – and yet, this is not the scientifically preferred result in an RCT.\textsuperscript{174} Thus, Brody concludes that the RCT “may do as poor a job of assessing at least some conventional remedies as it may in assessing at least some CAM remedies”.\textsuperscript{175}

It must be emphasized that while Brody presents a compelling argument on the “neutrality” of the RCT in testing both conventional and indigenous medicine, the foundation of his argument is that there is an interaction of the placebo effect and the pharmacologic (or pure therapeutic) effect in most alternative medical interventions as well as in conventional therapies.\textsuperscript{176} Thus, his argument is for the rejection of standard but unproven medication, not to accept equally unproven alternative medicine.\textsuperscript{177} This contention should be read alongside the author’s earlier observation that the PE “probably” works along the “same biomedical pathways” as most alternative medical interventions, such as mind-body modalities, which are composed of socio-psychological or philosophical elements. Having defined the placebo broadly (which arguably includes indigenous and alternative therapies that focus on the interaction of the mind and body), his view in summation is that indigenous medicine can be verified through the RCT.

\textsuperscript{172} Brody’s example is a hypothetical trial result for the drug Viagra, which is manufactured for the treatment of erectile dysfunction. He invites the reader to assume that the drug has been tested under different conditions, based on an “agreed-upon, reasonably objective measure of the successful treatment of erectile dysfunction”.\textsuperscript{172} In the results of this hypothetical trial, there was 90% of improvement when Viagra was administered under “open label” conditions and 70% when the subject was enrolled in double-blind RCT and told he will receive either Viagra or placebo, though he actually received Viagra. There was 40% improvement when the subject was enrolled in double-blind RCT, told he will receive either an unnamed, active drug or placebo, though he actually received Viagra. When Viagra was surreptitiously placed in the subject’s food, there was only 20% improvement. Brody concedes that no such documented study exists. However, the percentages indicated in this hypothetical trial are based on existing data on the effect of the placebo.\textsuperscript{172} The question, then, is which is the ‘right’ answer of the two RCT results?

\textsuperscript{173} Brody, supra note 46 at 79.
\textsuperscript{174} Ibid.
\textsuperscript{175} Ibid.
\textsuperscript{176} Ibid, “Law’s Dilemma,” supra note 4; Iyioha, Deregulation, supra note 4.
\textsuperscript{177} Ibid.
An acceptance of Brody’s argument – at least to the extent in which the argument achieves the goal of this thesis – would imply that we have overcome a major obstacle to the formal recognition of IMS given that RCT results of indigenous medicine influenced by the placebo effect will not be negatively interpreted. However, in order to reach the same conclusion as that asserted by Brody, there will need to be a reconceptualization or reformation of the clinical trial process to accommodate the PE as medicinal and as a significant element in the overall results of a trial. Given that the accepted scientific position is that a successful or valid RCT result is one that is dissociated from all externalities including socio-cultural and psychological factors that induce placebo effects, Brody’s argument fails to accommodate his intended conclusion, which advocates for liberal evaluation of the results of clinical trials of indigenous medicine.\footnote{Ibid.} In other words, although he argues that RCT results are in reality a manifestation of both the pure therapeutic effect of an intervention and the placebo effect produced by external factors, scientific interpretations of these results continue to separate these two aspects of an intervention. Thus, while Brody favours the use of the RCT for validating IMS – which would be beneficial for IMS if the RCT process was broadly constructed to accommodate external factors that positively influence the workings of a given therapy – the assessment of alternative medicines through the RCT will remain problematic so long as the scientific community continues to define the RCT as a system unaffected by external factors.

Nevertheless, it is important to note that one of the most informative aspects of Brody’s analysis is his identification of the role of pre-trial belief in the RCT. The next two subsections further explore the complexities surrounding Randomized Controlled Trials and pre-trial beliefs. At one level, this discussion highlights the reliance of law on science; that is, statutory regulation of health systems is often dependent on the evidence generated through scientific investigation. At another level, the discussion reiterates the problems associated with regulating IMS through the RCT methodology.
3.3.3. Testing the Hypothesis of Indigenous and Alternative Therapies: The Null Hypothesis and its Limitations

The process of setting up and testing a hypothesis involves the formulation of a theory. This theory is either believed to be correct or is simply applied as a basis for argument. In either case, the theory is usually unproven. A null hypothesis represents such a yet-to-be proven theory that is put forward as a basis of argument. An example is the claim that a given indigenous therapy is more effective than the biomedical alternative for the treatment of the same or a similar medical condition. The null hypothesis is important in clinical trials because it is the theory being tested. There is usually an alternative hypothesis to be accepted if the null is rejected. The result of the test is expressed in terms of the null hypothesis, and this implies that the null hypothesis could be “rejected in favour of the alternative hypothesis” or the conclusion may simply be “do not reject null hypothesis”. This is because a conclusion that the null hypothesis should not be rejected does not imply that the null hypothesis has been validated; rather, the implication is that there is not enough evidence against the null hypothesis in favour of the alternative. However, a rejection of the null hypothesis implicitly suggests that the alternative theory may be true.

The theory of the null hypothesis as it operates in clinical trials poses a number of problems. One such problem is that an acceptance of the alternative hypothesis “only commits us to a difference in observed parameters; it does not prove that the theory or principles that predicted such a difference is true, since it is always possible that the difference could be due to additional factors not recognized by the theory”. This point is significant for indigenous therapies that combine both observable and multiple subjective elements within the healing process. Of course, the latter categories of elements are not recognized by the theory underlining the trial. While the trial itself is constructed on a biomedical paradigm that rejects

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179 V.J. Easton and J.H. McColl, Hypothesis Testing, online: Statistics Glossary <http://www.stats.gla.ac.uk/steps/glossary/hypothesis_testing.html#h0>.
180 Ibid.
181 Ibid.
182 Ibid.
183 Ibid.
184 Ibid.
the validity of phenomena outside the natural ontological realm, many indigenous modalities are “complex and multi-stranded” and may require a diverse range of behavioural changes, such as life style or diet changes,\(^{186}\) which are complementary to the indigenous therapy being administered to the patient. These complementary strategies are not usually considered as part of the desired clinical result in the trial procedure. Thus, the positive impacts of such strategies are not reflected in trial outcomes.

A different problem occurs where the investigator has a strong belief in the alternative hypothesis of the trial. As noted above, the investigator must be unbiased or have genuine interest in obtaining an objective outcome. A strong conviction in the alternative hypothesis renders the null hypothesis the antithesis of what the experimenter actually believes. This implies that the null hypothesis is presented only to allow the given data to contradict it.\(^{187}\) This is usually the case where the investigator or data interpreter has no genuine interest in obtaining a positive result in the trial of an indigenous therapy.\(^{188}\) The poor results of some homeopathy trials may be traced to this problem.\(^{189}\) The rejection of the homeopathic theory of disease by the scientific community, and the consequential absence of legal recognition, may be explored through a closer analysis of the significance of the investigator’s objectivity in the trial process. The ‘Bayesian Theory’, a concept within medical epidemiology, provides the tools for this analysis.

### 3.3.4. The Bayesian Theory and Statutory Regulation

As already highlighted in the discussion of the ‘null hypothesis’, evidence put forward in support of a new theory is not evaluated in a vacuum. Within medical epidemiology and philosophy, evidence is evaluated within a continuum of already existing information.\(^{190}\) The interpretation of new evidence partly depends on the pre-existing information about the intervention.\(^{191}\) This information constitutes old evidence which interacts with the new evidence to produce the clinical result. This phenomenon is denoted as the ‘Bayesian Perspective’. According to this theory, “observers evaluate new evidence in the light of their background

\(^{186}\) Barry, \textit{supra} note 165 at 2651.
\(^{187}\) \textit{Null Hypothesis, supra} note 185.
\(^{188}\) Iyioha, “Law’s Dilemma”, \textit{supra} note 4.
\(^{189}\) See Hrobjartsson and Brorson, \textit{supra} note 150 at 115.
\(^{191}\) Hrobjartsson and Brorson, \textit{supra} note 150 at 113.
knowledge.” 192 In evaluating new medical evidence – for example, evidence establishing the efficacy of a new herbal therapy – there is an estimated probability that a given result will occur, and this is called the “prior probability”. 193 The prior probability is crucial to the interpretation of new evidence. 194 At the other end of the spectrum is the ‘posterior probability’, which is evaluated based on the prior probability as well as the strength of the new evidence.

When there is little belief in the effectiveness of the subject of investigation, the prior probability is said to be low. When the prior probability is low, a significant amount of positive evidence is needed to change the posterior probability. 195 Thus, when the prior probability is based on an implausible mechanism or is believed to be scientifically illogical, the prior probability falls towards zero. Given the interplay of reducible and subjective forms of evidence in many indigenous therapies, the prior probability of indigenous medicine has generally been estimated as very low such that the posterior probability in trials of indigenous interventions hardly changes positively. 196 In Hrobjartsson and Brorson’s view, this makes the RCT a non-neutral “algorithm” for ascertaining the effectiveness of a clinical intervention. 197

Further, it is of importance that in a clinical trial, the objective is to ascertain the existence or lack of therapeutic effect in the intervention; the focus is not on deciphering the underlying mechanism of action of the intervention. 198 Put simply, the hypothesis to be tested is not related to “how” the therapy works, but “whether” it does. In explaining this point, Willis and White have stated that in a Randomized Controlled Trial, it is the outcome of an intervention that is important and not the “underlying paradigm of disease causation or treatment”. 199 Regardless of this position, it is important to note that in the interpretation of evidence in a clinical trial, there is a close relationship between the probability of the underlying mechanism of action and the projected prior probability of the intervention, which is the estimated or expected outcome of the intervention. 200

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192 Ibid.
193 Ibid.
194 Ibid.
195 Ibid.
196 Ibid.
197 Ibid.
198 Ibid.
199 Willis and White, supra note 18 at 55.
200 Hrobjartsson and Brorson, supra note 150 at 114.
This implies that when the postulated mechanism of action for an intervention is implausible or not scientifically interpretable (as in the case of an indigenous therapy that operates on what is significantly an anti-scientific formula), the prior probability of the intervention to have any observable clinical effect falls.\footnote{A.J. Vickers, “Clinical Trials of Homeopathy and Placebo: Analysis of a Scientific Debate” (2000) 6:1 Journal of the American College of Allergy, Asthma & Immunology 49-56; see also Hrobjartsson and Brorson, \textit{ibid}.} When the underlying mechanism is considered seriously defective (for example, where the therapy under trial expressly contravenes conventional scientific theory), the prior probability of the intervention to have “significant” and observable clinical effects falls to zero.\footnote{Hrobjartsson and Brorson, \textit{ibid} at 115.} If the prior probability for the given intervention is zero, as clinical trial investigators presume in the case of homeopathy, a problem occurs: in such a case, the interpretation of evidence breaks down.\footnote{\textit{Ibid}.}

Thus, it is not surprising that homeopathy is not statutorily regulated in many jurisdictions. The homeopathic theory of disease along with its therapeutic regimen has been described as “absurd according to the standard scientific position”\footnote{\textit{Ibid}.}. Accordingly, the trend has been to ascribe a prior probability of zero to its hypothesis. The outcome of this trend is that the clinical trial results of homeopathy are classified as impossible to read.\footnote{\textit{Ibid}.} In contrast, while osteopathy, acupuncture and chiropractic are also founded on theories that are generally incompatible with biomedical philosophy, Western scientists have accepted aspects of their etiologies of disease and theories of treatment as plausible.\footnote{Hrobjartsson and Brorson, \textit{ibid}.} Osteopathy, acupuncture and chiropractic are statutorily recognized in some countries, such as the United Kingdom, Australia, and selected Canadian provinces. The selective acceptance of aspects of the theories underlying these modalities influenced the state’s decision to regulate the therapies.\footnote{\textit{Ibid}.}

A review of the histories of osteopathy, chiropractic, homeopathy and acupuncture from pre-regulation to post-regulation in the United Kingdom further reveals the interdependence

\footnote{Note, however, that there have been positive outcomes in homeopathy trials. In a study on the effect of integrating homeopathic treatment for atopic and allergic diseases in conventional treatment, Moshe Frenkel and Doron Hermoni found that fifty-six percent of patients in the study reduced their use of conventional medication for the treatment of allergic conditions after using homeopathic treatment: Moshe Frenkel and Doron Hermoni, “Effects of Homeopathic Intervention on Medication Consumption in Atopic and Allergic Disorders” (2002) 8 Alternative Therapies 76-79.}

\footnote{See section 3.5, \textit{infra} for a summary discussion of the Australian case where other considerations beyond scientific evidence influenced the decision of the government to regulate traditional Chinese medicine: Willis and White, \textit{supra} note 18.}
between law and science, and more importantly, the compromises these indigenous medical systems have had to make in order to obtain statutory recognition.

I. Osteopathy and Chiropractic

The early history of osteopathy and chiropractic in the UK reveals a process of downsizing from one philosophical level to another through external pressure exerted by the scientific community. As early as the 1920s, medical antagonism against osteopaths intensified because of the philosophical disparities between the healthcare paradigms. When the osteopaths sought state recognition through registration in 1931, the medical profession opposed the move on basis of “the lack of empirical evidence for the existence of osteopathic lesions” and the level of training of the practitioners. In 1935, 800 medical and biomedical scientists signed a statement denouncing the lack of scientific evidence for the theories of osteopathy. This statement was submitted to a Select Committee of the House of Lords. In the statement, the British Medical Association emphasized the incompatibility between osteopathic and “modern medical concepts of the nature of pathogens”. According to Cant and Sharma:

In Britain, the story was to be acceptance with subordination rather than acceptance with amalgamation. After the Second World War, there was a greater tolerance of osteopathy by British doctors, some of whom practiced it themselves… By this time, osteopathy itself had become a more restricted modality with less grandiose claims, increasingly specializing in a limited range of musculo-skeletal problems (though some osteopaths may have privately regretted these limitations)…

Evidently, this restriction on the scope of practice of the osteopaths was a precondition to acceptance within the scientific community. Thus, with the approval of the medical profession, the Osteopaths Act was passed in Parliament in 1993. While the Act provided for state registration, this was achieved at a cost. The osteopathic profession had to abandon its medical claims and accept a new definition as a “generic form of medicine”. Based on this new status as only a branch of the medical profession, osteopathy progressed from being a threat to

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208 Sarah Cant and Ursula Sharma, A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State (London: UCL Press, 1999) at 89 [‘Cant and Sharma’].
209 Ibid.
210 Ibid.
211 Ibid.
212 Ibid. Emphasis added.
213 Ibid
becoming a system of healthcare that was ancillary to medical care in the area of musculo-skeletal problems.\textsuperscript{214}

The UK Chiropractors Act of 1994 is similar to the Osteopaths Act in many ways. Both Acts have analogous details and were modelled after the Medical Act of 1983. The Chiropractors Act originated after a working party was set up to determine the feasibility of statutory recognition of chiropractic.\textsuperscript{215} A significant reason for the promulgation of the Act was the positive result of a Medical Research Council investigation via randomized control trial into the use of chiropractic care for the treatment of lower back pain. The trial weighed the results of chiropractic against conventional treatment.\textsuperscript{216}

It is noteworthy that the histories of the regulation of osteopathy and chiropractic in the UK lend some credence to Toke Barford’s concept of fragility discussed above. As statutorily regulated therapies, osteopathy and chiropractic are at the non-fragile end of Barford’s hypothetical spectrum. However, prior to obtaining statutory regulation, the therapies were at the fragile end of the continuum. In order to make them fit within a statutory framework that is largely dependent on the narrow definition of scientific evidence, the “non-medical” elements that placed the therapies at the fragile end of the continuum have been eliminated from their therapeutic theories.

While statutory regulation, which has the backing of the criminal law,\textsuperscript{217} will ensure standardization and quality control, policymakers still need to decide on how to regulate therapies that do not conform to conventional notions of what constitutes scientific knowledge. If the current regulatory trend which operates on a ‘science as law’ philosophy were to continue, many indigenous interventions that cannot or will not make the required theoretical compromises to become quantitative models of medical care will find it impossible to obtain legal status.

\textsuperscript{214} Ibid.
\textsuperscript{215} Stone and Matthews, supra note 1 at 153; see also Iyioha, “Law’s Dilemma”, supra note 4.
\textsuperscript{216} Ibid.
\textsuperscript{217} Stone and Matthews, ibid at 157.
II. Homeopathy and Acupuncture

The medical profession challenged the homeopathic theory in the second half of the 19th century.\textsuperscript{218} The dominant critiques were directed at favourable statistics that promoted the interests of the homeopathic profession.\textsuperscript{219} The medical professionals argued that the homeopathic theory of disease treatment was illogical in comparison to medical philosophy. In the 1950s, the ensuing antagonism led to attempts to have homeopathic practitioners charged in law courts for the death of patients under their care.\textsuperscript{220} Interestingly, the rise in the attack on the homeopathic theory resulted in a dramatic change in the practice of homeopathy. Homeopathic practitioners began to adopt more allopathic techniques, a process Nicholls aptly captures as the “bastardisation of homeopathy”.\textsuperscript{221} Cant and Sharma describe this development:

Homeopathy as practiced by the doctors trained in the Faculty of Homeopathy in London became a tolerated if insignificant and marginalized group within the broader medical profession, and when the National Health Service was established in 1948, homeopathy was grudgingly accorded a foothold within it.\textsuperscript{222}

This metamorphosis in homeopathic practice with the consequential goodwill it attracted from the medical profession led medically trained homeopaths to assert their right to an exclusive practice against non-medically trained homeopaths who emerged in Britain in the 1970s.\textsuperscript{223} It is significant to emphasize that the foci of attacks in this new campaign were the esoteric underpinnings and other non-medical philosophies of homeopathic theory. Again, the basis of the confrontation was “discreditation”:\textsuperscript{224}

\textldots\ [T]he non-medically qualified homeopaths were berated for their dangerous lack of medical training and their emphasis on the metaphysical. Medical homeopaths took a renewed interest in the vindication of their therapeutics – not so much through proof of the basic theory of homeopathy as through clinical trials of particular remedies.\textsuperscript{225}

\footnotesize{\textsuperscript{218} Cant and Sharma, \textit{supra} note 208 at 87.  
\textsuperscript{219} \textit{Ibid.}  
\textsuperscript{220} P. Nicholls, \textit{Homeopathy and the medical Profession} (London: Croom Helm, 1988) at 165ff.  
\textsuperscript{221} \textit{Ibid.}  
\textsuperscript{222} Cant and Sharma, \textit{supra} note 208 at 87.  
\textsuperscript{223} \textit{Ibid.}  
\textsuperscript{224} \textit{Ibid.}  
\textsuperscript{225} \textit{Ibid.} Emphasis added.}
Through these attacks, the medically trained homeopaths sought to distinguish themselves from the “‘non-scientific’ homeopaths”.\textsuperscript{226}

Acupuncture shares a similar history with homeopathy in the UK. As a generic therapy which originated in China, this therapy has also faced its own set of philosophical challenges regarding whether or not to metamorphose into a branch of medicine in order to be statutorily recognized. Acupuncture was practiced in the early 19\textsuperscript{th} century by both medically and non-medically qualified practitioners in Britain.\textsuperscript{227} While it was practiced in its traditional form in China, the practice of acupuncture to be accepted in Britain had to distance itself from some of its foundational theories.\textsuperscript{228} According to Cant and Sharma:

> On the whole, acupuncture as “naturalized” in Britain was divested of its classical theoretical underpinnings in Chinese diagnostics and understandings of the human person. From the mid-nineteenth to mid-twentieth century there was what Saks calls a “climate of rejection,” medical journals showing little interest in the therapy and denouncing non-medically qualified acupuncturists.\textsuperscript{229}

Acupuncture continues to grapple with this history today, especially as more medically trained professionals begin to practice in this area. The acceptance of acupuncture was based on its practice as a limited profession within the boundaries of biomedicine.\textsuperscript{230} Fulder identifies the attempt by medical acupuncturists to interpret acupuncture’s effect on pain in biomedical terms and theories of the nervous system.\textsuperscript{231}

Of importance is the fact that in the struggle to satisfy the requirements of the scientific validation process, the theories of acupuncture underwent a transmutation. The practice and range of conditions to which it could be applied were limited by this transformation. Hence, “medical acupuncture has been compartmentalized to the extent that it is used for a restricted range of conditions”.\textsuperscript{232} Unfortunately, this “compartmentalization” has created a distance between doctor acupuncturists and “the growing body of non-medically qualified

\begin{itemize}
\item \textsuperscript{226} \textit{Ibid.}
\item \textsuperscript{227} \textit{Ibid.}
\item \textsuperscript{228} \textit{Ibid}; Iyioha, “Law’s Dilemma”, \textit{supra} note 4; Iyioha, \textit{Deregulation, supra} note 4.
\item \textsuperscript{229} Cant and Sharma, \textit{supra} note 208 at 87.
\item \textsuperscript{230} \textit{Ibid.}
\item \textsuperscript{231} S. Fulder, \textit{The Handbook of Alternative and Complementary Medicine} (Oxford: Oxford University Press, 1996) at 133.
\item \textsuperscript{232} Cant and Sharma, \textit{supra} note 208 at 89.
\end{itemize}
acupuncturists who practice acupuncture as a more generic therapy and who regard themselves as more faithful to the original Chinese therapeutic tradition”.

While this history identifies the scientific hurdles that IMPs have to face before achieving legal status, it also highlights an important problem which the pro-science scholarship does not often emphasize. The trend towards the medicalization of non-biomedical therapies poses a problem for patient safety. Non-medical practitioners continue to practice acupuncture employing methods that are based on the Chinese therapeutic tradition, which in many cases constitutes the primary attraction for patients who patronize acupuncturists. Of course, it is now common knowledge that the majority of health consumers who use indigenous medicine are drawn to it by its holistic and consumer-centred approach to healing. It is expected that consumer patronage will continue regardless of the legal status of indigenous medicine; at present, US citizens are spending over $34 billion out-of-pocket annually on IMS in spite of the paucity of evidence of safety and efficacy of many of the services and products. The proliferation of unlicensed practitioners is hardly in the best interest of consumers. Hence, policymakers need to consider a range of methods to regulate interventions that are not scientifically interpretable.

As noted at the beginning of this section, the RCT research methodology has an affinity with the biomedical philosophy. Although indigenous medical theory shares an affiliation with the biomedical theory, its etiology transcends the biomedical philosophy of disease. The disparity between both healthcare domains accounts for the difficulties encountered in the attempt to measure the effectiveness of indigenous medicine through the RCT. In view of the difficulties and of the controversy regarding whether or not IMS can be scientifically interpreted, some medical anthropologists have suggested a different kind of approach to investigating and validating indigenous medicine. The anthropological model of research recognizes the inherent complexities of validating the non-biological etiologies of indigenous medicine through the RCT. Therefore, it approaches research into IMS through a methodology that is in many respects more akin to the holistic character of indigenous medicine.

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233 Ibid.
3.4. Anthropological Evidence

3.4.1. Anthropological Medical Research

Biomedical research is concerned with investigating “clinical outcomes”.\(^{235}\) To an extent, it is also implicitly concerned with the mechanisms of actions underlying a given therapy. In the investigation of IMS, biomedical analysis focuses on these same indices to the exclusion of non-measurable data. As Marc Micozzi has noted, “observations that are real in the clinical setting (at the level of the human experience and observation) and that cannot be understood or explained in a materialist, reductionist biomedical paradigm are revealing that paradigm to be incomplete”.\(^{236}\) Anthropological and social science research provide a different method for understanding the “limitations” in the biomedical model and for constructing a different model, which incorporates “observations from cross-cultural medical perspectives”.\(^{237}\)

Anthropological research is neither predetermined nor tightly structured.\(^{238}\) The methodology is structured around an observer situated in the context of the phenomenon under observation.\(^{239}\) This method of research is primarily ethnographic. It allows discovery of important elements that affect the results of a research which are not measurable through conventional research methods. Ethnographic research primarily examines the interaction between a patient and their specific healthcare provider.\(^{240}\) It utilizes embodied and inter-subjective data.\(^{241}\) The phenomena under investigation are analyzed over long periods and fieldwork extends over long timescales.\(^{242}\) The collection, evaluation and interpretation of evidence are not through randomization, standardization, or blinding techniques as in the case of biomedical research, but through personal, intuitive patterns of knowledge.

The scholarship on IMS suggests that standardization and blinding techniques employed in biomedical research produce inaccurate outcomes when applied to indigenous medicine. For example, Weatherly Jones reports that in an RCT conducted on homeopathy, trial investigators

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\(^{236}\) Ibid.


\(^{238}\) Barry, supra note 165 at 2646-57.

\(^{239}\) Ibid.

\(^{240}\) Ibid.

\(^{241}\) Ibid.

\(^{242}\) Ibid.
were of the view that the blinding “interfered with their normal practice routines, to produce a radically different version of their normal therapeutic practice”. In homeopathic practice, a remedy to be active has to match the total symptom picture to that of the patient; thus, while both biomedicine and alternative medicine may have a similar diagnosis for the same symptoms, many biomedical prescriptions for the same ailment will be “useless” and “inert” for the patient in homeopathic theory.

One way of explaining this outcome is that indigenous medicine is primarily concerned with outcomes rather than with the mechanisms of operation of given therapies. As Barry has noted, in the view of non-biomedically trained complementary and alternative medical practitioners, the evidence required to validate complementary and alternative medicine is “that which investigates not whether a therapy is effective according to biomedical or scientific criteria, but whether it is making a difference to the bodies, beliefs, social and cultural experiences” of the patients, and whether these “patients keep coming back”.

In focusing on the subjective aspects of the therapeutic regimen, the anthropological research method can be said to be better suited to validating IMS. Indeed, this method of research draws attention to the multiple ways of testing the efficacy of a given intervention. It also highlights the need for policymakers to consider a variety of evidential paradigms in the regulation of IMS. Nevertheless, this method of research has its limitations. Anthropological forms of evidence de-emphasize the relevance of the RCT in validating “non-fragile” IMS modalities, such as herbal medicines, which share a closer identity with biomedicine. These classes of therapy are either ingestible or invasive, and therefore require a research paradigm structured along the biomedical model. Evidently, ethnographic research is not relevant for all IMS interventions. Therefore, the assumption that this research paradigm is a better research

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244 Ibid.

245 Barry, supra note 165 at 2655. Note that Barry’s observation here is relevant to jurisdictions where there is at least an adequate supply of biomedical and alternative practitioners as well as those, such as countries in the South, where there is shortage of healthcare workers. In the latter jurisdictions where patients continue to patronize IMPs whether or not biomedical healthcare centres are accessible, the non-biomedically trained IMP remains concerned about the effect of a therapy on patients because of the competitive relationship that exists between IMPs. The high level of competition that exists between practitioners renders mandatory the satisfactory delivery of medical services to patients.

246 See Barry, supra note 165.
methodology to be employed exclusively for validating indigenous medicine falls to the same fallacy that the RCT is the best method for validating medical interventions.

3.4.2. Population-Based Healthcare: The Whole Systems Approach

Medical interventions that affect the health of populations are generally complex and often “context-dependent”. These interventions could require changes to health policies as well as to conventional approaches to healthcare delivery. The evidence required to establish the effectiveness of these interventions must be “sufficiently comprehensive” to address the complexity of the interventions under study. Indigenous and alternative therapies are such complex and “context-dependent” public health or population-based interventions that require a comprehensive research methodology for evaluating their contributions to healthcare delivery. In response to the limitations of RCTs in evaluating population-based health strategies, emerging schools of thought emphasize the need for a different approach to evaluating medical interventions, especially when those interventions are designed to address population needs. In fact, some medical scholars adopt an oppositional stance to the idea that medicine is a science. Describing the supposition that medicine is pure science as “a fundamental misdescription”, Miles and Loughlin assert that:

Since such misdescription continues to be perpetuated by the EBM camp as part of their ideology, it is worth reiterating that fundamental truth … that few questions in clinical medicine are ‘scientific’ in the sense intended by EBM enthusiasts and therefore cannot be answered by science as they understand it.

Population-health scholars have rightly observed that the application of the RCT to population health is “likely to encounter methodologic, pragmatic, and theoretical limitations”, while limiting the “knowledge base needed to make sound decisions about

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249 Ibid.
public health priorities and policies". This is because population-based interventions – beyond involving multiple approaches – often operate through complex mechanisms or pathways such that what works in a given context may be ineffective in another, and this presents significant challenges to international health policies or recommendations.

An approach that has emerged in response to the limitations of the RCT research model in the context of populated-based interventions is the whole systems research. The whole systems research involves a combination of approaches that focus on holistic outcome measures rather than on only the “active ingredients of a system” while emphasizing the equal importance of quantitative and qualitative research methods. Given the complexity of whole systems, this approach emphasizes the validity of diverse methods because no single method can effectively provide answers relevant for policy decisions. The whole systems research emphasizes the relevance of a range of factors that can influence health research outcomes, including social and psychological factors as well as the utility and values placed on specific interventions. Thus, this emerging approach may be better suited to the task of evaluating complex healthcare interventions such as indigenous/alternative and complementary medicines.

Emerging public health scholarship advances a similar approach to evaluating population-based interventions. The scholarship emphasizes the difference between the assessment of evidence and the making of policies or “operational decisions on the implementation of interventions”.

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253 Ibid.
255 Ibid.
257 Rychetnik et al’, supra note 247 at 119.
factors” to be considered in such decisions.\textsuperscript{258} Thus, while asserting that “study design alone cannot suffice as the main criteria for the credibility of evidence about public health interventions”, the authors propose an “expansion” of the criteria presently employed in clinical medicine for evaluating medical interventions.\textsuperscript{259} According to the authors:

The social, organisational and political setting (or context) in which a public health intervention is implemented usually influences the intervention’s effectiveness.\textsuperscript{260} It is important to distinguish between components of interventions that are highly context dependent (for example, a public education campaign to enhance immunisation uptake) and those that may be less so (for example, the efficacy of the vaccine itself among healthy infants). Contextual factors that influence the generalisability of evidence about interventions include literacy, income, cultural values and access to media and services.\textsuperscript{261}

The authors’ view above clearly captures the arguments outlined here in support of an expanded approach to the evaluation of healthcare interventions. The next section summarizes the foregoing discussion and relates it to the ongoing trend in judicial decision-making in which judgments are often based on the judges’ perceptions of what constitutes relevant medical evidence for the statutory recognition of a medical intervention.

\textbf{3.5. The Need for a Composite Research Paradigm}

The foregoing discussion has addressed the limitations and strengths of two different research methods for testing indigenous medical interventions. It has been noted that systematic reviews of the RCT are positioned at the highest level of the hierarchy of scientific evidence for testing healthcare interventions. Based on the rise and persistence of the evidence-based medicine (EBM) paradigm, it is argued that governments and policymakers may be less interested in

\textsuperscript{258} Ibid.
\textsuperscript{259} Ibid at 121 and 119.
regulating, supporting, or funding new interventions without evidence that the interventions are effective and safe.

Interestingly, not all scholars agree that the EBM paradigm has such unequivocal effect on the regulation of new medical interventions. For example, Willis and White’s sociological analysis of the implications of the EBM theory for the future development of CAM suggests that EBM will not play a decisive role in CAM regulation because the history of health services reveals that “as a basis for politico-legal legitimacy” clinical legitimacy (that is, the continuous patronage of a therapy by consumers willing to pay for it) is more significant than scientific legitimacy. Citing chiropractic as an example, Willis and White assert that the reason for the survival of the modality has little to do with scientifically acceptable evidence; rather, the primary influence was clinical legitimacy – the belief of patients who experienced relief from it.

The early controversies surrounding the clinical efficacy of psychoanalysis provide some insights into the authors’ argument. The acceptance of psychoanalysis has been due largely to its clinical efficacy; the controversies regarding the authenticity of its theories did not affect the grant of legal recognition to the profession. Willis and White suggest that “social processes external to the health system” constitute the major factors that would influence the state to regulate a given therapy. Two examples highlighted by the authors include the registration of Traditional Chinese Medicine (‘TCM’) and regulation of natural therapies in Australia, both of which were achieved without positive scientific evidence. As noted by the authors, there was clearly a lack of connection between the patchy results of RCTs conducted on TCM and the passing of an Act to regulate TCM.

Nonetheless, it is noteworthy that the authors concede that the EBM paradigm remains a potent mechanism for validating or discrediting IMS. Accordingly, therapies found to be effective through the RCT, which are incorporated into biomedical practice, may lose their uniqueness to biomedicine. The authors cite acupuncture and chiropractic in the Australian context as examples, noting that there was serious attempt to restrict the practice of these therapies found to be effective through RCTs conducted on TCM.

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262 See generally Greschner, supra note 6.
263 Willis and White, supra note 18 at 58.
265 Willis and White, supra note 18 at 58.
therapies to orthodox practitioners.\(^\text{267}\) It is noteworthy that the authors’ argument tallies with the conclusions reached in section 3.2.4 above regarding the early history of the regulation of osteopathy, chiropractic, homeopathy and acupuncture in the UK. Simply, for many therapies, regulation based on positive RCT evidence can result in IMS becoming only a substrate of biomedicine.

While some commentators may argue that this outcome is best for patient safety, it will be an adverse outcome for consumers whose primary interest in IMS lies in its unique philosophy of health. Willis and White’s discussion of the regulation of acupuncture and chiropractic in Australia as being based on clinical rather than scientific legitimacy reveals that many patients remain ardent patrons of indigenous healthcare regardless of the paucity of scientific evidence on the modality. For these patients, what matters – to employ Christine Barry’s argument – is whether the therapy is making a difference to their “bodies, beliefs, and social and cultural experiences”.\(^\text{268}\) The influence over state regulation tacitly exerted by consumers is reinforced by the fact that IMS is a manifestation of changes in medicine’s institutional authority initiated by a consumer-driven healthcare environment,\(^\text{269}\) and by the (re)new(ed) patient interest in having their values incorporated into healthcare delivery. Since consumer protection, as observed at the outset, is imperative in an imperfect healthcare market, then states must devise a more inclusive validation method for IMS that transcends the limits of specific research methodologies.\(^\text{270}\)

The first step towards the search for a new methodology is to acknowledge that the RCT, while beneficial in its approach to medical research, is not designed to provide optimal outcomes in studies that combine subjective feelings and experiences with the pure therapeutic effect of a medical intervention. Guido Giarelli affirms that research methodologies “are not considered to be independent from their paradigm of reference”; therefore, “the methods used…for conventional medical research reflect the paradigm on which they were founded”.\(^\text{271}\) The scientific paradigm on which the RCT is founded is “structured to remove any human

\(^{267}\) Willis and White, \textit{supra} note 18.
\(^{268}\) Barry, \textit{supra} note 165 at 2655.
\(^{269}\) Kaptchuk and Eisenberg, \textit{supra} note 142.
\(^{270}\) Iyioha, “Law’s Dilemma”, \textit{supra} note 4; Iyioha, \textit{Deregulation, supra} note 4.
\(^{271}\) Giarelli, \textit{supra} note 24 at 55.
factors from the context of the study, setting up a model that is detached from feelings, meaning and subjective experiences”.  

These limitations underscore the concern that the adoption of a single evidential paradigm for testing IMS will be suboptimal. As Walach et al. have observed, “no single research methodology in itself yields all the knowledge necessary with respect to effectiveness, efficacy, safety and patient/doctor treatment preferences”. On a similar note, Vickers affirms that the RCT “does not aim to” provide the answer to “all questions of interest in health care”. These views reinforce the call for multiple research methodologies in the area of indigenous medicine. The question that needs to be asked is whether it is possible to “develop a pluralistic approach to research methods that retains the value of Western science for medicine and yet respects the diversity of radically different concepts about life, health and service”.  

This study contends that such an approach is possible and should be actively pursued. The arguments and evidence presented in the foregoing discussion advances an approach that recognizes the conceptual limits of the RCT in the context of evaluating indigenous therapeutic systems. This approach takes the very limitations of the RCT as a starting point for the investigation of indigenous medicine. A new model of research should integrate the philosophies of indigenous therapies as a component of the therapeutic process itself. Historically, these philosophies have been denigrated as ‘placebo’, and this term implicitly reaffirms popular biomedical views about IMS. As I have argued elsewhere, “a randomized clinical process that is (re)designed to integrate the indigenous medical paradigm, a paradigm that seeks its therapeutic strengths from within and without the pharmacologic effects of the

278 Ibid.
279 Ibid.
therapy itself, ensures the transfer of knowledge between medical systems”. It also constitutes an important platform for ensuring patient safety.

As acknowledged at the beginning of this chapter, science and the EBM paradigm are the primary policy arguments employed to discredit indigenous medicine. There has been a long history of affinity between state law and science. The EBM paradigm, bolstered by the force of law, can be easily deployed to exclude holistic indigenous therapies from the ambit of regulation. Knowledge of the increasing use of IMS by patients with serious medical conditions, in situations where biomedicine is ineffective, and in circumstances where there is little or no access to biomedical care constitute valid grounds for the state to embrace research paradigms beyond the reductionistic framework of the RCT in the making of policies. In the interest of millions of patients worldwide who depend on IMS for their healthcare needs, the evidence-based paradigm can be “reconceptualized to accept not only the evidence from systematic reviews of RCTs, but also that from studies which incorporate non-reducible socio-cultural belief patterns, which themselves are crucial to the therapeutic process”. An acceptance of pluralism in the choice of evidence for validating IMS may prove to be a political tool for facilitating the much-needed reform in research paradigms.

However, beyond simply making a proposal for a new research framework for trial investigators, protecting consumer interests and ensuring patient safety require us to address the challenges posed by the court’s judgment in cases involving physicians’ practice of alternative or integrated medicine. It also requires an examination of the trend of judicial opinion in cases involving constitutional challenges against the non-inclusion of certain interventions on the Medicare list or against the exclusionary provisions regarding the availability of the medical expense tax relief. These categories of cases have been chosen for illustrative purposes because they show how judicial opinions on the issue of scientific evidence of safety and efficacy of alternative medicine often reinforce the laws and policies that limit patients’ access to alternative medicines. Most judicial pronouncements in these cases adopt what is fundamentally a pro-science approach that reiterates the lack of scientific evidence of safety and efficacy for the therapies utilized by patients. By incorporating the EBM argument into judicial analysis of

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280 Ibid.
281 Ibid.
282 Barry, supra note 165 at 2656.
impugned laws such as the *Canadian Income Tax Act*, the court is supposedly able to provide a less controversial basis for rejecting the constitutional claims brought by consumers.\(^{283}\)

While critiquing the courts’ neutral though empathetic attitude regarding the impugned legislation in this area, the discussion casts, and specifically concentrates on, the court as an agent for reform. This is because policy and legislative reform have been slow in coming. As stated in chapter one, although the major route to integrated healthcare is through legislative and institutional reform, consumers are making appeals to the courts to lend their support to speeding up the reform process. The discussions in the final sections of this chapter foreground the analysis of legislative reform and inventive judicial interpretation in chapter six. The discussion here acknowledges that it is not the responsibility of the courts to make policies or devise systems of regulation. Therefore, the argument that the courts should play a greater role in engendering policy reform on this subject is founded on the administrative weaknesses of the decision-making process itself as well as on the significant gaps in the limited scientific data that supposedly supports the legislation.

These final sections focus on how the court can deploy its interpretive role towards ensuring that policy is brought to the service of health consumers. The argument is that the court’s interpretation of extant policies can be influential in generating the much-needed evidence for regulating IMS. The necessary evidence, as is argued below, should encompass both a pluralistic vision of trial methods as well as a pragmatic acceptance that the evidence required for the regulation of IMS transcends that of safety and efficacy of the therapy itself. This argument does not propose that the court should become involved with policy reform. Rather, it urges the courts to make pronouncements on the substantial gaps in the standards upon which the impugned legislative provisions are formulated as well as on the shortcomings of the process that produced the relevant provisions.


#### 3.6.1. *The Issues*

In Canada and the United States, the courts are increasingly called upon to review medical disciplinary committee decisions in which physicians who practice alternative or integrated

\(^{283}\) See generally Greschner, *supra* note 6.
medicine are charged with professional misconduct. The courts have also had to address the rising number of legal matters involving patients’ right to access and be reimbursed for indigenous and alternative medicines. There appears to be more cases involving disciplinary action against physicians than there are against persons practicing medicine without a license. In the former case, the medical disciplinary committee charges a physician with medical malpractice for employing a method that is not ‘traditional’ to biomedical practice. The courts’ reviews of these cases have often recapitulated the scientific/unscientific debate about alternative medicines. The more liberal cases in which the court’s opinion supports an expanded view of medicine and scientific accuracy have come up in the United States. Canadian jurisprudence on this issue continues to evince a conservative judicial approach to what constitutes medicine. In the Canadian case of Ravikovich v. College of Physicians and Surgeons of Ontario, the Disciplinary Committee of the College of Physicians and Surgeons of Ontario found the physician guilty of professional misconduct for employing diagnostic and therapeutic methods of treatment (including homeopathic medicine) that allegedly had no scientific validity. The Disciplinary Committee of the College alleged that the efficacy of the treatments employed by the physician was unproven.

In the U.S. case of Re Guess, Dr. Guess practiced homeopathic medicine in circumstances where all other treatment methods were unsuccessful for treating his patient’s conditions. The North Carolina Board of Medical Examiners indicted him for professional misconduct, alleging that the physician deviated from “standards of acceptable and prevailing medical practice in North Carolina”. Guess supplied evidence confirming that homeopathy is a recognized profession in three US states and several foreign countries. He also had positive testimonies from his patients who gave evidence that they had benefited from the physician’s treatment. Nonetheless, the board found him guilty of professional misconduct and revoked his license. On appeal, the court observed that the board “neither charged nor found that Dr. Guess’s departure from approved and prevailing medical practice either endangered or harmed his patients or the public”. The court reversed the board’s decision, and noted in its judgment that “conduct that is merely different from that of other practitioners” did not suffice as a basis.

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285 Re Guess 393 S.E.2d at 833 [‘Re Guess’].
287 Re Guess, ibid.
for revoking a physician’s license. The broader decision of the court suggests that the proper basis for revoking the physician’s license would be if the physician’s conduct falls below the expected standard of safety and causes harm to the public. However, the North Carolina Supreme Court reversed this decision on the ground that the relevant legislation did not require the establishment of harm in order to find a physician liable for misconduct in the circumstances stipulated by the legislation.\textsuperscript{288}

In \textit{Rogers v. State Board of Medical Examiners},\textsuperscript{289} a physician who practiced chelation therapy was placed on a one-year probation by the Florida state medical board. In his application for judicial review, the court found that the therapy administered by the physician had not harmed the patients, and that the physician had provided his patients full information about the medical community’s negative opinions about the treatment. In its judgment, the court opined that:

\begin{quote}
We can only wonder what would have been the condition of the world today and the field of medicine in particular had those in the midstream of their profession been permitted to prohibit continued treatment and thereby impede progress in those and other fields of science and the healing arts…..\textsuperscript{290}
\end{quote}

The decision in \textit{Rogers} is one of a number of liberal judgments on the practice and use of alternative medicines by physicians and patients respectively in the United States. A number of other U.S. decisions are akin to the Canadian approach to the issue, finding practitioners guilty of utilizing ‘unsafe’, ‘untested’ or ‘unproven’ therapies in the treatment of their patients.\textsuperscript{291}

In the area of financing for alternative medicines, a growing number of patients in Canada and the United States are instituting legal challenges against specific laws that deny access to or fail to cover alternative medicines. In Canada, the most commonly contested provision is section 118.2 of the Canadian \textit{Income Tax Act},\textsuperscript{292} which provides tax relief to tax payers who

\textsuperscript{288} Note that the North Carolina statute has been reformed. The new medical disciplinary legislation (N.C. Gen. Stat. S. 90-14(a)(6)), which has relaxed the rules under which Dr. Guess was found guilty, was introduced as a response to \textit{Re Guess}. See chapter 6, \textit{infra}, for a further discussion of this new legislation.

\textsuperscript{289} \textit{Rogers v. State Board of Medical Examiners}, 371So. 2d at 1037.

\textsuperscript{290} \textit{Ibid} at 1041-1042.

\textsuperscript{291} See chapter 6, \textit{infra}, for further discussion of some of these cases.

\textsuperscript{292} \textit{Income Tax Act, supra} note 3.
have spent a significant part of their income on out-of-pocket medical expenses.\textsuperscript{293} The Act allows patients to claim the medical expense tax credit (METC) for only those expenses paid for services provided by practitioners who are legally authorized to practice in the provinces where the service was provided.\textsuperscript{294} Thus, the availability of the METC depends on whether the particular alternative healthcare system utilized by the claimant is regulated in the province in which it was used. According to section 118.2 of the Act, a medical expense is “an amount paid to a medical practitioner, dentist or nurse or a public or licensed private hospital in respect of medical or dental services provided to a person”.\textsuperscript{295} Section 118.4 defines a medical practitioner for the purposes of the Act as follows:

(2) For the purposes of sections 63, 118.2, 118.3 and 118.6, a reference to an audiologist, dentist, medical doctor, medical practitioner, nurse, occupational therapist, optometrist, pharmacist, psychologist or speech-language pathologist is a reference to a person authorized to practise as such,

(a) where the reference is used in respect of a service rendered to a taxpayer, pursuant to the laws of the jurisdiction in which the service is rendered.

In the case of drugs and medicaments, section 118.2(2)(n), which has attracted the highest number of legal challenges, disallows tax relief for expenses on medical products that are not prescribed by a medical practitioner or dentist and recorded by a pharmacist. According to section 118.2(2)(n), a medical expense is:

[an amount paid] for drugs, medicaments or other preparations or substances ... manufactured, sold or represented for use in the diagnosis, treatment or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof or in restoring, correcting or modifying an organic function, purchased for use by the patient as prescribed by a medical practitioner or dentist and as recorded by a pharmacist.\textsuperscript{296}

Thus, expenses on drugs and medicaments may be denied regardless of the province in which they were bought so long as the stipulated requirements are not met.\textsuperscript{297} Note, however, that expenses on cosmetic and elective surgery (including “hair transplants, botox injections,
liposuction, and breast augmentation surgery”) are eligible for the METC. According to the Canada Revenue Agency (CRA), “when an amount is paid to a medical doctor in respect of surgery of any kind, whether cosmetic or elective, there is a presumption that the surgery is beneficial to the patient’s health”.299

Patrons of alternative medicines have often claimed that the Income Tax Act contravenes section 15, the equality provision of the Canadian Charter of Rights and Freedom.300 For example, in Noddin v. The Queen,301 the appellant challenged the provisions of s.118.2 of the Canadian Income Tax Act as a violation of her section 15 rights. The appellant who suffered from severe chronic pain challenged the denial of her claim under paragraph 118.2(2)(a) for massage therapy expenses. The therapy was administered in New Brunswick where massage therapists are unregulated. The court took the view that the impugned law made no distinction with respect to the personal characteristics of the taxpayer to warrant a finding of discrimination under section 15 of the Charter. The court found that the distinction made by law was whether there was “some legislated assurance of competence of the person administering the service”.302

As would be seen in other Canadian cases on this point discussed below, the court expressly construed the disputed provisions as based on policy concerns about clinical safety. Other legal and constitutional principles that consumers have invoked include the principles of autonomy, multiculturalism, freedom of conscience, and fundamental justice.303 Even in the context of these claims, the courts have often invoked what it believes to be policy concerns about the safety, efficacy and cost-effectiveness of the products or services utilized by the patient; and based on this balancing act, Canadian courts have often upheld the validity of section 118.2 of the Income Tax Act.

However, there are a few cases where the courts have creatively interpreted section 118.2 to allow litigants claim expenses on natural health products. In the specific cases, the products

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299 C.R.A. Document no. 9907115 (April 26, 1999). See Shaw, supra note 293 at 48, ibid, where the author summarily outlines the controversial nature of the presumption regarding health benefits from cosmetic surgery.
300 See for example, Franklin D. Tall v. The Queen, 2009 DTC 1036; 2008 TCC 677; Noddin v. The Queen, 2004 D.T.C. 3577; 2004 TCC 687 [‘Noddin’].
301 Noddin, ibid.
303 See chapter six, infra, for an analysis of the fundamental justice clause and its possible application to the issues discussed here. Canadian Charter of Rights and Freedom, section 27 (multiculturalism), section 2 (freedom of conscience), section 7 (fundamental justice) and section 15 (equality).
were prescribed by a physician and purchased off the shelf in a pharmacy, that is without a pharmacist’s signature.\textsuperscript{304} In these cases, the courts reasoned that a sales slip or invoice was sufficient to meet the statutory requirements of section 118.2(2)(n). However, the Federal Court of Appeal rejected this reasoning in \textit{Ray v. R.}\textsuperscript{305} holding that:

\begin{quote}
A record in that form cannot meet the apparent function of the recording requirement. There must be a record kept by the pharmacist in his or her capacity as pharmacist. That necessarily excludes substances, however useful or beneficial, that are purchased off the shelf.\textsuperscript{306}
\end{quote}

The Federal Court held that it was not open to the court “to disregard statutory requirements imposed by Parliament, even if they are difficult to rationalize on policy grounds”.\textsuperscript{307}

In the United States, there have been a number of similar constitutional challenges in which consumers have claimed a right to new and experimental treatments that are yet to receive FDA approval or that have not been accepted by the biomedical profession. In these cases, consumers have invoked the constitutional right to privacy on the contention that they have a protected right to access the therapy of their choice. However, while the courts have held that the US constitution protects more specific medical matters like “contraception, abortion and the right to be disconnected from artificial life support”,\textsuperscript{308} the courts have often declined to find that there exists a right to select the treatment of choice based on the constitutional right to privacy.\textsuperscript{309}

Before the recent rise in legal challenges against the absence of insurance coverage for indigenous healthcare, constitutional challenges to health policies had already been on the rise in Canada. For example, there have been numerous challenges to the government’s healthcare funding decisions and policies related to the payment structure and delivery of care.\textsuperscript{310} Most challenges have been founded on the ‘equality’ and ‘liberty and security of the person’

\begin{footnotes}
\textsuperscript{305} \textit{Ray v. R.}, 2004 D.T.C. 6028, 2004 FCA 1 [‘Ray’].
\textsuperscript{306} \textit{Ibid} at para. 13.
\textsuperscript{307} \textit{Ibid} at para. 11.
\textsuperscript{310} Greschner, \textit{supra} note 6 at 43.
\end{footnotes}
provisions of the Canadian *Charter of Rights and Freedom*.\(^{311}\) Cases related to the government’s funding decisions or listing of medical services often request an expansion of insured services to cover medical services that the litigant health consumer finds beneficial.\(^{312}\) However, these challenges generally have met with little success.\(^{313}\) The courts have more often deferred to government’s policies on funding decisions.\(^{314}\) The decisions are usually based on the supposed pragmatism and rigour involved in governmental decision-making. Essentially, the process is assumed to be evidence-based which, by implication, leaves no room for judicial activism. However, some scholars have questioned the appropriateness of such judicial attitude, especially given the shortcomings in the decision-making process.\(^{315}\)

### 3.6.2. The Decision-making Process

Perhaps, the most significant weakness in the system in the Ontarian Province of Canada as identified by Flood *et al.* is the absence of openness and public participation in the decision-making process. This process, which is governed by physicians and biomedical actors, provides no opportunity for public participation.\(^{316}\) The decision-making process comprises at least four bodies, which include the Physician Services Committee, Medical Directors, the Health Services Appeal and Review Board, and the Courts.\(^{317}\) The decisions on what healthcare services to fund or enlist in the health insurance package are made by the first three bodies. As has been noted, these bodies are managed by physicians who have had a long relationship with the state. The courts, as the case law and scholarship reveal, are often reluctant to disrupt this relationship. Decisions on the enlisting or delisting of medical services are often based on the availability of scientific evidence as conventionally defined or on comparisons between

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\(^{312}\) Greschner, *ibid*.


\(^{314}\) Flood *et al.*, *ibid* at 4.

\(^{315}\) *Ibid*.

\(^{316}\) For a full discussion of this process, see Flood *et al.*, *ibid* at 15-41.

\(^{317}\) *Ibid* at 18.
provincial plans. The decision-makers are less concerned about economic evidence, such as the cost-utility of medical services.

The healthcare decision-making process in Nigeria is comprised of a similar bureaucratic system manned by physicians and other members of the biomedical profession. The National Council on Health (NCH) is the highest policymaking body on healthcare matters in the country. The NCH is comprised of the federal Minister of Health, Commissioners of Health of the states, Secretary of Health and Human Services in the Federal Capital Territory, and the Permanent Secretary of the Federal Ministry of Health. The permanent secretary of the Ministry of Health is also the secretary to the NCH. The NCH determines the structure, time-frames, and guidelines for the formulation of both national and state health plans.

Much like the Canadian system, decision-making within the system is closed to public participation. External participation in matters handled by the NCH comes in the form of the technical advice rendered by the Technical Committee which sits as an advisory body to the NCH. The Technical Committee is comprised of a long list of members drawn from different biomedical institutions. Although section 6(2) (l) of the Act identifies “one representative each of the registered health professional associations including trado-medical practitioners” as members of the Committee, it is questionable whether these members have any real influence over decisions reached by the NCH. The skepticism regarding the influence of the representatives of the indigenous/alternative health professions in the Committee arises because the Technical Committee is largely dominated by members of the biomedical profession, and

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318 Ibid at 22.
319 See ibid, noting that the medical directors are not concerned with conducting any kind of cost-effectiveness analysis.
320 See section 5 (1), National Health Act, 2008 (SB.50), on file with author.
321 Ibid, section 5 (2).
322 Trado-medical practitioners is an abbreviation of ‘traditional medical’ practitioners.
323 According to section 6(2) of the law, the Technical Committee comprises: “(a) the Permanent Secretary of the Federal Ministry of Health who shall be the Chairman; (b) all Directors of the Federal Ministry of Health; (c) the Legal Adviser of the Federal Ministry of Health; (d) the Permanent Secretaries and any two Directors of all State Ministries of Health and FCT Department for Health and Human Services; (e) one representative each of the Christian and Muslim umbrella health organizations; (f) one representative each of the Armed Forces Medical Corps; that is, Army, Air Force and Navy; (g) one representative of the Prisons Medical Services; (h) one representative of the Police Medical Services; (i) one representative each of the parastatal of the Federal Ministry of Health; (j) one representative each of all statutory health regulatory agencies or councils; (k) the Chairman of the Committee of Chief Executives of Teaching and Specialist Hospitals and Federal Medical Centres; (l) one representative each of the registered health professional associations including trado-medical practitioners; and (m) one representative of the private health providers.
its decisions are expected to be those of the majority where the Committee is unable to reach a consensus. According to section 7(2) of the *National health Act*:

> (2) The Technical Committee shall strive to reach its decisions by consensus but where a decision cannot be reached by consensus, the decision of the majority of the members shall prevail and be regarded as the decision of the Technical Committee.\(^{324}\)

Thus, it is highly unlikely that the representatives of the indigenous and alternative health professions in the country will have enough votes to make their opinions and interests prevail where these conflict with those of the other members of the Committee.

Furthermore, decision-making in the area of healthcare financing and choice of services and products to be funded is restricted to biomedical actors. The country’s National Health Act effectively directs funding to biomedical and physician services. Although the Act recognizes indigenous medical systems as part of the overall national healthcare delivery system,\(^ {325}\) it does not make concrete provisions for the inclusion of indigenous forms of medical care within the lists of covered services.\(^ {326}\) Given the closed nature of the decision-making process and the dominance of biomedical actors within the system, it is unlikely that matters such as the growing consumer demand for indigenous therapies or the possible role of IMS in national healthcare delivery would be relevant to the decision-makers. Thus, the legal challenges in Canada, the US and different parts of the world may be viewed as an attempt on the part of tax paying healthcare consumers to be heard on issues that matter to them.

### 3.6.3. The Courts as Decision-makers

Canadian and United States case law on medical expenses reimbursement claims and other legal claims related to the use of IMS provides insight into how the courts currently resolve consumers’ discontent with the state of the law. As noted above, the courts appear to be reluctant to interfere with the relationship between the state and the medical profession. In overt deference to the type of scientific skepticism that has kept IMS out of policy discourses, the courts have often expressed what it believes to be the sentiments of policymakers regarding the supposed lack of evidence for indigenous and alternative medicines. Thus, basing their

\(^{324}\) Section 7(2), *ibid.*

\(^{325}\) Section 1(1) (h), *ibid.*

\(^{326}\) See *National Health Insurance Scheme Act*, CAP 35 LFN 1999.
decisions on the legislator’s concerns regarding the safety and quality of the medical services utilized by patients, Canadian judges have often upheld government policy or simply held themselves bound by the provisions of the relevant laws.

In *Chevalier v. Canada*, Justice Bédard captured this judicial attitude in the following words:

The Appellant argues that subsection 118.2(2) is not about the safety and efficacy of medical products and services. I disagree; the legislator limited the application of the medical expense tax credit provision in order to avoid abuse and ensure that the provision is in line with concerns for safety and efficacy.

This case involved a 56 years old Quebec resident who served with the Canadian Forces as an aerospace engineer. Severe health problems forced the appellant to leave the Canadian Forces, after which she began consulting doctors for her medical condition. The appellant was diagnosed with chronic fatigue syndrome. She also suffered from severe sensitivities to food, drinks and even clothing. She was intolerant to gluten and lactose, and reacted strongly to pharmaceutical products. The appellant relied on the services of a naturopath and an osteopath. In the 2002 taxation year, she claimed the sum of $18,252.79 as medical expenses paid to the naturopath and osteopath as well as money expended on organic products and foods. The Minister of National Revenue conceded only $3,253.74 as medical expenses on the ground that the expenses claimed did not fall within s.118.2(2) of the *Canadian Income Tax Act*. In the present action, the appellant challenged the constitutional validity of s.118.2(2) of the *Income Tax Act* on the ground that the subsection is an infringement on the equality provisions of s.15(1) of the Canadian *Charter of Rights and Freedom*.

It will be recalled that s.118.2(2)(n) of the Act requires that for medicines or other curative substances to qualify as medical services, they must be prescribed by a medical practitioner or dentist and recorded by a pharmacist. In dismissing the appellant’s claim, Justice Bédard cited with approval the decision of Justice Woods in *Ali v. Canada* where the latter held, regarding the “recorded by a pharmacist” requirement of paragraph 118.2(2)(n) of the *Canadian Income Tax Act*, that:

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328 Ibid at para 70.
Assurance of safety and efficacy would not be met if the pharmacist-recording requirement were removed. The evidence as a whole suggests that the efficacy of natural health products is very controversial. In terms of the safety and efficacy of dietary supplements to treat FMS and CFS, Health Canada generally has not required clinical trials for these products and the FMS Report and CFS Report suggest that there is no general acceptance that NHPs generally are efficacious to treat these conditions.\textsuperscript{331}

In validating the impugned legislative provisions, Justice Bédard clearly linked the statutory provisions to concerns regarding scientific evidence of safety and efficacy. Accordingly, the objective of the impugned law was to “ensure that the benefit provides tax relief with respect to safe and efficacious medical products and services as well as to limit abuse and control costs in order to maintain the credit’s financial sustainability”.\textsuperscript{332} The court noted that “controlling the safety and efficacy of medication is a pressing and substantive objective”,\textsuperscript{333} which justifies the government’s interference with the equality rights of the claimants. The court evidently deferred to the scientific criteria that underlie the legislation when it submitted that:

…[W]hether alternative medicines, such as natural medicaments, are safe is not for this Court to determine, but is for Parliament to debate. What matters at this stage of the analysis is that the safety and efficacy of medical products and services was taken into consideration by the legislator when determining the scope of subsection 118.2(2) of the Act.\textsuperscript{334}

Ironically, this decision presupposes that the legislative provisions are based on clear, perceptible evidence of disparity in the effectiveness and safety of IMS \textit{vis a vis} biomedical services and products. This assumption is troubling because the impugned provisions, in the absence of evidence of harm and inefficacy of IMS, are not evidence-based. In fact, although the government is yet to conduct or support substantive clinical trial research into alternative medical services, Health Canada through its drugs and natural health products website declares, with regards to the safety standard of the therapies, that:

\textsuperscript{331} \textit{Ibid} at para 133.
\textsuperscript{332} \textit{Chevalier}, supra note 327 at para. 72.
\textsuperscript{333} \textit{Ibid} at para. 71.
\textsuperscript{334} \textit{Ibid}.
Through the Natural Health Products Directorate, Health Canada ensures that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

The Natural Health Products Research Program supports natural health products research and knowledge-based development through various means, both individually and in partnerships with other funding agencies, most notably the Canadian Institutes of Health Research.335

The Directorate also sets standards for the regulation of natural health products, which practitioners are required to meet.336 There are penalties, including monetary and prison term consequences, for failure to comply with the guidelines.337 The question, therefore, is if the government through the Natural Health Products Directorate guarantees that it scrutinizes the natural health therapies utilized by Canadian consumers to ensure that they are safe and effective, why are they not listed under the relevant tax credit provisions? This incongruous state of affairs ought to be addressed in judicial decisions. Thus, it is ironic that the courts consistently base their decisions on a supposed lack of evidence of safety and efficacy of natural health products. In Banman v. The Queen, while acknowledging that “alternative medicines and homeopathic treatment are making great progress these days,” Bowman, J. noted that “there is as yet not very much control in the labeling or the sale of alternative medicines and that needs to be done”.338 The prevailing ethos is simply that IMS is anti-science and the law is drafted to reflect this notion.

Thus, drawing upon the supposed evidential base upon which parliament enacted the impugned provisions, the Chevalier court failed to act upon the appellant’s entreaty that “it is time for this Honourable Court to take a fresh new approach”.339 A different approach, which Justice Miller has often suggested and actively supported, is to ask parliament to consider amending the impugned provisions so that the law can “eventually” catch up to society’s behaviour.340 However, although Justice Miller has often adopted this laudable approach in his judgments, the Canadian courts, armed with knowledge of the faulty policy process that has

337 See Natural Health Products Regulations (effective January 1, 2004), established under the Food and Drugs Act, R.S., 1985, c. F-27.
338 Banman v. The Queen, [2001] 2 C.T.C. 2111 (SK) at para. 5.
339 Ibid at 70. Emphasis added.
340 Davar, supra note 17 at paras. 6 & 8.
produced the problematic legal texts, can condemn proactively and definitively the injustice inherent in the legislation. The US courts have sometimes adopted a proactive approach in order to protect consumers’ interest irrespective of legislative apathy on the subject in a given jurisdiction. In several court decisions, the US courts have favoured an approach that extends reimbursement for medical expenses beyond biomedicine to alternative healthcare. For example in *Harvey v. Travelers Insurance Co.*, where an insured patient who had suffered brain injury consulted an environmental therapist for the injury, the court observed that the therapy was targeted at developing the patient’s “ability to actively and productively engage in social intercourse; to treat and attempt to cure her mental and/or emotional deficiencies, and not necessarily to diagnose and care for her physical illnesses”. This liberal attitude is also evident in *Tudor v. Metropolitan Life Insurance Co.*, where the court held a method of treatment based on nutritional deficiencies and food allergies to be medically necessary.

In other contexts, the courts have simply followed the lead of existing legislations that recognize the evolution in consumer healthcare behaviour. Several US states have mandated insurance coverage of some complementary and alternative healthcare. At least forty-six states in the US, including Virginia, Louisiana, Alaska and Washington, have provision(s) mandating insurers to cover some alternative therapies. For example, a 1996 Washington law mandates all commercial health insurance companies to cover the services provided by every category of licensed provider, and this includes licensed CAM practitioners. It is noteworthy that the response to the law has sometimes been controversial. Some insurers attempted to avoid the provisions of the law by adopting a narrow interpretation of its provisions. The insurers sought to exclude specific plans or providers, and created conditions and limitations for some

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341 For a further discussion of how law can constitute a barrier to an equitable and efficient healthcare system, see Flood et al., *supra* note 16 at 15-41.
344 *Ibid* at 265.
348 Cohen, *Legal Boundaries and Regulatory Perspectives*, *supra* note 309 at 100.
The state insurance commissioner in several bulletins responded by emphasizing that insurers could not exclude particular providers on the basis that the provider did not meet the insurer’s mandates for providing “cost-effective and clinically efficacious health services”. The commissioner mandated the coverage of services within the provider’s scope of practice “without discrimination on the basis of provider type”.

The commissioner’s response is at odds with the apathetic attitude in Canada and many nations of the global South. While the majority of US states may be adopting a selective approach with regards to the alternative therapies that are covered (given that only state-certified/licensed alternative providers may be covered), it remains remarkable that both legislation and case law in the US are more receptive to the changes in consumer healthcare behaviour than in other countries. Even in cases where the Canadian court has acknowledged and accepted the evidence from physicians and patients regarding the efficacy of the alternative treatment, the decisions of the courts have remained conservative on the reasoning that no liberal interpretation of section 118.2 could produce the legal outcomes sought by litigants.

For example, Tardif J. in Roy v. The Queen expressed the following opinion:

I understand that most taxpayers faced with health problems clearly feel that expenses paid to alternative medical practitioners should entitle them to the medical expense credit, especially when the treatments in question reduced or even cured or eliminated the pain that conventional medicine could not. However, it is not up to this Court to resolve this issue.

In Bley v. Canada, No. 2000-3259(IT)I, April 5, 2001, [2001 UDTC 151] [2001] T.C.J. No. 206 (QL), Judge Margeson of the Tax Court of Canada closed with the following words of sympathy for the taxpayer: “The Court takes note of the Appellant’s arguments, and it has great sympathy for her and realizes that she has spent a large amount of money in trying to benefit herself and improve her condition but there is no section of the Act or the Regulations which would allow the Court to allow the appeal and grant the deductions which are sought.”

Based on the wording of the law and the absence of a provision on which to grant the appellant’s claim, the court dismissed the claim.
In *Melnychuk v. Canada*, the Canadian court again empathized with the patient and acknowledged that alternative treatments can and do provide benefits. However, the court dismissed the patient’s claim on the basis of legislative provisions. According to the court:

> It would be common sense to permit the deductions claimed and I understand the Appellant's frustration… My feelings in this appeal are better stated by Judge Bowman in Banman v. The Queen, [2001] 2 C.T.C. 2111, where in an instance somewhat similar to the present facts, Judge Bowman stated at paragraphs 5 and 6:

> I might just add one further point. I am aware from what the Appellant tells me and I am aware generally that alternative medicines and homeopathic treatment are making great progress these days. I can well understand why in paragraph (n) the government requires that certain medications be prescribed by a medical practitioner, because there is as yet not very much control in the labeling or the sale of alternative medicines and that needs to be done.

> Sooner or later, however, I think the government is going to have to face the fact that homeopathic medicines, alternative forms of treatment, herbs, natural healing, that sort of thing are so prevalent it should consider an amendment to the Income Tax Act that would permit a tax credit in respect of these things...

> The Appellant is a very good example of a person who has used alternative methods successfully. I am sorry that I cannot give him relief, but I do commend him for his courage in coming to Court. For the above reasons, the appeal is dismissed.  

Similarly, in *Bissonnette v. Canada*, while upholding s.118 of the *Income Tax Act*, Miller, J. stated on a positive note:

> At this stage in the evolution of Canada's medical practice, alternative treatments are just starting to gain some recognition as justified, well-researched medical treatments. I believe case law over the next few years will expand our understanding of what can legitimately be considered medical services.

While Miller J.’s obiter is empathetic and optimistic, this and other judicial opinions appear dissociated from the reality that the case law remains dependent on the provisions of the extant law. It was Miller, J. who noted in *Davar v. The Queen* that it was impossible for the court to “turn a blind eye to the real and exact meaning of the law, no matter how unfair the

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356 *Ibid* at paras. 11, 12 and 13.  
357 *Ibid* at paras. 12.  
358 *Bissonnette, supra* note 2.
taxpayer believes it to be”.\textsuperscript{359} Echoing Miller, J. in \textit{Davar}, Justice Bédard in \textit{Chevalier} stated that he too could not ignore the real meaning of the law. The cases reveal that the courts are unwilling to depart from the positivistic line of reasoning adopted in previous judgments on the issue. In fact, as Justice Bédard stated in \textit{Chevalier}, “[T]his is not the first time that this Court has had to determine whether alternative medical products qualify as medical expenses under subsection 118.2(2) of the Act. On the contrary, the case law is quite extensive and dictates a clear and concise approach to the interpretation of this provision”.\textsuperscript{360} This approach – as observed above – is a deferential attitude to the government’s policy, which itself is assumed to be based on expert medical evidence of the absence of safety, efficacy and cost-effectiveness of the products and services utilized by the consumer-litigant. Yet, at least one study has shown that within the closed system of medical decision-making in one Canadian province, the decision-makers do not include evidence of cost-effectiveness (even for biomedical services) among the most important considerations in the policymaking process.

According to Flood \textit{et al.} in their study of how healthcare decisions are made in Ontario, when asked the considerations that guide their decisions on applications for public funding, most Medical Directors put either medical evidence or cross-provincial comparisons before economic considerations.\textsuperscript{361} According to Flood \textit{et al.}, “this hierarchy suggests that Medical Directors are primarily concerned with discussing matters relevant to medical efficacy and cross-provincial uniformity than with conducting any kind of cost-effectiveness analysis”.\textsuperscript{362} The decision-makers evidently focus on narrow criteria to reach decisions that have a significant impact on the lives and wellbeing of Ontarians. Even in the context of biomedical healthcare services, such a narrow determination process can result in injustice to healthcare consumers. With no public input into the decision-making process, it is open to conjecture whether comparative studies of biomedicine and IMS will be conducted. Unfortunately, Canadian courts continue to ground their decisions on a non-existent body of evidence.\textsuperscript{363}

\textsuperscript{359} \textit{Davar}, supra note 17 at para. 6.  
\textsuperscript{360} \textit{Chevalier}, supra note 327.  
\textsuperscript{361} Flood \textit{et al.}, supra note 16 at 22.  
\textsuperscript{362} Ibid.  
\textsuperscript{363} An interesting opinion proffered by Willis and White is that consumers’ interest and demand for complementary and alternative medicine is the most significant factor that influences policy reform. This view suggests that while medical or scientific evidence is necessary, it is not at all determinative of the state’s response to the current consumer movement towards alternative medicine. This sociological analysis of the implications of
3.6.4. Devising an Approach: Any Role for the Courts?

The courts’ deference to government policy as well as its largely uncritical acceptance of the state of the law has often resulted in mounting frustration and a feeling of helplessness on the part of patients who use IMS. The feeling of powerlessness is heightened by the fact that a significant proportion of those who prefer indigenous healthcare to biomedical care often belong to a vulnerable class of immigrants who hold particular values – cultural and religious – about indigenous medicine. A continued indifference to the values and preferences of consumers on the part of the government and the judiciary may result in “disillusionment on the part of those whom Medicare is meant to serve and undermining political support for it”. An example of this outcome may be found in the case of Davar, where the appellants wrote a letter to the government of New Brunswick requesting changes to the legislation. The court noted that the Davars were “frustrated” and “offended” by the situation and asked whom they could turn to. The Davars are only a couple of several millions of patients whose expectations conflict with the state of the law.

The question, therefore, is what type of approach can the court adopt in handling the present conflict between consumer expectations and positive law? One argument against the courts taking any steps beyond that of a literal meaning interpretation of the relevant law is that it is not the responsibility of the courts to create policy. This argument casts judges who become actively involved in institutional reform litigation as ‘judicial activists’. The expectation is that judges conservatively play their role as ‘neutral arbiters’, and that role as articulated by Sandler and Schoenbrod is to “to enforce the laws, including the constitutional law, that elected officials adopt”. When judges go beyond the interpretation of laws, they may be seen to “usurp the policy-making function of elected officials”. The problem with this narrow view of the judicial role is that “the judge determines liability and awards relief without regard to the policy consequences of his actions or of policy-based precedents set by other courts under similar

the theory of EBM for the future development of alternative medicine provides a different viewpoint from the common belief that alternative medicine will not survive the EBM movement: see Willis and White, supra note 18. Flood et al., supra note 16 at 26, writing in the context of the role of the Ontario Health Service and Review Board, which reviews appeals against the government’s decision not to fund particular treatments and services. Davar, supra 17 at para. 6.


Ibid.
circumstances”. In this limited judicial role, while sometimes empathetically acknowledging the detrimental results of a judgment on litigants the violation of whose rights may be patently obvious, the judge refrains from making the impact of the law on legal subjects a determining consideration in the ensuing judgment.

This judicial attitude clearly counters the functional theory of law articulated by some legal theorists and advocated in this work. The functional theory, it will be recalled, recognizes that the “life-history” of a legal rule extends beyond when the rule is obeyed or disobeyed, or by implication when it operates to determine rights and entitlements as between legal subjects. As Cohen stated (and it is important to reproduce his statement again):

> In writing the life-history of a legal rule, one does not reach the end of the story when the rule is obeyed or disobeyed. There remains to be told the meaning of obedience or disobedience, in terms of social institutions and customs, in terms of the material things over which law gives control, in terms of human habits, modes of thought, fears, hopes, pleasures and pains.

There is, perhaps, no better example of the extensive impact of a legal rule than that exemplified in the present case. The decision – whether or not a litigant is entitled to claim the METC under the impugned provisions – often rests on technicalities based on the narrowly constructed nature of the statute. This narrow construction, while causing significant losses to patrons of IMS, patently allows claims based on expenses from cosmetic surgery so long as it was performed by a medical doctor. The eligibility of claims based on cosmetic surgery obviously follows from the technical nature of the provisions of the Act. As Shaw has explained:

> [T]he CRA’s position (on cosmetic surgery) can likely be explained by the wording of subsection 118.2(2), rather than by a carefully considered policy choice. As the section is now worded, in order to deny a claim, the CRA would have to take the position that cosmetic surgery was not a medical service. This position would be difficult to defend where a medical doctor had performed the procedure.

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372 Shaw, supra note 293 at 48.
It is this type of needless technicality – a bureaucratic enforcement of the law irrespective of its absurdity – that judges must obviate. The avoidance – through practical and meaningful interpretation of the law – of the injustice procured by the law as it is should not be cast as ‘policymaking’ or ‘activism’. The intention of the trial judge in Ray v. R. was certainly not to legislate or make policy when the judge opined that “[i]f the medications are prescribed by a doctor and they make the difference between life and death or functioning or not functioning, they should fall under paragraph 118.2(2)(n)” and that in such cases, the “recorded by a pharmacist” requirement could be disregarded. This was a case where the facts clearly showed that the applicant’s health had significantly improved, and that she could now live a substantially normal life following the use of the natural health products. The applicant, Mrs. Ray had chronic fatigue syndrome and fibromyalgia with debilitating symptoms. Her physician prescribed herbs, vitamins, natural and organic foods, and vitamins. She bought these from a pharmacy, though they were not recorded by the pharmacist. The trial judge’s application of the facts to the law was evidently a functional interpretive approach to avoid the injustice that would have resulted if the literal approach had been adopted. This approach reflects the judicial responsibility to ensure fairness in the application of rules to the lives of legal subjects.

Of course, it is necessary to keep in perspective that the ideal reform initiative is legislative amendment of the law through parliament’s adoption of a functional approach to the promulgation of laws. Indeed, it will be recalled that the functional theory of law is both a theory for lawmaking as well as a hermeneutical theory for legal texts. However, considering that parliamentary reform is slow in coming, and that consumers continue to turn to the courts for relief, the courts can exercise their prerogative to interpret the legislation in a manner that maintains the legislative intent to support consumers who incur significant sums on out-of-pocket medical expenses, while protecting legal subjects from the prejudicial outcomes often produced by the law as it is.

Another argument against a role for the courts in the resolution of the conflict between law and social norms in the present context is that the court’s positivistic attitude is based on the need to ensure that products utilized by consumers meet the standards of safety and efficacy; and since the courts presume that alternative healthcare products are yet to meet these

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373 Ray, supra note 305. See also Pagnotta, supra note 304; Frank, supra note 304.
374 Ray, ibid at paras. 20-21.
standards, their judgment arguably cannot be faulted. However, the conflicting interests involved here – patients’ rights, values and expectations versus patient safety – necessitate that adjudicators go beyond the presumptions inherent in the legislation to question whether proper considerations have been factored into the legislative or policy decisions. While the task of legislative and policy reform ultimately lies with the lawmakers, if policies or legislations fall short of the standards of fairness expected in a democratic society, then it falls squarely in the jurisdiction of the courts to make pronouncements towards ensuring legislative or policy changes.

Notably, in Chevalier the court remarked that the appellant was seeking legislative change and not judicial review. By this construction, the court conveniently discharged itself from any responsibility to facilitate the necessary change. This attitude evinces the erroneous view that the courts have a limited role in resolving conflicts in healthcare issues. Contrary to this view, the courts have a greater role in ensuring healthcare laws and policies are fair than they have allowed themselves in the recent past. Some commentators have opined that judges are in a distinctive position to defend the rights of the “disenfranchised”, and that “[e]ven those who criticize or condemn judicial policy-making acknowledge that the nonmajoritarian branch has a duty to defend the rights of those not represented in the political branches”.

Needless to state, this is the primary task of the judiciary: to intervene in the interests of the “disenfranchised”. As one judge has observed, “a democracy of the strong would devour the weak”. Hence, rather than view a more definitive judgment on the unfairness of the METC provisions and a functional interpretation of the provisions as judicial legislation, the role of the judiciary in these institutional reform litigations can simply be interpreted as “to protect the rights of the weak from the apathy of the strong”. In this role, judges can take a more active stand in emphasizing the inequitable nature of the present law, and in ensuring that decision-makers address the important considerations in the regulation and funding of IMS. These considerations necessarily include evidence of safety and efficacy and cost-effectiveness of the services and products comparative to existing options. Beyond these, however, other

375 Chevalier, supra note 327 at para. 81.
376 Payne, supra note 369 at 13.
377 Ibid.
379 Payne, Ibid at 13.
types of evidence that are crucial to decisions about regulation and integration include data related to economic and social demographics of healthcare consumers, financial accessibility of healthcare services and products, availability of healthcare resources (including human and technological resources) within specific societies, geographical access to healthcare clinics and institutions, as well as data regarding underlying reasons for consumers’ preference for one form of healthcare over another. These types of evidence have received little attention in the subject of medical integration.

While these categories of evidence are to be implemented by policymakers, they are highlighted here as part of the discussion on the role of EBM in judicial decisions to demonstrate the theoretical and practical gaps in the biomedically constructed notion of evidence-based medicine. These shortcomings in the EBM paradigm are often overlooked in the application of the paradigm to legal matters affecting individual and population health. The final sections examine the types of evidence that the EBM paradigm – as presently framed by the scientific community – cannot produce without a shift in the scientific community’s notion of what constitutes ‘scientific evidence’. For the EBM paradigm to be relevant in producing these types of evidence, the scientific community would have to broaden the notion of ‘scientific evidence’ to include non-measurable or non-quantifiable experiential phenomena that are critical to the notions of ‘medical efficacy’ and ‘effectiveness’ in the individual case as well as to policy decisions about population health.

While medical efficacy refers to evidence in relation to the “effects produced by a therapy in an experimental context” and is usually determined through the conventional RCT method of scientific enquiry, ‘effectiveness’ refers to the “evaluation of the impact of an intervention in an ordinary clinical context”. Based on the range of external factors that are involved in the clinical context, medical effectiveness is best determined through observational and qualitative research techniques, which are part of a composite research paradigm. Thus, the evidence examined in the next section aspire to address questions of medical effectiveness, for example, what is the practical utility of a positive RCT result of a given medical intervention? The types of evidence examined include the results of some studies of cost-utility, cost-

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380 Giarelli, supra note 24 at 74, 67.
381 See ibid at 67.
382 Ibid.
identification, cost-minimization, and cost-effectiveness analyses of alternative medicine carried out in different countries, including Canada, Israel, Italy and Amsterdam. The section also pools together and analyzes comparative data on financial and geographical accessibility of healthcare facilities and on the availability of human resources in healthcare in an urban town and three rural communities in Nigeria. Following this discussion, section six draws on existing research on the subject to outline a composite research paradigm.

3.7. Other Types of Evidence


The general trend in the case law as noted above is judicial deference to legislative provisions. The court has often expressed its role as simply to decide between one or both of two approaches: to uphold the law as written or to call upon parliament to make the necessary legislative changes. The court has often settled on the first approach in conformity with what is presumed to be a pressing and substantive legislative objective. The latter approach, which is evident in Justice Miller’s judgments, sets the pace for a greater judicial role in ensuring extant health policies serve the best interests of the populace. Part of the objective in this section is to investigate through an examination of other types of relevant evidence the sufficiency of the current notion of ‘scientific evidence’ as conventionally represented by the EBM paradigm and applied by the judiciary.

Evidence from many Northern and Southern states reveals that healthcare consumers experience financial hardship in meeting their healthcare needs. Even among the wealthy nations of the North, there are concerns about the sustainability of the biomedical healthcare system. The present configuration of the healthcare system emphasizes the biomedical paradigm above other forms of care, such as preventive care or cultural medicine. For example, the US operates what is largely a technology-based and expensive healthcare system circumscribed by an institutional framework that emphasizes disease treatment to the neglect of health maintenance. \(^{383}\) Healthcare financing has also focused predominantly on curative medicine. \(^{384}\) The commonly held assumption is that technological care offers the best form of

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\(^{384}\) *Ibid.*
medical care. Further, there is an emphasis on costly pharmaceutical intervention even where there are low-cost scientifically proven options. With over $643 billion dollars a year in pharmaceutical profits and an ever-growing reliance on technological care, the US healthcare system faces a dual problem related to both the cost of care and the form of financing for the system. Indeed, some scholars have noted that “the cost of highly technical interventions adds to the rising costs of health care, making it more difficult for employers to extend insurance to part-time workers or for insurance companies to lower their premiums.”

An objective consideration of non-technological, non-conventional medical options would reveal that there are established benefits in terms of costs and efficiency to be derived from balancing these forms of care with biomedical and technological care. In a systematic review of studies that have investigated the cost-effectiveness of complementary and alternative medicine (CAM), Patricia Herman et al. concluded that CAM is cost-effective compared to conventional care for a number of medical conditions. The authors reviewed previous studies in order to examine the scope and quality of economic evaluations for complementary and alternative medicine. They subjected the studies to two forms of quality review: a 35-item checklist for reporting quality, and a set of four criteria for study quality – randomization, prospective collection of economic data, comparison to usual care, and no blinding. The authors found the study quality in 36% of the studies to meet all four criteria. It was concluded that while “the reporting quality of the full evaluations was poor for certain items”, it was certainly “comparable to the quality found by systematic reviews of economic evaluations in conventional medicine”. According to the authors, the “exemplary” studies indicated that CAM therapies –

…may be considered cost-effective compared to usual care for various conditions: acupuncture for migraine, manual therapy for neck pain, spa therapy for Parkinson's, self-administered stress management for cancer patients undergoing chemotherapy, pre- and post-operative oral nutritional supplementation for lower gastrointestinal tract surgery, biofeedback for patients with “functional” disorders (eg, irritable bowel syndrome), and guided imagery, relaxation therapy, and potassium-rich diet for cardiac patients.

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385 Ibid at 10.
386 Ibid.
387 Herman et al., supra note 234.
388 Ibid
389 Ibid.
390 Ibid.
It was established that though complementary and alternative therapies may be given in addition to usual care, they can improve clinical outcomes without increase in cost. Indeed, a number of positive studies exist that confirm that the use of alternative medicine can achieve a reduction in overhead healthcare costs.

Korthals-de Bos et al. conducted a comparative cost-utility study to evaluate the cost-effectiveness of physiotherapy, manual therapy, and care by a general practitioner for patients with neck pain. The study design involved economic evaluation alongside a randomized controlled trial. There were 183 patients with neck pain enrolled in the study; 60 patients were randomly allocated to manual therapy (spinal mobilization), 59 to physiotherapy (primarily exercise), and 64 to general practitioner care (involving counseling, education, and drugs). The clinical outcomes were measured by perceived recovery, intensity of pain, functional disability, and quality of life. The patients kept cost diaries for one year which were used by the investigators to measure direct and indirect costs between the groups.

The study outcomes revealed that the manual therapy group showed a more rapid improvement than the physiotherapy group and the general practitioner care group up to 26 weeks; however, the differences in the improvement rate between the groups were minor by follow up at 52 weeks. The overall cost of manual therapy was a significant €447 (equivalent of £273 and $402), which was about one third of the costs of physiotherapy (€1297) and general practitioner care (€1379). Through the cost effectiveness ratios and the cost utility ratios – which showed lower costs and a higher Quality-Adjusted Life Year (QALY) in the use of manual therapy – the study established that manual therapy (spinal mobilization) was more

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391 Ibid at 11.
393 Ibid.
394 Ibid.
395 The Quality-Adjusted Life Year (QALY) is a measure of the quality and the quantity of life lived relative to disease burden in a given year. It is used in cost-utility analysis to assess the value for money of a given medical intervention. It is calculated based on the number of years gained from the use of the intervention. Every year in perfect health is assigned a value of 1.0. Where death results, a value of 0.0 is assigned. The data may be used to allocate healthcare resources, in which case the preferred intervention is one with a lower cost relative to the QALY saved ratio: see generally Ceri Phillips, “What is QALY?” (2009) Health Economics 1, online: Bandolier <http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/QALY.pdf>; Measuring Effectiveness and Cost-Effectiveness: The QALY, online: National Institute for Health and Clinical Excellence, UK <http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectiveness/theqaly.jsp>; Christopher J.L. Murray and Alan D. Lopez, The Global Burden of Disease (Cambridge, MA: Harvard University Press, 1996); and Christopher J.L. Murray and Alan D. Lopez, The Global Burden of Disease and Injury Series (Geneva: WHO, 1996).
effective and less expensive for treating neck pain than physiotherapy or general practitioner care for the same condition.

Frenkel and Hermoni carried out a cost-identification study to investigate the effect of integrating homeopathic treatment in atopic and allergic diseases in conventional treatment within a health maintenance organization.\textsuperscript{396} The trial was conducted in a complementary medicine clinic affiliated to an Israeli health maintenance organization. The study, which was conducted over a period of one year, was designed as a retrospective comparison of medication costs three months before and three months after the homeopathic intervention.\textsuperscript{397} Forty-eight patients were treated using homeopathic and conventional medication. The conventional medication consumption for each patient was evaluated using a computerized medication chart. The results showed that fifty-six percent of patients in the study reduced their use of conventional medication following the homeopathic treatment.\textsuperscript{398} Patients who utilized conventional therapy reduced their medication expense by an average of 60%. This resulted in an average savings of $24 per patient in 3-month medication costs following the homeopathic treatment. The study established that following the homeopathic intervention, there was a “modest but significant reduction” in the use of conventional medications commonly used to treat allergic conditions and their complications.\textsuperscript{399}

Herron and Hillis designed a 14-year pre- and post-intervention cost-minimization study to investigate the impact of the practice of transcendental meditation (TM) on medical expenses in Quebec, Canada.\textsuperscript{400} The study involved 1418 Quebec health insurance enrollees who practiced the TM technique. This group of enrollees was compared with 1418 randomly selected enrollees of the same age, sex, and region who did not practice the TM technique. The study compared government payments to physicians for each group of enrollees. The overall long-term health outcomes were assumed to be the same for each group. The investigators found that before starting medication, both groups had a similar yearly rate of increase in payments. Once transcendental meditation had commenced, the annual government payment to

\textsuperscript{397} Ibid.
\textsuperscript{398} Ibid.
\textsuperscript{399} Ibid.
physicians for the meditation group declined 1% to 2% annually, while the payment for the comparison group increased up to 11.73% annually for over a 6-year period. There was a significant difference of 13.78% in the annual payments for the two groups. In the overall, the outcomes showed that transcendental meditation reduced payments to physicians between 5% and 13% annually.

Franzosi et al. conducted a randomized cost-effectiveness study of omega-3 polyunsaturated fatty acids (n-3 PUFA) as secondary prevention for patients with recent myocardial infarction. The analysis was based on morbidity and mortality data and economic outcomes obtained prospectively during the 3.5-year follow-up period of the study. Employing the perspective of a third party payer, the cost-effectiveness analysis considered the number of life-years gained and the incremental costs for hospital admissions, diagnostic tests and medications with a 5% discount rate. The incremental cost-effectiveness ratio for the intervention over 3.5 years was 24,603 euro (about US$25,415) per life-year gained, while the incremental cost discounted over 3.5 years per patient was €817. The investigators concluded that the clinical benefit of n-3 PUFA is additive and the cost effectiveness of long-term treatment with the modality is comparable with other drugs for the same medical condition.

3.7.2. Comparative Data on Financial and Geographical Accessibility of Healthcare Facilities and on the Availability of Human Resources in Healthcare: Results of a Study Conducted in an Urban Town and Three Rural Communities in Nigeria

Research was conducted to obtain the perspectives of users of biomedicine and indigenous medicine on the following issues: usage of indigenous products and services and reasons for usage, wait-times in biomedical clinics versus wait times in indigenous healthcare centres, payment methods for indigenous medicine, support and rationale for medical integration, coverage of indigenous medicine within the National Health Insurance Scheme (NHIS), and the possible role of IMPs in primary healthcare/community healthcare delivery. The questions on integration, NHIS coverage and IMPs’ role in community healthcare were intended to confirm or debunk the popular perception regarding the financial and geographical accessibility of

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IMPs. Thus, respondents were required to state their reasons for supporting any of these three agendas.

The questionnaires were administered to respondents in Benin City and three rural communities – Ogwa, Ewu, and Ekpoma – all within Edo State, Nigeria. These four communities are typical of most urban and rural communities in Nigeria. As explained in the introductory chapter, while the local languages spoken in these four communities were the most accessible to the investigator and researchers, there were no unique considerations in the choice of the localities. All four communities have commonalities with other cities or rural communities in Nigeria as regards access to essential social services, including healthcare services. The questionnaires were distributed at university campuses, public centres, markets and shopping centres, and in hospitals. Considering the study’s emphasis on confidentiality, respondents gave their consent and completed the questionnaires at the same time they were approached to participate in the study. The research was inclusive and representative of adult consumers of all genders and social and professional classes who had utilized either biomedicine or indigenous medicine. A total number of 220 questionnaires were returned. The number of responses to each question varied. The results are based on computations of the percentage of responses to each question.

As regards the question on usage of indigenous medicine, 62% of the respondents said they had used an indigenous medical service, while 71% had used a Natural Health Product (NHP). The data showed that 60% had utilized an indigenous medical service or natural health product to cure a disease or an illness, while 20% had used it for health maintenance. This outcome confirms that indigenous medicine can be used for both purposes. Table 3.1 and Figures 3.1 and 3.2 provide the responses, including reasons for use of the products:
Table 3.1: Usage of Indigenous Medicine and Reasons for Usage (Urban and Rural Areas)

<table>
<thead>
<tr>
<th>Usage</th>
<th>Percentage Citing Yes</th>
<th>Percentage Citing No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services</td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td>Products</td>
<td>71%</td>
<td>29%</td>
</tr>
</tbody>
</table>

**Reasons for Usage**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>For health maintenance</td>
<td>20%</td>
</tr>
<tr>
<td>To improve quality of life</td>
<td>7.3%</td>
</tr>
<tr>
<td>To prevent disease or ailment</td>
<td>7.3%</td>
</tr>
<tr>
<td>To cure a disease or an ailment</td>
<td>60%</td>
</tr>
<tr>
<td>To reduce stress</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

Figure 3.1: Usage of Indigenous Medicine (Urban and Rural Centres)
Figure 3.2: Reasons for Usage of Indigenous Medicine

The results on the issue of wait-times in biomedical clinics and indigenous healthcare centres revealed that while 63% of respondents spent between 1-4 hours in the waiting room in biomedical healthcare centres, only 18.9% of respondents indicated a 1-4 hours time-frame in the waiting room at an indigenous healthcare centre. In fact, 82% of respondents spent thirty minutes or less in the waiting room at an indigenous healthcare centre. Tables 3.2 and 3.3 show the distribution of results while Figure 3.3 provides a comparative illustration of both outcomes:

Table 3.2: Wait-times in Biomedical Clinics (Rural and Urban areas)

<table>
<thead>
<tr>
<th>Wait Times in the Hospital</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thirty Minutes</td>
<td>37%</td>
</tr>
<tr>
<td>One to two hours</td>
<td>43%</td>
</tr>
<tr>
<td>Three hours</td>
<td>7%</td>
</tr>
<tr>
<td>Four hours and over</td>
<td>13%</td>
</tr>
</tbody>
</table>
Table 3.3: Wait-times in Indigenous Healthcare Centres (IHC) (Rural and Urban areas)

<table>
<thead>
<tr>
<th>Wait Times in the IHC</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thirty Minutes or Less</td>
<td>81.9%</td>
</tr>
<tr>
<td>One to two hours</td>
<td>12.6%</td>
</tr>
<tr>
<td>Three hours</td>
<td>0.9%</td>
</tr>
<tr>
<td>Four hours and over</td>
<td>4.5%</td>
</tr>
</tbody>
</table>

Figure 3.3: Comparative Illustration of Wait Times in Biomedical and Indigenous healthcare Centres
Respondents were also asked whether they thought the National Health Insurance Scheme (NHIS) should cover indigenous medicine, whether indigenous medical systems and biomedicine should be integrated, and whether IMPs could play a role in primary healthcare/community healthcare delivery. Respondents were required to provide reasons for supporting any of these propositions. The answers obtained revealed what the respondents considered as problems with the state healthcare delivery system, which they thought one or all of these proposals could address. The answers also confirmed the popular perception regarding the financial and geographical accessibility of IMPs. The Tables and Figure below provide the outcomes.

Table 3.4: Role of IMPs in Community Healthcare Delivery

<table>
<thead>
<tr>
<th>Do you think IMPs could play a role in Community healthcare delivery and why?</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>76%</td>
</tr>
<tr>
<td>No</td>
<td>24%</td>
</tr>
</tbody>
</table>

Table 3.5: Opinion on Integration of IMS and Biomedicine

<table>
<thead>
<tr>
<th>Do you think the government should integrate indigenous healthcare systems into the conventional healthcare delivery system?</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>62%</td>
</tr>
<tr>
<td>No</td>
<td>38%</td>
</tr>
</tbody>
</table>
Table 3.6: Opinion on Coverage of IMS in the National Health Insurance Scheme

<table>
<thead>
<tr>
<th>Do you think the National Health Insurance Scheme should cover indigenous medicine?</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>56%</td>
</tr>
<tr>
<td>No</td>
<td>44%</td>
</tr>
</tbody>
</table>

Figure 3.4: Opinions Supporting NHIS Coverage, Integration and IMPs’ Role in Primary/Community Healthcare

Respondents provided a broad range of reasons for their support for one or all of the above three proposals. As shown in figure 3.5 and table 3.7 below, 40% of respondents explained that their support for medical integration, NHIS coverage of indigenous medicine, and the role of IMPs in primary/community healthcare delivery was based on the geographical proximity of IMPs to the community as well as the financial accessibility of the practitioners. In fact, the recurrent word was “accessible” used variously to explain the ease of financial
payment as well as the high number of IMPs located in the community as opposed to biomedical clinics where the “crowd was too much and the personnel were few” and where “there were not enough doctors for the people [*patients]” or where “there was a doctor but the people waiting to meet the doctor were too many”. The term ‘accessible’ was also used to explain the receptive nature of the IMPs as opposed to doctors “acting busy and inaccessible”, the physical proximity of IMPs and indigenous healthcare centres (IHCs) to community members and the speed of service at IHCs as opposed to biomedical clinics where you had to “wait for hours before seeing a doctor”.

Figure 3.5: Percentage allocations of reasons cited for the need for NHIS Coverage, Integration and Community Role

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402 Statements by respondents regarding their experiences in biomedical clinics in Nigeria: Iyioha, *International Research*, *supra* note 82.
Table 3.7: Reasons Cited for the need for NHIS Coverage, Integration and Community Role

<table>
<thead>
<tr>
<th>Geographical and Financial Accessibility</th>
<th>40%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Reasons:</td>
<td>60%</td>
</tr>
<tr>
<td><strong>Efficacy/Safety/Quality</strong></td>
<td></td>
</tr>
<tr>
<td>Belief in the efficacy and safety of NHPs and IMPs</td>
<td></td>
</tr>
<tr>
<td>Belief in the Superiority of some IMS and NHPs over Biomedicine</td>
<td></td>
</tr>
<tr>
<td>Adverse effects of Biomedicine</td>
<td></td>
</tr>
<tr>
<td>Reliability</td>
<td></td>
</tr>
<tr>
<td>Quality Control</td>
<td></td>
</tr>
<tr>
<td>Standardization [of the dosage for NHPs]</td>
<td></td>
</tr>
<tr>
<td>IMS and NHPs are user-friendly</td>
<td></td>
</tr>
<tr>
<td><strong>Rights/Equality</strong></td>
<td></td>
</tr>
<tr>
<td>Diversity</td>
<td></td>
</tr>
<tr>
<td>Equality [*between medical systems]</td>
<td></td>
</tr>
<tr>
<td>Recognition of consumers’ preferences and ‘Informed Choice’</td>
<td></td>
</tr>
<tr>
<td>Cultural significance of indigenous medicine</td>
<td></td>
</tr>
<tr>
<td>Popularity of IMS and NHPs</td>
<td></td>
</tr>
<tr>
<td><strong>Comprehensive Healthcare/Knowledge Transfer</strong></td>
<td></td>
</tr>
<tr>
<td>NHIS must be [comprehensive] in coverage and application</td>
<td></td>
</tr>
<tr>
<td>NHIS will benefit from it</td>
<td></td>
</tr>
<tr>
<td>Exchange of Ideas [between the medical systems]</td>
<td></td>
</tr>
<tr>
<td>IMPs’ knowledge of the community and the kinds of illness that afflict members</td>
<td></td>
</tr>
<tr>
<td>Reduce the pressure on conventional healthcare practitioners</td>
<td></td>
</tr>
<tr>
<td>To ensure comprehensive and efficient healthcare delivery</td>
<td></td>
</tr>
<tr>
<td><strong>Development of IMS</strong></td>
<td></td>
</tr>
<tr>
<td>Encourage IMPs</td>
<td></td>
</tr>
<tr>
<td>To ensure full disclosure of NHP Constituents to NAFDAC</td>
<td></td>
</tr>
<tr>
<td>Development of the indigenous healthcare system</td>
<td></td>
</tr>
<tr>
<td>*Development of ‘Traditional’ Orthopaedic Practice</td>
<td></td>
</tr>
<tr>
<td>**Development of ‘Traditional’ Birth Attendance (TBA) and support for midwives</td>
<td></td>
</tr>
</tbody>
</table>

*There is said to be a common tradition of referral from physicians to IMPs in this area because of the latter’s exceptional skill.

**Traditional Birth Attendants have become very useful in community settings where maternity homes are few.
Although the 44% of respondents who rejected the idea of NHIS coverage for indigenous medicine did not typically provide reasons for their position, it can be inferred from the data on payment methods provided below that the mixed opinions were due to the flexible payment methods within indigenous healthcare systems. In some cases, patients were asked to pay for the services rendered only after they had experienced positive results. If the IMP’s treatment had no effect, there was no need to pay for the treatment. In other cases, treatment was free because a family member had provided the NHP or the IMP was a family friend. Thus, the logical inference is that their rejection of the idea of NHIS coverage for IMS is based on the assumption that NHIS coverage may put an end to this flexible payment method.

Table 3.8: Payment Methods (including Waivers and Deferrals)
[Urban and Rural Centres]

<table>
<thead>
<tr>
<th>Payment Method</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>61%</td>
</tr>
<tr>
<td>Cash by installment</td>
<td>21%</td>
</tr>
<tr>
<td>Gifts</td>
<td>12%</td>
</tr>
<tr>
<td>Rendering services</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Payment Waiver</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22%</td>
</tr>
<tr>
<td>No</td>
<td>78%</td>
</tr>
<tr>
<td><strong>Payment Deferral</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13%</td>
</tr>
<tr>
<td>No</td>
<td>87%</td>
</tr>
</tbody>
</table>
Box 3.1: Common Reasons Provided for Waiver or Deferral of Payment

1. I pay the balance of the money after I have been cured by his or her medicine (Deferral).
2. I only pay anytime I visit to keep good record of payment (Deferral).
3. The medicine was unable to cure the illness (Waiver).
4. I had no money (Waiver).
5. The herbal practitioner was a well-known relative of mine from the same village community (Waiver).
6. Practitioner was a relative (Waiver).
7. To promote… togetherness in [the] society (Waiver).
8. The materials [*for the NHP] were sought and collected by a family member (Free).
9. My Pastor provided the medicine [*He would not accept money] (Free).
10. It [*payment] reduces the communal love of the Africans (Free).


In the preceding sections, the recurrent theme has been that policymakers need to accept a broader notion of ‘scientific evidence’ in the regulation of indigenous and alternative medicines. Commentators have observed that at the heart of the difficulty with investigating and validating IMS is the “concept of scientific proof”. The problem with the concept inheres in the fact that there is a plurality of scientific evidence. Scholars in this area have sought to establish a symmetrical relationship between conventional research methods and observational and qualitative research techniques (as aptly represented by the anthropological research method studied above). Observational and qualitative techniques in themselves constitute

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406 Giarelli, *ibid* at 64.
scientific proof. These techniques focus on investigating and answering research questions within the matrix of issues that ought to guide healthcare regulation that cannot be answered through conventional research methods. Wayne B. Jonas, a former director of the United States Office of Alternative Medicine, explains the importance of a “shift” from “the single orientation to a dual orientation in research methods”.407 According to Jonas:

A more explicit “balance” in research and evaluation strategies between the criteria of internal validity (focused on identifying causal links) and external validity (focused on clarifying impact and utility) is needed… Rather than assuming studies with high internal validity are “better” than others (the hierarchy approach), a dual orientation recognizes that both internal and external validity have intrinsic value and different purposes. Understanding assumptions about causality in both Western medicine and non-Western systems of medicine is important for expanding this dual orientation and seeking “methodological balance” in a global medicine perspective.408

Rebalancing the ‘hierarchy of evidence’ typical of the EBM paradigm, Jonas creates what he terms an ‘Evidence House’ in which he relocates conventional research methods and observational techniques within the two parts of a pyramid.

Jonas places conventional research methodology, which investigates the causes and effects of modalities, on the left side and positions observational methods, which evaluate the utility of a given modality in the clinical or practical context, on the right side. Jonas’ ‘Evidence House’ depicts six research methods that represent both paradigms of research: Reviews and Meta-analysis, Randomized Control Trials, and Laboratory research (conventional research methods that establish the internal validity of a modality) and Health Services Research, Epidemiological outcomes, and Qualitative Case Reports (observational techniques that investigate external validity). The author suggests that “the definition of “scientifically established” should incorporate information derived from the use of all six types of research methods.409

Systematic reviews and Meta-analysis involve methods for assessing the “accuracy and the precision of clinical research based on expert review”, and is designed to answer the question: “[w]hat degree of trust can we have in the effects of individual treatments in clinical

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407 Jonas, supra note 405 at 127.
408 Ibid.
409 Ibid at 123.
Randomized Controlled Trials, as discussed above, are designed to “isolate and compare the specific contributions attributed to different treatments with respect to their outcomes; RCTs address the question: [w]hat efficacy is attributable to a specific treatment?” Basic Laboratory Research investigates the “biological plausibility” of mechanisms and practices which underlie clinical effectiveness. It seeks to know “what happens and why”. These three types of research confirm the internal validity of a given medical intervention.

On the other side of the ‘Evidence House’ are the research methods that address the complex relationships between particular interventions, the individual users of the interventions, and the external dynamics that affect accessibility. Health Services Research represents one approach to investigating the validity of an intervention in the clinical context. This type of research – depicted by the study conducted in Nigeria – relates to the use of surveys that examine the utility and impact of interventions on patients in the context of social factors such as access, cost, practicability, practitioner competence, patient compliance, etc. These types of research seek to answer the question “[w]hat impact does a specific intervention have in general terms of acceptance and adoption?”

Observational Studies or Epidemiological Study of Outcomes is about audits, outcome research, and other types of observational surveys that explain the association between modalities and outcomes, and addresses the question “[w]hat effects does the treatment produce in clinical practice?” Finally, Qualitative Reports and Case Studies relate to patient interviews, anecdotes, histories, and case studies that investigate patient preferences. These methods seek to answer the question: [w]hat does the patient think about a given intervention and “what are his or her preferences?”

All of these six types of evidence are relevant for making healthcare decisions. While the first three types of evidence explain the effects or mechanisms of specific treatments, the latter set of evidence provide information on the “probability, extent and pertinence of a
treatment’s impact” when administered in clinical practice amongst other relevant information on the utility and acceptance of the intervention in the clinical context. According to Jonas, this balanced structure of evidence “respects the information preferences sought by various audiences and acknowledges their intrinsic contribution to medical knowledge.” Further:

It also allows for scientific evidence and its ethical application to remain as the foundation of medicine. Yet, it provides the flexibility to ask an expanded set of questions in the context of the differing assumptions about causation and the diverse values placed on information.

While asserting that none of these six types of evidence in isolation can address the questions raised in the regulation of IMS, Giarelli observes that it would be difficult to harmonize all six types of evidence in a single research project. Given the problems that might arise in an attempt to combine all six forms of evidence within the same research project, a composite model that is designed to apply all six types of evidence would involve successive trials and investigations. Each of these six types of evidence is incorporated successively within a broad multi-part research project designed to account for each evidence and eschew the extant hierarchy in medical research.

3.9. Conclusion: Law as an Instrument for Policy Reform

The above types of evidence, including evidence of the cost-effectiveness, cost-utility, cost identification and cost-minimization analyses and the small-scale study in Nigeria, reveal a pressing need for research into IMS – research that takes into consideration a range of factors that define the state of healthcare delivery in a particular society. These factors as noted above include but are not limited to the availability of human resources in healthcare, financial and geographical accessibility of healthcare facilities, wait times, and payment modalities; others include patients’ preferences and values and the impact of these on the clinical effectiveness of the intervention, and practitioner-patient relationships and how these influence the effect of the intervention.

419 Ibid.
420 Jonas, supra note 405 at 134.
421 Giarelli, supra note 24 at 69.
Although governments continue to direct healthcare expenditure to biomedical forms of care, there is a growing body of evidence to show that high budgetary allocation to this form of healthcare cannot displace health maintenance, preventive care and primary healthcare. Although indigenous medical systems are also curative forms of medicine, they are predominantly well suited to provide preventive and primary healthcare, especially at the grassroots level. The various types of evidence derived from the Nigerian study provide the rationale for the efficiency of IMS in the primary healthcare context; simply stated, the rationale for IMS’s success in the primary health context include its geographical proximity to community members, low cost of care, the existence of a high number of practitioners regularly on duty comparative to the number available in biomedical healthcare centres, and in some cases, the value-based payment schemes for the products and services. These forms of evidence (and indeed the totality of the different types of evidence studied above) provide compelling grounds for changes not only in government policy and legislation, but also in the judicial approach on the subject. In fact, as this chapter has argued, the current approach to healthcare regulation, which privileges specific types of evidence considered ‘scientifically valid’ by both governments and judiciaries, has a significant implication for ethical principles of justice. According to Jonas:

> From the clinical perspective, the ultimate goal of all of these domains of knowledge is the identification of optimal medical management... Progress of an intervention from investigation to evaluation to validation requires a research strategy that provides a balanced portfolio feeding all of these knowledge domains. *Excessive focus on one domain to the neglect of another will likely impede progress toward validation, violate the moral principles of justice and respect for persons, and may result in harm when applied to chronic disease and complex treatment systems.*

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Therefore, it is not enough for the courts to acknowledge the evolution in the healthcare landscape and simply express the need for parliament to make changes at some undetermined date to fit with current trends in healthcare delivery and usage. With knowledge of this range of evidence, there is a critical need for the courts to rule on the lapses in the present decision-making process and the inequitable nature of the resultant rules. While the task of legal reform ultimately lies with the legislature, court judgments that make pronouncements on the patently...

unfair provisions of the law and on the undemocratic decision-making processes that produced the law are likely to lead policymakers to initiate the necessary protocols required to generate the needed evidence for the regulation and integration of IMS. Although the court in Davar v. R., and Pagnotta v. Canada fell short of pronouncing a specific directive for policy reform, the words of Miller, J. aptly capture the urgent need for reform. In Davar, Justice Miller stated that:

While this Court has interpreted these laws liberally and compassionately, the Court cannot turn a blind eye to the real and exact meaning of the law, no matter how unfair the taxpayer believes it to be ... Sometimes the law leads society in a certain direction, but often times societal behaviour leads the law. In the case of medical expenses, it is a matter of the law eventually catching up to society's behaviour and I am hopeful the legislators will do that. They, however, are not there yet regarding the types of alternative treatment expenses you seek. You must appreciate it is not for me to rewrite the legislation. But by bringing your concerns to this Court, you will, as many others have, make the legislators aware of your concerns regarding alternative treatments. I appreciate your effort in doing this, but I cannot allow your appeal.423

Justice Miller’s dicta in Pagnotta again implicitly reveal knowledge of the disparity between consumers’ values and expectations and legislative provisions:

The overall impression left by Drs. Papp and Aung regarding the use of alternative medicines, otherwise known as complementary medicine, or as Dr. Aung would suggest, “integrated” medicine (a combination of western and Chinese methods) was that North American society is in a transition stage from non-acceptance of anything other than the traditional western methods of medical practice to an acceptance of a wide variety of alternative methods. This is especially so in patients who suffer long term chronic pain as does Mrs. Pagnotta. We have seen in recent years the growing trend of patients who turn to acupuncture, chelation, nutrition, massage and other non-traditional forms of treatment. The issue is whether the terms of the Income Tax Act, as they pertain to medical expenses, can be interpreted as written to accommodate this emerging form of health care, or whether the legislators must acknowledge what is occurring in the world of health care and make appropriate legislative changes.424

These extracts from the judgments reveal that the courts are often convinced of the unfairness of the current state of the law. The courts have also conceded that the law does not reflect contemporary trends. Hence, it is troubling that the judges hold themselves bound by the literal meaning of the law, especially considering that the legislative intent to protect the health and health economy of Canadians can still be achieved through the type of functional interpretation

423 Davar, supra note 17 at paras. 6 & 8. Emphasis added.
424 Pagnotta, supra at 304 at para. 15. Emphasis added.
adopted by the court in *Ray v. R.*\(^{425}\) The interpretation adopted in *Ray* did not seek to *change* the existing rule; it only sought to give effect to the objective underlying the rule by accepting a ‘receipt’ issued by a pharmacy to satisfy the “recorded by a pharmacy” rule in a situation where every other statutory requirement, including the unstated condition of safety and efficacy of the therapy, had been met.

Unlike the Canadian judicial position, some US courts that have acknowledged that medicine is always evolving have extended the meaning of specific terms used in the law to protect consumer’s use of ‘alternative’ healthcare. For example, some US courts have extended the concept of ‘medical necessity’ beyond its biomedical origins.\(^{426}\) The concept of medical necessity, which favours healthcare services and products administered or prescribed by biomedical practitioners, has been employed in many cases by insurance companies to deny reimbursement to patients who use alternative or new healthcare products and services on the ground that the products and services utilized were not medically required. In the US case of *Shumake v. Travelers Insurance Company*\(^{427}\) where a cancer patient sought reimbursement for expenses on laetrile, the court chose to interpret ‘medically necessary’ liberally such that the term could encompass a range of treatments that may deviate from the standard of care recognized in biomedicine. The insurance policy in dispute allowed payment for “covered medical expenses” that were “necessarily incurred”. Covered medical expenses were categorized as costs incurred on the recommendation and approval of the attending physician, which were “required in connection with” the patient’s treatment.

In determining the meaning of “necessary”, the court examined a number of cases, and concluded that the term was ambiguous because it could mean “appropriate,” “wise in light of facts known at the time rendered,” and “reasonably calculated to shorten and relieve an ordeal of agonizing pain and thereby effectuate the most rapid recovery possible”.\(^{428}\) A broad range of

\(^{425}\) See *Ray*, supra note 305 and the discussion of this case in section 3.4.3, *supra*. See also *Pagnotta and Frank*, *supra* note 304.


\(^{427}\) Ibid.

\(^{428}\) *Abernathy v. Prudential Ins. Co. of America*, 274 S.C. 368, 264 S.E. 2d 836 (1980) (“necessary treatment” was described as appropriate treatment); *Victum v. Martin*, 367 Mass. 440, 326 N.E. 2d 12 (1975) (“necessary” was stated to mean “wise in light of the facts known at the time rendered”); *McLaughlin v. Connecticut General Life Ins., Co.*, 565 F. Supp. 434 N.D. Cal. 1983 (“necessary care” was equated with care that is to an extent beneficial to the patient); and *Group Hospitalization, Inc. v. Levin*, 305 A. 2d 248 C.D.C. App 1973 (“necessary” implied “reasonably calculated to shorten and relieve pain and effectuate the most rapid recovery possible”).
medical treatments could conveniently come under any of these meanings. Based on the ambiguity of the term and on the absence of a provision entitling the insurer to determine what constitutes medical necessity, the court opted to defer to the physician’s prescription and interpreted the term in favour of the patient. The insurer was ordered to reimburse the patient for the cost of his laetrile treatment for cancer. Effectively, the court extended the standard of care in medical treatment to a range of treatments that were at least accepted by “a strong and viable minority” of healthcare practitioners irrespective of the fact that the “weight of authority” might oppose the choice of treatment.\footnote{Shumake, supra note 426 at 262.}

It is important to reiterate that the judicial attitude exemplified in Canadian case law accords with the general low threshold of responsibility which the courts are generally deemed to have in health policy matters. This, of course, is because health policy decisions are deemed technical decisions, which the government with its array of medical and economic experts can best handle. However, although the role of the law and of the courts have often been “underestimated” by those who make health policy decisions,\footnote{C.M. Flood, “Introduction” in Flood et al., supra note 16 at 11.} yet law and legal institutions can and often do “exacerbate and ameliorate unfair or unprincipled allocation decisions”.\footnote{Ibid.} As Flood\textit{ et al.} have noted, “[I]law and legal institutions can be both barriers and facilitators to an equitable and efficient health care system”; for example, the \textit{Canada Health Act} privileges and skews public funds towards hospital and physician services while neglecting some other types of care such as community care, public health, and preventive care.\footnote{Flood\textit{ et al.}, supra note 16 at 35.} Similarly, Nigeria’s \textit{National Health Act} directs healthcare resources towards biomedical services and products and makes no provisions for the type of community-based and preventive care that is crucial to primary healthcare.

Hence, although “law can be a powerful force, entrenching values and protecting entitlements, it can also result in inflexibility and present barriers to reform if it fails to keep pace with changing technology, expectations, and health care needs”.\footnote{Ibid.} Evidently, extant laws that impede access to IMS constitute significant barriers to integrated healthcare. Where consumer-litigants are unable to meet the technical requirements of a constitution- or Charter-
based argument on discrimination, the court can help alleviate the present frustration among consumers by identifying the inequitable nature of impugned laws and applying a functional interpretation of the law to the experiences of healthcare consumers. This does not require the court to overlook the need for evidence; on the contrary, it mandates the court to adjudicate based only on valid and comprehensive evidence. Presently, the courts’ decisions are not based on any such evidence.

Ironically, while the courts and policymakers consistently uphold the supremacy of evidence-based medicine, studies in Northern nations have shown that about 30%-40% of physician recommended services lack evidence of effectiveness or have very little convincing evidential base to support their therapeutic claims. Although, it is hardly disputable that evidence is necessary, the importance of values and consumer interests in health policymaking also cannot be discounted. Flood et al. have noted the importance of values and consumer participation in healthcare decision-making as well as the conflict that may sometimes exist between these two elements on the one hand and the need for evidence on the other hand. According to the authors:

Indeed, there may not be good evidence for the kinds of care that citizens value. For example, caring services and palliative care are difficult to measure in terms of health outcomes, as are traditional healing practices and treatments. Also difficult to measure is the extent to which patients are treated with respect and dignity and in accordance with their culture. The importance of values is increasingly being recognized, as is the idea that citizens need a voice in governance structures and are no longer content to assume that governments or physicians sufficiently represent the public interest in these matters.

The judgments of Canadian courts on integrated healthcare practices among patients and practitioners reveal that there has been little or no consideration of the importance of consumer values and public interest in the policymaking process.

It is, therefore, no over-amplification of the courts’ attitude to conclude that the courts have unduly fettered their power to ensure fairness and public participation in healthcare

435 Flood et al., ibid at 34.
decision-making. Specifically, the courts have failed to consider the range of factors that policymakers need to consider while making decisions to fund or reject a healthcare modality. Granted that the court is not equipped to make certain determinations regarding cost-efficacy or resource availability amongst others, yet the court can highlight the significant gaps inherent in extant policies while ruling on the necessity for policymakers to evaluate the important parametres before making the serious decision to enlist or delist a healthcare service. In ignoring the lapses in the policy-making process and upholding legislative provisions based on an unfair decision-making system, the court condones inequity.

Fairness requires that a number of actions and considerations should be part of a system of policymaking. First, the decision-making process, which (as noted in the Canadian and Nigerian examples) is closed to the public, must welcome consumer input. Beyond simply ensuring that the process is transparent, in which case the public needs to know how and on what grounds decisions are made, it is also important for the decision-makers who control the process to take into consideration consumer healthcare behaviour. As part of this initiative, policymakers need to support more studies on alternative therapies while engaging researchers in parts of the decision-making process to ensure that health research is used in policymaking. The court can ensure public participation in healthcare decision-making by providing a ruling not only on the injustice inherent in the current decision-making process, but also on the need for a restructuring of the system. Second, equity requires that proper considerations are incorporated into healthcare decision-making. The case law reveals that the courts have often relied on unsubstantiated presumptions about the (in)efficacy and (lack of) safety of indigenous therapies, and these presumptions are framed as “pressing and substantive” legislative objectives.

Rather than tailor its judgment restrictively along a science-is-law paradigm, the court should concern itself with ensuring that impugned legislations have been promulgated based on a comprehensive, evidence-based analysis of relevant considerations in the enlisting, delisting or integration of specific therapies in the healthcare scheme. For example, questions that need

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437 See chapter 6, infra, for a further discussion of this. Chapter 6 argues that while consumers may have failed to convince the court that the extant rules are discriminatory, the Canadian courts in fulfillment of their obligation to ensure fairness in health policy-making can find that the rules are in breach of s.7, the fundamental justice clause of the Charter.

to be asked include whether a safety/efficacy study of a specific treatment has been carried out; whether a comparative cost-identification/effectiveness/utility/minimization evaluation of IMS and their biomedical counterparts have been undertaken to rule out or confirm presumptions about the alternative treatment. Where cost-effectiveness data provides positive results for the new treatment, has the policymaker weighed the available resources (limited resources being a frequent argument against funding new therapies) against the overall benefit of the therapy and its value to consumers?

Furthermore, is it possible that funding the therapy will have overall long term cost reduction value for public expenditure? Even where utility results are not overly impressive relative to the biomedical alternative, has the policy maker considered the likelihood that the new modality, while not as optimal as its biomedical counterpart, may reduce the long wait times and pressure on physicians? In the case of Southern nations where human and technological resources in healthcare are limited, has the policy-maker considered the long term benefit of funding non-technological, preventive or basic primary healthcare that is easily available through the significantly large number of indigenous medical providers in the society?

Have demographic factors, especially regarding the preferred choice of treatment in a particular locality or among a particular group of consumers been considered? Has the policy-maker considered geographical or financial access to healthcare or the general availability of some biomedical services and products in certain localities? Should the evidence (anecdotal and scientific) that some indigenous therapies outperform their biomedical alternatives not be a significant indication that delisting some extant services and enlisting new therapies might be fiscally and medically expedient?

These are only some of the crucial questions which policymakers must address, and the courts can assist in ensuring that due consideration is given to these questions by ruling unequivocally on the inequitable state of the current legal and policy framework. Regrettably, the majority of these questions cannot be answered by recourse to an RCT-based methodology or to the EBM paradigm which, as presently conceived, narrowly measures acceptable evidence through the RCT. The court needs to reach definite decisions and make pronouncements that would highlight the difficulties encountered by alternative healthcare consumers and, hopefully, this would lead the government to consider not only the safety/efficacy evidence for new and emerging therapies, but also to weigh the evidence from clinical trials alongside existing
demographics in healthcare delivery. For example, where RCT results show the efficacy or utility ratio for an indigenous therapy to be nearly equal to that of its biomedical counterpart designed for the same medical condition, is it expedient for the government to refuse to list this product if the following cumulative elements exist:

1. The therapy is safe and provides an acceptable level of relief for patients.
2. In the case of Southern (or even Northern) countries, there is scarcity of biomedical doctors to provide the biomedical counterpart or –
3. In the case of both Southern and Northern countries, the biomedical counterpart is unaffordable by the majority of health consumers.
4. The new or indigenous therapy (even though less effective than its biomedical counterpart) is far less expensive, less invasive and sufficiently ensures less reliance on expensive technological care.439

While this kind of analysis is not the task of the courts, the court’s responsibility is to ensure that those equipped to do so carry out such analysis in the interest of health equity. The courts have an important responsibility to check governmental policymaking (which increasingly emphasizes “the objective of restraining government spending” while declaring interest in cost-effectiveness) “that may unlawfully discriminate against marginalized and vulnerable groups of people”.440 A clearly worded judgment that recognizes the injustice inherent in the current disparity between law/policy and societal values/expectations is imperative, and will speed up the much-needed legislative reform.

It is important to recall, however, that some IMPs and ‘alternative’ healthcare practitioners remain wary of RCT trials and economic evaluations of indigenous healthcare services and products because of the belief that evidence of medical and economic benefits may lead to increased pressure to standardize plant-based medicines and nutritional supplements in line with the biomedical approach. There are concerns that such positive evidence may be used

439 See Gemme v. Goldberg, 626 A.2d 318 (Conn. App. Ct. 1993), a U.S. case on informed consent where the court stated that a jury can determine that a physician is in violation of his duty to inform if he failed “to disclose a viable alternative that might have produced a less perfect result but may have represented a safer or less invasive procedure”.
440 Flood et al., supra note 16 at 30.
for the purpose of third party reimbursement which would reduce the autonomy of IMPs.\textsuperscript{441} Many practitioners are content with the rising expenditure on IMS.\textsuperscript{442} It is believed that the managed care model in biomedicine could radically alter the manner in which indigenous healthcare is paid for and practiced “by decreasing the use of multidimensional multicomponent interventions, by institutionalizing care into conventional health care systems, and by limiting the individualization of care”\textsuperscript{443}

While these concerns are legitimate, many other IMPs are taking advantage of a rapidly globalizing world where medications need to be packaged for retail to reach a larger population. Data from Nigeria suggests a gradual trend towards standardization of plant-based medicines in spite of legitimate worries about the process of standardization. The available data reveals that many practitioners have retained an individualized form of practice while standardizing their therapies. The next chapter examines the science and intellectual property debate at the root of the dissatisfaction with formal standardization and governmental supervision.

\textsuperscript{441} S.L. McKernan, “Why Naturopathic Medicine Should Not Embrace the Managed Care Model in Medicine” (2007) 7 Journal of Naturopathic Medicine 65-66; see also Herman et al, supra note 232 [‘McKernan’].
\textsuperscript{442} Recall that out-of-pocket expenditure on CAM in the U.S. exceeds $34 billion annually regardless of the absence of studies indicating safety and efficacy of many of the products and services: Herman et al., supra note 232.
\textsuperscript{443} McKernan, supra note 441.
CHAPTER 4. SCIENCE, LAW AND THE (MIS)CONSTRUCTION OF KNOWLEDGE OF PLANT GENETIC RESOURCES IN THE INTERNATIONAL PATENT REGIME

Farmers’ fields and forests are laboratories. Farmers and healers are researchers. Every season is an experiment.

The Crucible Group.¹

4.1. Introduction

The last chapter discussed the implications and role of science and the evidence-based medicine (EBM) paradigm in the regulation of indigenous and alternative medicines. It was noted that some indigenous medical practitioners (IMPs) are skeptical of the process of scientific validation of indigenous therapies. For many practitioners in Canada, this skepticism is founded on the belief that evidence of medical and economic benefits may result in the standardization of plant-based medicines and nutritional supplements along the frameworks of biomedical products. Professionals are concerned that the statutory regulatory framework, which is based on a scientific model of regulation, does not recognize the inherent differences between indigenous medical systems (IMS) and biomedicine.² Such a model of regulation is deemed capable of reducing the autonomy of alternative healthcare practitioners in Canada, while empowering third party payers and biomedical practitioners to dominate the practice of indigenous medicine. Thus, it was not surprising when practitioners in Canada opposed Bill C-51, an Act proposed to amend the Canadian Food and Drugs Act and other statutes, which was interpreted as an attempt by the government to regulate natural health products as prescription drugs.³

¹ The Crucible Group I, People, Plants and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society (Ottawa: IDRC, 1994) at xviii.
² See the submission made by the Chinese Canadian National Council (CCNC) in their response to the Parliamentary Standing Committee on Health, entitled “Access to Multicultural Health: The Rights of Consumers of Chinese Herbs and Herbal Products” cited in Frank D. Tall v. The Queen, 2005 DTC 1782. The CCNC applied to intervene in this matter.
A similar oppositional stance is evident in Nigeria. In that country, IMPs have opposed the standardization of natural health products on the ground that the process will enable third party interests to capitalize on the research and inventions of the practitioners. These investors include national and international pharmaceutical corporations, independent local and international researchers and institutes, and even the government. While, like their Canadian counterparts, Nigerian IMPs are concerned about loss of autonomy to practice in a holistic fashion, they are also concerned that the scientific regulatory process will result in a loss of trade secrets to third party interests. The latter concern is aggravated by the lack of intellectual property protection for natural health products. The practitioners are of the view that the existence of intellectual property protection for these products would prevent the loss of trade secrets. Interviews conducted with practitioners in both Canada and Nigeria reveal mutual concerns that the interrelationship between biomedicine, the managed care model of healthcare delivery, and the pharmaceutical industry’s mercantilist handling of scientifically validated products through the monopoly of patents forms a tripartite obstacle to formal standardization and development of IMS.

This chapter examines the science and intellectual property debate at the root of these concerns. The chapter analyzes the connections between science, the regulation of indigenous medicines based on the EBM methodology and the intellectual property law controversy regarding indigenous medicinal knowledge. With specific focus on the role of science in the construction of knowledge systems in international and national patent laws, the chapter examines how (a fixed and culturally-specific notion of) science functions as an instrument for determining which innovations or ‘creations’ (to use a value-neutral term) can be legally recognized under the Intellectual Property Law regime (IPL). It is evident from the transplantation of the West’s IPL norms to other nations that knowledge and property in most national laws is constituted by a set of science-based legal norms drawn from the Western legal tradition, which also governs IPL at the international level. While national IPLs are not universally identical, yet IPLs share a common origin located within a culture that places reducible and quantifiable forms of knowledge above other cultural forms of knowledge.

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bill, see Criticism of Natural Health Products Bill C-51 Mounts, online: CBC News <http://www.cbc.ca/health/story/2008/05/09/bill-c51.html>.
In a 2002 survey undertaken by the World Intellectual Property Organization (WIPO), it was observed that nine out of twenty-one states surveyed currently have no property right protection for indigenous knowledge.\(^4\) The IPL discourse is relevant to this thesis because of the central role it plays in (dis)enabling a medical integration agenda at the national level, with particular regards to its influence in the food and drug agency’s scrutiny of indigenous medicinal products. Specifically, the IPL discourse has taken centre stage in some jurisdictions, such as Nigeria, where indigenous/herbal medical practitioners have cited the absence of intellectual property protection (specifically patent protection) for indigenous medicines as a significant barrier to their active participation in the drug review process requested by the country’s National Agency for Food and Drug Administration and Control (NAFDAC). This process requires indigenous medical practitioners (IMPs) to outline the constituents of their herbal and medicinal products. The general opinion, as research conducted in Nigeria reveals,\(^5\) is that information disclosed to the relevant regulatory agency may be appropriated by both national and international interests for commercial purposes. Further, such appropriation may result in a co-optive approach to indigenous healthcare delivery which will involve the delivery of indigenous medicine by biomedical practitioners. Canadian IMPs hold a similar view that the regulation of natural health products as prescription drugs will result in what will be more or less a co-optive model of alternative healthcare delivery.\(^6\)

There are vivid examples of how the alleged appropriation of indigenous knowledge and the concomitant rejection of indigenous epistemology as unsuitable for juridical protection have played out in the national and international scenes. In one incident, Nigerian farmers developed an insect-resistant cowpea, which was not published in any peer-reviewed journal.\(^7\) Specimens of the cowpea seeds were ‘discovered’ by Angharad Gatehouse, a scientist at the University of Durban when he visited West Africa. Employing ‘standard’ Western techniques, Gatehouse


\(^6\) Criticism of Natural Health Products Bill C-51 Mounts, supra note 3. See chapter 5 infra for a discussion of the legal and ethical problems with ‘co-optation’ as a model for governing medical pluralism.

\(^7\) Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants and Indigenous Knowledge* (Vancouver: UBC Press, 2005) at 14 ['Mgbeoji, Global Biopiracy'].

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“identified in “scientific language” the genetic mechanism that causes the locally developed cowpeas to be insect-resistant”.\(^8\) Based on his ‘significant discovery’, Gatehouse left the University of Durban and joined the Agricultural Genetic Company of Cambridge where, in collaboration with the company, he applied for a patent over the ‘invention’.\(^9\) This and numerous other examples provide the factual background to the fears expressed by IMPs in Nigeria. The favoured approach to resolving this controversy between the regulators/bioprospectors and the IMPs is to reform the local patent law to protect the interests of the latter.

This chapter examines the feasibility of this proposal against the international law and scholarship on the subject. In order to provide a clear picture of the legal issues involved in the debate and how they relate to the regulation of natural health products and the integration of IMPs within the national healthcare system (NHS), the first section introduces the connection between the regulation and integration of plant-based medicines within the NHS and the absence of IP protection for plant-based medicines. The second section of the chapter discusses the issues at the core of the debate at the national and international levels. The section also discusses the concept of biopiracy which has been coined to capture the alleged appropriation of the South’s medicinal knowledge of plants by Western bioprospectors. The third section analyzes the legal requirements for patentability as outlined in the extant international intellectual property law on the subject, the *Trade-Related Aspects of Intellectual Property Rights Agreement* (TRIPS Agreement).\(^10\)

Section four examines the linkages between the charges against the TRIPS Agreement and post-colonial discourses. The interlinking narratives between the TRIPS Agreement and colonialism constitute a historical platform for understanding the concerns of indigenous innovators and healthcare providers. One aspect of this historical discourse relates to the disparities in the conceptions of knowledge and property between the North and the indigenous communities of the South. Section five addresses how science filtrates what counts as property. It highlights the central role that science, in its subjective definition as a creation of the West,

\(^{8}\) *Ibid.*


has played in delineating and delimiting what knowledge counts as innovative and, therefore, legally valid, at the world stage.

The section also examines the trend of the discourse by both Western and Southern academics on the nature of indigenous medical knowledge. Specifically, the section debunks the commonly held assumptions that IMS is ‘traditional,’ unoriginal and public domain knowledge possessed by all community members. These views negate the core requirements of patentability stipulated in the TRIPS Agreement. Section five analyzes these views against the progressive changes, and lack of homogeneity, in the concept of property in many indigenous communities, which the scholarship barely acknowledges. This aspect of the analysis draws insights from research conducted in Nigeria. The opinions of IMPs and data outcomes of a poll of 220 patrons of IMS on their knowledge of indigenous medical practice are pooled together to show that the perceptions of consumers and practitioners in at least four Nigerian urban and rural communities differ from that superimposed on them by the scholarship. The chapter concludes with a discussion of the options for the legal protection of indigenous therapeutic knowledge, and identifies some key questions that Southern states must address.

4.2. Intellectual Property Law and the Regulation of Natural Health Products (NHPs) in Canada and Nigeria

Federal Food and Drug Agencies have the responsibility to regulate medicines, foods, nutritional supplements, and natural health products. According to the Canadian Natural Health Products Regulations, natural health products (NHPs) include “vitamins and minerals, herbal medicines, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids”. NHPs are required to be safe for over-the-counter sale without the requirement of a doctor’s prescription. However, drugs or healthcare products requiring prescription (with the exception of

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11 Iyioha, International Research, supra note 5.
12 Natural Health Products Regulations (effective January 1, 2004), established under the Food and Drugs Act (R.S., 1985, c. F-27).
13 Ibid.
homeopathic medicines) are regulated under the Canadian Food and Drugs Act. Generally, the Food and Drugs Act regulates foods, drugs, cosmetics and therapeutic devices in Canada. The Canadian Food and Drug Regulations established under the Act stipulate the acceptable standards of composition, strength, potency, purity, quality and other property of the food or drug to which the regulations refer.

Bill C-51, the proposed amendment to the Food and Drugs Act and other statutes, introduced stringent standards for the regulation of NHPs and higher fines for violation of the law. While the standards were not much different from those under the extant Food and Drugs Act, the dissension of alternative healthcare practitioners in Canada was based on the fact that the proposed bill substituted a new term ‘therapeutic products’ in place of ‘drugs’, which had hitherto been employed under the old Act. According to the Bill, a therapeutic product is:

(a) a drug,
(b) a device,
(c) cells, tissues or organs that are distributed or represented for use in
(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, or
(ii) restoring, correcting or modifying the body structure of human beings or animals or the functioning of parts of the bodies of human beings or animals, or
(d) a combination of two or more of the things referred to in paragraphs (a) to (c);

By definition, this provision includes natural health products.

According to Lyle MacWilliam who served on Health Minister Allan Rock’s 17-Member team which set up the Office of Natural Health Products (now Natural Health Products Directorate), the proposed bill contained “good recommendations” when examined “under the lens of the drug industry, the pharmaceutical model”. However, when examined under the model of the natural health product, the bill places “natural health products that are much safer

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15 Food and Drugs Act, R.S., 1985, c. F-27. These products are listed under Schedule F of the Food and Drugs Regulation, C.R.C., c. 870.
16 Food and Drugs Act, Ibid.
17 The Food and Drugs Regulation, supra note 15.
18 Ibid, A.01.002.
19 See section 6, Bill C-51, supra note 3.
than drugs under a regulatory environment that is very stringent”.21 Linking these concerns to the absence of IP protection for NHPs, MacWilliam asserted that the intention of the big pharmaceutical companies was to limit access to NHPs based primarily on the fact that these products cannot be patented in their natural form. Arguing that in the absence of patenting rights, “there is no profit in it for the drug industry”, MacWilliam concluded that the bill was the result of “lobbying effort on behalf of big pharma”.22

In an interview conducted with Kiem Schutter, R.Ac., the clinical director of the Qi Integrated Health Centre in Vancouver as part of this research, the above views were reaffirmed. According to Schutter, “there was no clear definition of how [the new law] would be implemented. It was too grey. It left it open to too much interpretation in terms of what is a natural health product”.23 Schutter also highlighted the pharmaceutical corporation’s interest in monopoly and patents and the risks this interest poses to natural health products in Canada. The implication of the above views is that to comply with the provisions of the new law, Canadian IMPs would have been pitted against the big pharmaceutical companies. However, the lack of IP protection for natural health products meant that the IMPs would have had no huge monopoly profits to invest in clinical trial tests.

In Nigeria, the manufacture, distribution and advertisement of medicines, foods, and related products is the task of the National Agency for Food and Drug Administration and Control (NAFDAC). Generally, drugs are clinically tested to establish their safety, efficacy and quality, and the evaluation process usually requires that the drug manufacturer provide information about the product.24 Section 8 of the Drugs and Related Products (Registration, etc.) Act, 2003 (as amended) empowers the Agency to approve guidelines for the regulation of NHPs.25 The primary objective of the guidelines is to ensure the quality, safety, and efficacy of herbal, medicinal or other natural health products.26

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21 Ibid.
22 Ibid.
23 Iyioha, International Research, supra note 5.
26 Dora Akunyili, “Registration and Regulatory Requirements for Production and Marketing of Plant Based Medicines”: Paper presented by the Director General of the National Agency for Food and Drug Administration
The evaluation process for most NHPs is subject to less-stringent standards than those applied to pharmaceutical drugs. While elaborate tests, which include clinical trials and detailed product analysis, are reserved for the more complex medicines produced for the management of terminal illnesses, the Agency grants a “Listing status” to NHPs that have met some basic requirements. The primary requirement for this status is that the specific herbal product must pass the acute toxicity test; applicants must also provide evidence of efficacy by documentations or oral report from long usage, laboratory evaluations, and expert opinion on the product to establish that the product is safe for use. To satisfy these conditions, the product manufacturer must necessarily disclose the constituents of the medicine. Evidence from Nigeria reveals that many IMPs are opposed to these obligations under the *Drugs and Related Products (Registration, etc.) Act, 2003 (as amended)* based on apprehension over the possible appropriation of their knowledge by national and international pharmaceutical companies for the creation of new, patentable drugs over which the latter could exercise monopoly rights.

According to the Nigerian Federal Government in a statement issued through the Federal Minister of Health and the NAFDAC, medical integration would not be possible until the secrecy surrounding the practice of indigenous medicine is addressed. The government explained that while the indigenous medical sector is indispensable to the Nigerian healthcare system, the “inability of the practitioners to effectively disclose the actual contents of their products [arising from the] inadequate intellectual property rights laws and legislations have affected its integration in the health system of the country”. Interviews conducted with IMPs in Edo State, Nigeria confirm this concern. As indicated below, the views of the IMPs were affirmed in an interview with one Canadian Naturopath.

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27 In its regulatory procedure, the Agency considers “the long usage of herbal medicines…, the WHO recommendation to accept herbal products based on long history of safe use in a locality,” and the “positive placebo effect of some herbal medicines”: Akunyili, *ibid*. The process is designed to encourage herbalists and other practitioners to seek the Agency’s approval for therapeutic products.


4.2.1. Practitioners’ Views Regarding IP Rights and the Regulation of NHPs: Interviews with Nigerian IMPs

Interviews were conducted with four Nigerian IMPs in Edo State, Nigeria to elicit the practitioners’ reasons for their oppositional attitude towards the NHP regulatory process. The practitioners were interviewed on six IP-related questions. The questions inquired into the following issues: (1) the existence of special recipes or formulas for NHPs; (2) whether there is wide-spread lay or non-professional knowledge of the recipes; (3) the production cycle for NHPs; (4) disclosure of the constituents of NHPs to researchers or government personnel; (5) the oppositional attitude towards NHP regulation by the National Agency for Food and Drug Administration and Control (NAFDAC); and (6) the prospects of intellectual property protection for NHPs. The questions formulated on these issues were designed to elicit answers to commonly debated questions about the character of indigenous medicinal knowledge. The practitioners provided very brief answers to the question regarding the typical production cycle for an NHP. This was not surprising given the researcher’s background knowledge of their inhibitions about disclosing trade secrets. The first two questions (relating to the existence of special recipes or formulas for NHPs, and to lay or non-professional knowledge of the recipes) are addressed in the latter part of this chapter under section 4.5, which discusses the role of science in the construction of innovative knowledge. The sixth question is addressed in the concluding section of this chapter.

Questions four and five, which are in focus under this section, were framed as follows:

Question 1: Would you readily disclose the medicinal ingredients and process of producing your medicines? Would you readily enlighten an inquisitive person, researcher or government personnel about how you achieve your cures? If no, why not?

Question 2: If you provide full details of the products to NAFDAC, do you [think] this information is protected? Do you think an outside person or body who has access to it might use it illegally to reproduce your medicinal products?

According to one IMP who has 56 years of experience as an indigenous healthcare provider:30

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30 Interview conducted with Ehinoma Aiguobarueghian, a Nigerian IMP, obtained from ‘Iyioha, International Research’, supra note 5.
In the early days, our parents and elders would readily disclose the ingredients and process of producing medicinal products, because no [payment] or any form of gratification was made for services. But, today, herbalism is now a monetary profession. Factually, an inquisitive person, researcher or government personnel will only get peripheral information except it is rooted on a financial contract.

The research has undertaking of confidentiality; generally, no herbal traditional professional discloses full details of his or her medicinal constitutions to NAFDAC officials because they often trade such information to other people for financial benefits.

In the above quotation, ‘other people’ primarily denotes bioprospectors, researchers and members of the pharmaceutical profession.

Indeed, it is noteworthy that at the root of the problem of secrecy is the distrust that exists between indigenous medical providers and biomedical and pharmaceutical practitioners. Fr. Anselm Adodo, a Catholic Monk and director of the Pax Herbal Clinic and Diagnostic Laboratories who is arguably one of Nigeria’s leading proponents of indigenous medicine outlines the problem as follows:

It is said that Traditional practitioners are too secretive, and hide their knowledge so that others won’t profit from it. … Why would a traditional healer hand over his time-tested formulas to a ‘professional’ that will develop it and use it to make profit, and repay him with insults?

Our health care professionals treat Traditional healers as inferior, illiterate, ignorant, fetish [the list is endless] and still expect them to cooperate with them. …

The fact is that there must be an appropriate provision for intellectual property rights before traditional healers can disclose their knowledge. Until this is done, traditional healers will be justified in keeping their secret to themselves, just as the Coca cola Company, Guinness PLC, and others have kept their formulas secret.31

Another IMP who holds a Bachelors Degree in Microbiology from the University of Benin laid out the problem in the following words:32


32 Interview conducted with Musa Osahon, a Nigerian IMP, obtained from ‘Iyioha, International Research’], supra note 5.
No. I would not disclose my medicinal plants or the ingredients to anybody except on a contract basis or there is a law in place which can [prevent] the ingredients being used by another person without my permission.

… I have learned that some professors and lecturers who have the money to refine the products … [for] the market will go down to the herbal doctors and ask them questions about their products and at the end of the day, they will take the product probably to the government; and the family where that product comes from would not be recognized – meaning someone comes from nowhere and the research one has been working on over the years … somebody else comes and [adds] a minor touch and the glory goes to him.

On whether he would be willing to disclose the constituents of the products to the government for regulatory purposes, this IMP replied:

If we provide the full details to NAFDAC, we are selling our birthrights to outsiders …

I would be ready to enlighten the government on how to achieve the cures, but it will be based on an agreement, a contract that the products will not be used for any other thing after disclosure to the researcher.

Some of my products have NAFDAC numbers. … The ones I produce on a contract with other conventional [practitioners] … have NAFDAC numbers … but we did not provide the full details of the recipes. … We provided one or two of what makes up the herbal drugs, but the active ingredients [are] not in the details provided to NAFDAC. … If we provide the details to NAFDAC, they will use it for other things… monetary things to enrich themselves…

Reiterating an opinion earlier expressed by Fr. Adodo, the IMP stated that:

Guinness, Coca cola, and other big pharmaceutical companies do not reveal their formula. All the big pharmaceutical industries … the only way they reveal their formulas to other pharmacies is when what they put in research is being paid back times two or times ten… But in the herbals, there is nothing like this, no assurance that later in the future their research will be paid for... So, it is not protected; it is not advisable … (sic).

In an interview with Canadian Naturopath Dr. Erin Wiley, co-director of the Integrative Health Institute, Toronto, Canada, the above views were affirmed. Wiley recounted her meeting with an African IMP on a trip to South Africa where she went to work in hospices with medical doctors, home care workers, community groups providing HIV education, and indigenous healthcare practitioners. According to Wiley:
There was this one African woman, her name was Mama Kwena … and she was growing plants and she won't let us know what the plants were and what was in her medicinal tea that she was providing for clients… She had set up an HIV hospice. … and her clients were getting well, and not only did she have an hospice, but she was taking on HIV on a community perspective. ... She was providing food; she was making sure those orphans were going to school… She was teaching them life skills as well as taking care of their dying parents and using traditional plant-based medicines as part of the healing process.

The rest of our conversation on the subject is reproduced in Box 4.1 below. Wiley’s account of her conversation with the South African IMP reflects the concerns of Nigerian IMPs regarding a possible loss of their trade secrets if disclosed to researchers, healthcare practitioners, government agencies, and scholars whether local or foreign. The responses to the first two questions reproduced above provide an insight into the pervasive belief among Nigerian IMPs that their knowledge will be appropriated—even if disclosed to only the regulatory authorities. According to the practitioners, the only safeguard against appropriation is intellectual property protection for indigenous and alternative medicines.
<table>
<thead>
<tr>
<th>Question: And did she say why she didn’t want to tell you what was in the medicines?</th>
</tr>
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<tbody>
<tr>
<td>Answer: Obviously, she didn’t want us to take her ingredients…she didn’t want western people coming in to take her secret remedies.</td>
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<tr>
<th>Question: How would one regulate what she is doing if she is not willing to divulge the ingredients of her products?</th>
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<tr>
<td>Answer: I don’t know. It’s all about [where] you value the healthcare. She was providing community health. The healthcare benefits for those orphans with regards to food, clothing, education and love … I mean they far outweigh our traditional sense of what medicine is with regards to – you know, like they give you medicine vaccinating against something; and the fact that the parents felt taken care of while they were dying is medical…</td>
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<table>
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<tr>
<th>Question: Did you watch her make it (i.e. the medicines)?</th>
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<tbody>
<tr>
<td>Answer: No, we didn’t watch her make it…</td>
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<tr>
<th>Question: So, you wouldn’t know the processes involved?</th>
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<tr>
<td>Answer: No, she wasn’t willing to show us that…</td>
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<tr>
<th>Question: They are very convinced that they are putting a lot of hard work into this.</th>
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<tr>
<td>Answer: She was certainly hardworking…</td>
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<tr>
<th>Question: And don’t quite agree that it is just natural plant-based knowledge –</th>
</tr>
</thead>
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<tr>
<td>Answer: No, it’s everything else. And from our perspective, we really did respect where she was coming from. We were quite impressed with the work she was doing…</td>
</tr>
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</table>
4.2.2. The State of the Law at the National Level

The fears expressed by IMPs in the above excerpts are aggravated by the absence of an intellectual property law (IPL) regime that protects NHPs. The extant Nigerian Patents and Designs Act is closely modelled after the Agreement on Trade-Related Aspects of Intellectual Property Rights, which member countries of the WTO are obligated to adopt. As such, the general provisions governing patentable products under the Nigerian Act are similar to those of its international counterpart. According to section 1 of the Act, an invention is patentable:

If it is new, results from inventive activity and is capable of industrial application, or if it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application.  

Thus, NHPs are not patentable under the Act. The Nigerian National Agency for Food and Drug Administration and Control has identified the challenges this state of the law poses to the regulation of NHPs. The Agency has noted that [t]he regulation of “packaged herbal medicinal products and related substances” has been resisted by local practitioners based on fear of losing their “traditional knowledge” and intellectual property rights.

Practitioners wary of appropriation of their medicinal innovations are practicing secretively. Within this guarded practice, neither the concept of medical integration nor indigenous medicine itself can properly evolve to a more standardized system of medical care. This has been a major barrier to medical integration in Nigeria. Even in pre-colonial times, there were concerns about intellectual property rights among IMPs. This is because it spelt the success or failure of indigenous medical practice. Trade secrets have had to be employed in a historical-colonial legacy where new inventions were and still are easily reproducible based on minor modifications of indigenous knowledge. However, trade secrets have become quite ineffective in the face of a globalizing world, coupled with the ease of reverse engineering. Reverse engineering involves “starting with the known product and working backward to divine

33 Patents and Designs Act, CAP 344 LFN 1990.
34 Ibid at s. 1(1) (a) and (b).
36 See Ibid.
the process which aided in its development or manufacture”. A successful integration of medical systems will require a well-regulated indigenous healthcare paradigm involving pre- and post-market monitoring of indigenous pharmacopoeia. The success of the NHP review process in Nigeria is dependent on assurances that an effective intellectual property protection model can provide. Notably, comprehensive texts have been written on the intellectual property and indigenous knowledge debate. Thus, discussions of the debate in this chapter are only to the extent in which they affect medical integration.

4.3. Indigenous Medicinal Knowledge: The Problem at the International Level

Plant genetic resources have acquired a ‘political’ status in international intellectual property law. There is a major debate at the international community regarding whether therapeutic knowledge of plants should have juridical protection. An associated debate dwells on the impropriety of the alleged appropriation of indigenous medicinal resources by Western multinational pharmaceutical companies. As scholars and relevant international organizations explore the boundaries of this issue, it is evident that knowledge and ownership of medicinal plant resources have become the “new frontier” of heated debates between the West and some of its former colonial enclaves.

An aspect of this debate that is yet to be explored is the relationship between the alleged genetic resource appropriation and the development and sustenance of the indigenous medical systems of some Southern nations like Nigeria. Beyond the implications of genetic resource appropriation for the NHP review process already highlighted above, the connection between both discourses also arises in the context of the legal and fiscal implications associated with

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40 Oguamanam, ibid at 3.
bioprospecting. Bioprospecting involves the search for plant genetic resources or natural compounds existing in nature for the purposes of drug production.\textsuperscript{41} Western multinational pharmaceutical corporations engage in bioprospecting in regions rich in biodiversity, utilizing the knowledge and skills of the farmers and IMPs in the production of drugs. Pharmaceuticals developed from bioprospecting are patented and marketed by the corporations at significant profits. Pharmaceutical companies derive more than US$43 billion annually from the pharmaceutical products developed from indigenous medicinal knowledge.\textsuperscript{42}

Major strides in scientific ‘innovations’ in the areas of pharmaceutics and biotechnology “have been linked either directly” to indigenous medicinal knowledge “or indirectly to insights” gained from indigenous knowledge of biodiversity.\textsuperscript{43} Pharmaceutical companies can exercise the rights in the patents obtained over pharmaceutical products derived from bioprospecting against the countries in which bioprospecting was carried out. In specific countries where indigenous medical systems thrive on both the knowledge of the provider and the continued patronage of healthcare consumers, the grant of patents to international and even national firms over pharmaceutical ‘innovations’ based on virtually the same local resources which are contained in the herbal product can arguably pose problems for the indigenous pharmaceutical industry. The argument on this point is significant and deserves some scholarly attention.

‘Indigenous knowledge’ is not an abstract concept. It is a form of intellectual knowledge analogous to a written description of an invention under patent law. While many IMPs with university degrees are beginning to record this knowledge in written form, a greater number of IMPs are only able or prefer to secure the knowledge in oral form. In fact, the patent regime permits inventors to acquire patents based solely on a written description of the invention without creating the product which embodies the invention.\textsuperscript{44} However, while indigenous knowledge equates with a descriptive oral/written analysis of an invention, it is usually embodied in the wide range of healthcare products that help sustain rural, and in many cases


\textsuperscript{42} Darrel Posey and Graham Dutfield, \textit{Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities} (Ottawa: IDRC, 1996) at 95.

\textsuperscript{43} Oguamanam, \textit{supra} note 39 at 5.

urban, healthcare. The presentation and packaging of products of indigenous medicinal knowledge are diverse. As such, the products can and very often resemble Western pharmaceuticals. Given the changes in the concept of knowledge ownership in a Southern state such as Nigeria, which has led to growing interest in formal intellectual property protection by IMPs, the products of indigenous knowledge as they evolve may come to resemble the derivative work.\footnote{Daniel Gervais, “Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach” (2005) \textit{Michigan State Law Review} 137 at 157 [‘Gervais, “Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach”’].} The “perverse” result of this trend will be the application of the IP system against the original work by the progenitors of the derivative work.\footnote{Ibid.} Even where this result does not occur, the argument that medicinal resource appropriation is detrimental to the growth and development of indigenous healthcare remains formidable in the context of the competition which indigenous healthcare providers face against the powerful influence of international and national pharmaceutical firms.

The competition is even more significant considering that in the context of indigenous knowledge systems, knowledge of herbs or plant medicinal resources is not simply a “potential source of new drugs”.\footnote{Abayomi Sofowora, \textit{Medicinal Plants and Traditional Medicine in Africa} (Ibadan: Spectrum Books, 1993) at 105 [‘Sofowora’].} Rather, this knowledge in its varied and creative forms constitutes the key resource in the survival of indigenous medical practice. Once proliferated by powerful pharmaceutical corporations that are able to protect their investment in the finished product through patents, the indigenous pharmaceutical enterprise is left vulnerable in an unfair and capitalist market, where a continuation of practice might imply encroaching on newly created patent rights. Apart from the pragmatic and legal difficulties involved here, there is also a moral problem underlying this state of affairs. This moral issue surfaces when the only distinction between the innovativeness of a product from the South and that from the global North is the packaging.\footnote{Madhavi Sunder, “The Invention of Traditional Knowledge” (2006) \textit{UC Davis Legal Studies Research Paper} No. 75 at 17 [‘Sunder’].} This distinction effectively disappears when the Southern product is packaged like the common drugs and medicines in any pharmacy.

The assumption within both patent laws and the scholarship emanating predominantly from the West is that indigenous knowledge and medicinal plants are \textit{raw} materials for Western drug production. The question traded between the global North and the South is whether these
purported ‘innovations’ can be considered novel products of the Western pharmaceutical companies who hold patents over the drugs; or whether the products are innovations of the IMPs whose expert knowledge of herbs, gained through years of practicing herbalism, led to the discovery of the new drugs. The charge that the West appropriates the South’s biodiversity is captured by the term ‘biopiracy’. Biopiracy, which derives from “biodiversity” and “piracy”, was conceived by Canadian activist, Pat Mooney, to address the patenting of indigenous knowledge by Western pharmaceutical companies without recognition of the contributions of the people who supplied the patented knowledge.49 ‘Biopiracy’ captures the South’s angst over what they believe to be the unlawful appropriation or “pirating” of their natural resources without their due informed consent.50

For the purposes of this thesis, biopiracy implies the appropriation of indigenous healers’ medicinal knowledge of plants by Western and national or local pharmaceutical companies through intellectual property mechanisms. Although national companies have not become a major concern, they are included here because they might eventually come to the fore of the debate as Western corporations reduce their dependency on the South’s bio-knowledge. The classical narrative of biopiracy involves a corporation that produces pharmaceuticals and other medicinal or industrial products through the utilization of expert information provided by IMPs and (herbal) plant breeders in indigenous communities without the permission of the information holders. The term ‘biopiracy’ is pejorative and every conduct brought under its umbrella is hardly unobjectionable.

In the specific context of this thesis, the concern with biopiracy is limited to the intellectual property issues arising from the South’s discontent with the patenting of products derived from the exploitation of their knowledge of medicinal plants. Other strands of the biopiracy debate involving the subsequent mass harvesting of herbal plants within indigenous communities, which implicate issues of national sovereignty, are not within the framework of the present discussion. Although these aspects of biopiracy are interrelated, the specific task in this research is to assess how the therapeutic knowledge of indigenous peoples as well as the

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49 Mgbeoji, Global Biopiracy, supra note 7 at 12.
50 Ibid.
products of that knowledge may be legally protected at both the national and international levels.\textsuperscript{51}

The lack of legal protection for indigenous medicines under international and several domestic intellectual property laws further exacerbates the problem of ‘biopiracy’ and by implication the healthcare crisis in many Southern states. The patenting requirements outlined in the TRIPS Agreement are prohibitive for the majority of indigenous biodiversity experts in biodiversity-rich regions. The TRIPS Agreement’s restrictive requirements that a patented product must be novel, inventive or non-obvious and capable of industrial application have frustrated attempts by Southern IMPs and agriculturists to seek legal protection for the medicinal products which they have generated from their knowledge of biodiversity.\textsuperscript{52} The next section examines the problematic requirements of the TRIPS Agreement in some detail, with references to the similarities between the Agreement and the Nigerian \textit{Patents and Designs Act}.\textsuperscript{53}

\subsection*{4.4. The TRIPS Agreement}

The TRIPS Agreement embodies the rules that govern intellectual property rights in member-states of the World Trade Organization (WTO). WTO Agreements are created from trade negotiations between countries that have vastly different bargaining powers and economic strengths.\textsuperscript{54} These negotiations are often “more of a response to business interests than to social welfare interests”.\textsuperscript{55} WTO Agreements have a significant impact on national policies and domestic laws since they must be incorporated into domestic laws of member-states.\textsuperscript{56} To ensure compliance with TRIPS, member-states that fail to fulfill their obligations under the Agreement may be brought before a trade tribunal. Where it is determined that the country is indeed in breach of its obligations under TRIPS, the “complainant country” with authorization from the WTO can impose trade sanctions on “the offending country in retaliation, including in

\textsuperscript{51} In either case, both of these forms of biopiracy are objectionable as long as the prior informed consent of the knowledge holders was not sought and no contractual agreement was entered into before the exploitation.

\textsuperscript{52} See Art. 27(2) TRIPS Agreement, supra note 10.

\textsuperscript{53} \textit{Patents and Designs Act}, supra note 33.

\textsuperscript{54} Roxanne Mykitiuk and Michelle Dagnino, “The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Implications for Health Care” in Colleen Flood, ed., \textit{Just Medicare: What’s In, What’s Out, How We Decide} (Toronto: University of Toronto Press, 2006) at 309 [‘Mykitiuk and Dagnino’].

\textsuperscript{55} \textit{Ibid}.

\textsuperscript{56} \textit{Ibid} at 309 and 312.
other areas of trade”. The nature of the sanctions is such that the so-called ‘developing’ countries may be subjected to “punitive unilateral sanctions” and isolated from the global trading system if they failed to meet the obligations outlined in the Agreement.

The TRIPS Agreement is a product of concerted lobbying effort led by the United States, with major support from the European Commission and Japan, research-based pharmaceutical companies, as well as the entertainment and software industries. It is the product of power play facilitated through the membership of certain big pharmaceutical companies on a key advisory committee. Public health scholar, Scott Burris has noted that “the use of campaign contributions, public relations, and direct advocacy led the United States to adopt an intellectual property agreement as a key goal of its GATT (General Agreement on Tariffs and Trade) strategy”. The “resultant Agreement reflects neither the interests nor the pharmacopoeic traditions of indigenous peoples”, nor the diverse concepts of property and invention in indigenous communities.

4.4.1. Defining Patents
The patent is perhaps the most discussed instrument among the intellectual property instruments created by law. Apart from the fact that it is the most suitable IP instrument for the protection of pharmaceuticals, discussions of the TRIPS Agreement often focus on patents because of its central role in facilitating the interests that led to the creation of the TRIPS Agreement. A patent may be defined as an instrument “which confers the right to secure the enforcement power of the state in excluding unauthorized persons, for a specified number of years, from making commercial use of a clearly defined invention”. A patent prohibits others from “making,
using, selling, or importing the patented invention without explicit permission or compensation” of the patentee or rights holder. The TRIPS Agreement requires that the rights in the patent to remake, use or make profits from the invention be conferred for a period of 20 years.

A number of reasons have been proffered to explain and support the existence of patents. The dominant view is that patents constitute an economic incentive to encourage innovation. This view, which is one of four leading theories that justify the existence of patents, fits specifically within the ‘Encouragement of Invention Theory’, which posits that inventions are spurred by the grant of patents. Other explanations for the existence of patents are the ‘Natural Rights’, ‘Contract/Disclosure of Secrets’, and ‘Reward’ Theories. According to the ‘Encouragement of Invention Theory’, there is an economic relationship between patents and creativity or inventiveness. This theory suggests that there would be no research and development without patents. However, some scholars have described this view as fallacious as most studies of patent systems have failed to establish a connection between the grant of patents and inventiveness. Mgbeoji argues that:

The most fundamental difficulty in making any rational claim for or against the alleged relationship between patents and inventiveness is the impossibility of separating out other factors that contribute to technological inventiveness, such as local resource endowment, type and quality of education of the labour force, availability of capital, and dynamism of the local market.

The ‘Natural Rights Theory’ proposes that patents are an inherent right, which belongs to the inventor. The state is presumed to have a responsibility to acknowledge and protect the inventor’s right. Although this view of patents is persuasive, the theory is fallacious. A number of authorities, including the Secretary-General of the United Nations, have repudiated the theory. In a major Report, the UN Secretary General noted that “patent legislation has never been based solely on the concept of the patent as the confirmation of an inherent, rather than the

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64 Myktiuk and Dagnino, supra note 54 at 312.
68 Ibid at 3.
creation of a statutory, property right”. The Report noted that “such a concept would have left no room” for statutory limitations on patent rights such as the fixed term of a patent, its forfeiture for failure to work them, its exclusion for inventions in certain fields,” and such other restraints as the compulsory licensing of patents. Along these lines, scholars have noted that the natural rights theory fails to capture the realities of the patent regime in different nation-states. The grant of patents has often been based on a “social policy” and on “policies of economic and political orientation” that prioritize national interests and benefits. However, while states have the leverage to determine whether and on what conditions to grant patents, it is pertinent to note that the absence of juridical protection for indigenous knowledge may give rise to claims of discrimination and human rights violation.

The ‘Reward Theory’ suggests that patents offer profits to inventors. The theory proposes that inventions are based on the economic ‘reward’ derivable from patents. A major critique against this theory is that it assumes that monetary interests drive all inventions. This is often not the case with products of indigenous knowledge in many cultures. Historically, products of indigenous knowledge have been created to serve the common good. Thus, the reward theory appears to be another culturally specific viewpoint, which fails to capture the realities in other cultures. While indigenous knowledge may be applied for personal economic ends today, it remains arguable that the grant of patents as a reward is not at the forefront of inventions based on indigenous knowledge. This argument is especially compelling given that indigenous peoples continue to create new knowledge even though the current IP regime creates little incentive for their inventions.

Within the ‘Contract/Disclosure of Secrets Theory’, patents are presumed to create a contractual agreement between the state and the inventor, in which the state grants certain rights (i.e. fixed-term monopoly) to the inventor in return for the creative knowledge embodied in the invention. There are shortcomings in this theory of patents. It can be argued that inventors seek patents only because they are constrained to do so in a political-economy wherein other forms

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69 The Role of Patents in the Transfer of Technology to Developing Countries, Report of the Secretary-General, United Nations (New York: Martinus Nijhoff, 1964) at 9.
70 Ibid.
72 Mgbeoji, “Beyond Patents”, supra note 65 at 3.
73 Ibid.
74 Mgbeoji, Global Biopiracy, supra note 7 at 20.
of IPRs such as trade secrets have limited utility. It cannot be assumed that the patent system, with all its costs and complexities, would have been the first option for inventors were it not for the realities of the day. In fact, it has been suggested that “where secrecy is possible, investors and industry prefer to employ legal protection through trade secrets”.  

Nevertheless, irrespective of the limitations inherent in the above theories of patents, the patent system provides a fundamental guarantee that the rights that inhere in an invention, whether individually or communally held, are protected from infringement. Whether or not the inventor seeks economic gains, the patent system provides assurance that intellectual investments will not be appropriated and commercialized to the detriment of the knowledge holders. Thus, for biodiversity-rich communities as well as for IMPs, some of whom may be uninterested in large-scale commercialization of their knowledge, the interest in seeking legal recognition for their creative knowledge and for products of indigenous knowledge may be located on the need to prevent infringement and appropriation.

4.4.2. Criteria for Patentability

According to Article 27(2) of the TRIPS Agreement, patents are intellectual property instruments designed to protect products or processes “that are new, involve an inventive step, are useful and capable of industrial application”.  

The requirements for patentability in the Nigerian Patents and Designs Act are similar to those of the TRIPS Agreement. Section I of the Act defines an invention as patentable “if it is new, results from inventive activity and is capable of industrial application, or if it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application”.  

Similarly, Article 52 of the European Patent Convention provides that “European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step”.  

These definitions provide the following basic criteria that must be met for an invention to be patentable: (i) Novelty (ii) Inventiveness (or

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75 Mgbeoji, “Beyond Patents”, supra note 65 at 3.
76 See Art. 27(2), TRIPS Agreement, supra note 10.
77 Patents and Designs Act, CAP 344 LFN 1990, s. 1(1) (a) and (b).
79 Article 52(1), ibid.
non-obviousness) (iii) Suitability for Industrial Application/Utility of Invention. These criteria have been interpreted as “major obstacles”\(^{80}\) to the grant of patent protection for indigenous knowledge. The following subsections examine each of these standards.\(^{81}\)

4.4.2.1. The Novelty Requirement

The novelty criterion requires that patented products must be original. The requirement seeks to prevent the appropriation of ‘prior art’, which refers to knowledge that has either been published or openly used before the filing date of the patent application.\(^{82}\) The characterization of indigenous medicine as communally held or public domain knowledge might imply that it lacks novelty and, therefore, falls below the standard of the patent system.\(^{83}\) For example, according to Article 54 of the European Patent Convention (EPC),\(^{84}\) an invention is new is “if it does not form part of the state of the art”; and the state of the art comprises “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”.\(^{85}\) Thus, the novelty criterion will generally prevent the grant of patents for knowledge openly used within a community prior to the filing date of the patent application.

However, an interesting scenario that contradicts the above provisions involves the secretive creation of natural health products by IMPs based on a combination of materials that may (or may not) be commonly known or available in the relevant community or openly disclosed to the community. It has been noted that where indigenous medical providers have attempted to keep certain aspects of their therapies as a secret, then novelty is not lost.\(^{86}\) Thus, evidence that an IMP has employed trade secrets to protect his or her therapeutic innovations can be an indicator of novelty. However, this analysis may not match Western interpretations of the novelty requirement. For example, under the European Patent Convention, a hidden or

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\(^{80}\) Correa, supra note 39 at 40.

\(^{81}\) For a further discussion of the TRIPS Agreement, see Peter Drahos and John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy (New York: New Press, 2003).

\(^{82}\) Ibid.


\(^{84}\) European Patent Convention (EPC), 1973, supra note 78.

\(^{85}\) Article 54(1) and (2), ibid. Emphasis added.

\(^{86}\) Correa, supra note 39 at 41.
secret use which has not been made available to the public is not an acceptable ground for contesting the validity of a European patent. A more stringent requirement established by the Convention is that the ‘technical’ details of the invention would have to be publicized for novelty to be lost. Similarly, the interpretation of ‘novelty’ within US patent law contrasts with the view that a secret creation or secret use of a product meets the novelty criterion. As is examined in further detail below, the principal issue under the novelty requirement is that of how the information contained in the alleged invention is represented.

According to section 102 of the United States Patent Law:

A Person shall be entitled to a patent unless:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or;

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or sale in this country, more than one year to the date of the application for patent in the United States, or;

... 

(g) before the applicant’s invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.

As evident from the wording of this section, US courts have the discretion to embrace, and in many cases have adopted, a very liberal interpretation of the novelty requirement. This has often created a result that is skewed to recognizing prior art or knowledge existing in indigenous communities as ‘novel’ in Western nations. This result is achieved through the wording of section 102. Section 102 assigns different weights to published inventions (that is, as described in a printed publication) or unpublished inventions in public use within US state boundaries, and unpublished inventions in public use in foreign jurisdictions.

By implication, the published inventions or inventions in public use within the US are considered prior art and therefore not original, while unpublished inventions which may be commonly known to members of the community in a foreign jurisdiction are categorized as novel, and as such patentable, once transplanted from the foreign community to the United States. Thus, it is only prior use within the US jurisdiction and/or printed publication outside the

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89 Ibid. Emphasis added.
US jurisdiction that “suffices” to “bar” the grant of a patent.\textsuperscript{90} The implication of this legal regime for members of biodiversity-rich communities who neither pursue patents nor publish/print their ideas or inventions in “formal outlets of knowledge”\textsuperscript{91} is the appropriation of indigenous ‘foreign’ knowledge. In fact, the ‘relative novelty’ standard of the United States Patent Act has facilitated the grant of several US patents over genetic materials and indigenous knowledge obtained from Southern countries. These patents have been granted to US researchers or firms by the United States Patent and Trademark Office.\textsuperscript{92}

Another aspect of the issue involving how the intellectual information contained in an alleged invention may be represented relates to the technical or scientific requirements of the patent system. The issue whether the innovative information should be expressed in scientific or basic terms lies at the heart of the novelty requirement and is fundamental to the indigenous knowledge and IP debate. The legal question is “whether novelty should be deemed to exist in cases where the chemical structure of the active substance responsible for the therapeutic effect of an openly used product was not known”.\textsuperscript{93} A United Kingdom decision on this issue, Merrell Dow Pharmaceuticals Inc. v. N.H. Norton & Co.\textsuperscript{94} positively suggests that indigenous medicinal knowledge may remain public domain material (in which case it is not appropriable by biospropectors) whether or not the knowledge holders are able to describe the knowledge in scientific terms.\textsuperscript{95}

The case involved Merrell Dow Pharmaceutical Incorporated, a US pharmaceutical company with a subsidiary in the United Kingdom. The company held a 1972 UK patent for an anti-histamine drug known as terfenadine for the treatment of hay fever and similar allergies. The new drug did not have the side effect of drowsiness associated with other drugs. After a renewal of the patents in 1977 and its expiration in 1992, other companies began to manufacture and sell terfenadine. In the present case, Merrell Dow claimed a continuous monopoly over terfenadine. Their argument was that after the initial patent on terfenadine, they discovered the mechanism of action of the substance. Having discovered the active chemical compound, the ‘acid metabolite’ inherent in the drug and why the drug produced no side

\textsuperscript{90} Mgbeoji, Global Biopiracy, supra note 7 at 176.
\textsuperscript{91} Ibid at 177.
\textsuperscript{92} Correa, supra note 39 at 42.
\textsuperscript{93} Ibid.
\textsuperscript{94} Merrell Dow Pharmaceuticals v. Norton & Co., supra note 87.
\textsuperscript{95} Correa, supra note 39 at 41-42.
effects, they obtained a patent for the newly discovered compound. It was Merrell Dow’s claim that any other company that supplied terfenadine infringed the patent under section 60(2) of the UK Patents Act of 1977. This Act was promulgated to give effect to the European Patent Convention.

The lower courts held the patents to be invalid. At the House of Lords, their Lordships considered the definition of novelty as provided under s.2 of the UK Act, which is equivalent to Article 54 of the EPC. The court also considered the decisions of the European Patent Office as regards the construction of the EPC. On the issue of the supposed novelty of terfenadine, the court observed that:

A patent is granted for a new invention. But in 1980 there was nothing new about terfenadine. Full information about its chemical composition and method of use had been published in its patent specification in 1972. Participants in clinical trials had actually been taking the drug. Making and using terfenadine was therefore part of the state of the art. What did the acid metabolite patent teach the person who was using terfenadine? It gave him some information about how the product worked in terms of chemical reactions within the body. But it did not enable him to do anything which he had not been doing before. Why, therefore, should the later patent confer a right to stop people from doing what they had done before?96

Counsel for the appellant argued that the 1977 Act replaced the former rules under the UK patent regime as established under the Patents Act of 1949. The new Act was passed to establish a new law of patents. Thus, under the European Patents Convention, the principle that a patent cannot enable the patentee to stop someone doing what he has done before was no longer applicable. According to counsel, section 2(2) of the Act which defines state of the art no longer simply requires that something should have been done before for novelty to be lost. The new law requires that information about what was being done should have been disclosed to the public. Counsel argued that since Merrell Dow Pharmaceuticals did not make any information about the acid metabolite available to the public before the priority date of the later patent, novelty had not been lost.

On the other hand, the respondent’s counsel argued that there had been “anticipation” of the invention prior to the filing of the patents. As noted by the court, “anticipation” is the “traditional English term for that part of the state of the art which is inconsistent with the

96 Merrell Dow Pharmaceuticals Inc., supra note 87 at 83.
invention being new”. Counsel for the respondent argued that there had been two types of anticipation, “anticipation by use” based on the common use of terfenadine before the filing date of the patents and “anticipation by disclosure” due to the available information about the drug in clinical trials and in the specification details contained in the initial patent on terfenadine.

While noting that under the old law (i.e. the 1949 UK Act), “uninformative use” of the product prior to the filing of the patent would have invalidated the patent, the court held that the new law required more than prior use to invalidate a patented invention. However, the court agreed with the second arm of the respondent’s argument that there had been anticipation of the invention by disclosure. The invention had been disclosed in the initial patent specification, which had made it part of the state of the art. The court elaborately explained the similarities and differences between ‘anticipation by use’ and ‘anticipation by disclosure’. According to the court:

In both cases no one was aware that the acid metabolite was being made. In the case of anticipation by use, however, the acts relied upon conveyed no information which would have enabled anyone to work the invention, i.e. to make the acid metabolite. The anticipation in this form relies solely upon the fact that the acid metabolite was made … It disavows any reliance upon extraneous information, such as the formula for making terfenadine and the instructions to take it for its anti-histamine effect. Anticipation by disclosure, on the other hand, relies upon the communication to the public of information which enables it to do an act having the inevitable consequence of making the acid metabolite. The terfenadine specification teaches that the ingestion of terfenadine will produce a chemical reaction in the body and for the purposes of working the invention in this form, this is a sufficient description of the making of the acid metabolite. Under the description the acid metabolite was part of the state of the art.  

There is arguably an analogy between ‘anticipation by disclosure’ and the process of bioprospecting. In the latter case, IMPs usually possess and provide information about a medicinal recipe sufficient to enable the making of a drug based on the initial invention or description.

Given the distinction between the two forms of anticipation, the question the court had to decide was whether there was sufficient information in the specification to enable the ordinary skilled person to work the invention irrespective of the absence of technical information about the invention. This question was important because the appellant’s counsel argued that the exact

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97 Ibid at 84.
98 Ibid at 91. Emphasis added.
mechanism of action of the chemical invention contained in terfenadine could not have been known by the existence of the propensities of terfenadine in the public domain. In response to counsel’s argument, the court stated that what Merrell Dow Pharmaceuticals had discovered was something that was known and could be “given a chemical description” or known by one name or the other.\textsuperscript{99} Where the effect of the product is found to be known, then novelty is lost, whether or not the ‘newly discovered’ properties of the products are expressed in exact scientific language.\textsuperscript{100} The court further noted that “if the recipe which inevitably produces the substance is part of the state of the art, so is the substance as made by that recipe”.\textsuperscript{101} What is important in deciding the question of novelty is whether or not the product has a pre-existing and publicly disclosed utility.

The effect of the decision in \textit{Merrell Dow Pharmaceuticals v. Norton & Co.}\textsuperscript{102} is that the fact that a chemical structure or mechanism of action of a substance was unknown at the time a patent was filed does not make the substance novel.\textsuperscript{103} It was sufficient that the effect of the substance was already known prior to the filing of the patent. Lord Hoffmann cited the case of the Amazonian Indians who for several centuries had used the powdered form of the cinchona bark in the treatment of malarial and other types of fever. The Amazonians linked the curative effect of the cinchona bark on malaria to ‘the magic spirit of the bark’.\textsuperscript{104} According to the court, after the 1820 discovery by French scientists that the active ingredient, an alkaloid called quinine, could be extracted and used in the form of sulphate of quinine, the Amazonians could not be said to have been ignorant about quinine simply because they could not describe its chemical structure.\textsuperscript{105}

The \textit{Merrell Dow Pharmaceuticals} decision provides an important interpretation of the novelty standard. There is a significant difference between its interpretation and the US definition and interpretation of ‘novelty’. As earlier explained, the US adopts a \textit{relative} novelty standard incorporated in section 102 of its \textit{Patent Law}.\textsuperscript{106} It will be recalled that while knowledge that is already in public use in the US is not patentable (since it is considered to

\textsuperscript{99} Ibid at 87.
\textsuperscript{100} Ibid at 90.
\textsuperscript{101} Ibid.
\textsuperscript{102} Ibid.
\textsuperscript{103} Ibid.
\textsuperscript{104} Ibid at 88.
\textsuperscript{105} Ibid.
\textsuperscript{106} Patent Act, supra note 88.
have lost its novelty), section 102 of the US Patent Law considers knowledge that already exists in the public domain in a foreign jurisdiction to be novel. Based on this reading, such knowledge can be patented in the United States even though the novelty standard under the TRIPS Agreement is intended to prevent the appropriation of knowledge that has been published or openly used before the filing date of the patent application.\textsuperscript{107} The *Merrell Dow Pharmaceuticals* decision holds that a product cannot be the subject of a patent if knowledge of its utility already exists in the public domain.

Thus, at one level, the *Merrell Dow Pharmaceuticals* decision resolves science-related technicalities in the determination of novelty in favour of holders of indigenous knowledge where the knowledge is commonly available to the majority of members of a given community; the decision effectively bars foreign appropriation of such communally held knowledge. At another level, the decision empowers an IMP who has taken steps through trade secrets to protect his or her expert knowledge of a commercialized medicinal composition to contest a patent granted over the same knowledge whether or not the IMP knows the scientific terms used to describe the active compounds in the composition. Under US patent law, knowledge of the active compounds or chemical components of an invention already in use in a foreign country (details of which may have been orally published) would suffice for the grant of patents.

4.4.2.2. The Inventive Step/Non-Obviousness Requirement

The inventive step or non-obviousness requirement is the second standard of patentability that must be met before an inventor can be granted patent rights. This step requires that the invention sought to be patented must be non-obvious to a person with ordinary skills in a given technical field.\textsuperscript{108} According to Article 56 of the *European Patent Convention*,\textsuperscript{109} “[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art”\textsuperscript{110}. Although an invention may be found to be novel, it will not be patentable if it is proven to be obvious or lacks an inventive step.\textsuperscript{111} Patent offices assess ‘obviousness’ through the lenses of Western knowledge given that indigenous

\textsuperscript{107} Correa, *supra* note 39 at 40.
\textsuperscript{108} *Ibid* at 43.
\textsuperscript{109} Article 56, EPC, *supra* note 78.
\textsuperscript{110} Correa, *supra* note 39 at 43.
\textsuperscript{111} *Ibid*. 
medicine is not recognized as a valid system of knowledge. This highlights the epistemological rift between the North and the South on what constitutes ‘medicine’ and on what is patentable. Thus, indigenous therapy that may be obvious to members of a particular indigenous medical system can be considered inventive and patentable to a foreign researcher.

It is noteworthy that there are no international standards, agreements or uniform guidelines for determining the criterion of non-obviousness. This has created an avenue for subjective judicial interpretations of the requirement. This interpretive approach has resulted in the grant of a large number of patents in Western countries, especially the US, “for minor, sometimes trivial developments”. Furthermore, there is no unanimous definition of the term, ‘invention’, among scholars and jurists. Mykitiuk and Dagnino suggest that an invention is “a thing, a way of making a thing, a way of doing something that is new, non-obvious and useful, and does not exist in nature in the same form”. While much of the information provided in this definition is already stated under Article 27 of the TRIPS Agreement, it however highlights that natural products, such as plant-based medicines, must meet a higher test to be considered inventions. The question that arises, therefore, is what types of indigenous therapies – which draw their primary raw materials and/or active ingredients from natural sources – can be patented? This question is fundamental in the present analyses because it directly implicates the issue of inventiveness of indigenous therapeutic knowledge. This issue is examined under the criteria for Reproducibility and Industrial Application below.

4.4.2.3. Suitability for Industrial Application (or the Criterion of Reproducibility)

A patentable invention must be capable of industrial application. This means that the invention must be capable of being put to industrial use. An associated requirement for patentability is that the invention must be reproducible or repeatable through the same means by

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112 Ibid.
113 Ibid.
114 Jerome Reichman, “From the Free Riders to Fair Followers: Global Competition under the TRIPs Agreement” (1996-97) International Law and Politics 11.
115 Correa, supra note 39 at 44.
116 Mykitiuk and Dagnino, supra note 54 at 312.
117 See Article 57 of the European Patent Convention, supra note 78, which provides that “[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture”.

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which it was first created. These requirements are fashioned to ensure a “mechanized” concept of industrialization and “mechanized deployment of capital”.\textsuperscript{118} In the context of natural health products, they further a mercantilist conception of healthcare delivery. In this area, the issue to be determined is whether indigenous therapies can meet the above requirements of industrial utility and reproducibility. The query fundamentally is “the extent to which a substance existing in nature for which a certain use has been identified, may be deemed to be an “invention” or a mere “discovery””.\textsuperscript{119} Correa suggests that “such use may have been identified with regard to a product whose properties were not known, or in respect of products whose properties were known, the “invention” eventually being the determination of its chemical or genetic structure”.\textsuperscript{120} This criterion for invention – which permits the grant of patents based on the discovery of the active ingredients in a product – is tailored towards legitimizing and prioritizing scientifically reducible forms of information and knowledge.

It is important to clarify that the question is not whether indigenous therapies are reducible forms of information or knowledge. Multinational pharmaceutical corporations that undertake bioprospecting in biodiversity-rich countries are known to produce drugs and other medicines from indigenous therapies or knowledge. Rather, the question is whether these therapies should be reduced in the manner of Western pharmaceuticals given the broader significance of plant-based medicines in indigenous medical tradition. This question is the crux of the debate between the North and some schools of thought sympathetic to the interests of Southern states. Before discussing this issue, it is important to examine the different classes of patentable (or non-patentable) subject matter to which indigenous therapies belong.

Indigenous therapies, as already noted are primarily produced from plant- or animal-based sources. The medicines could also be based on mineral materials, extracts and mixtures.\textsuperscript{121} Natural products may not be patentable if they are based on unprocessed or unmodified natural materials. On the other hand, extracts and formulations from natural products can be patented. Extracts and formulations are mixtures of active ingredients “with certain excipients” of natural products.\textsuperscript{122} Combinations and preparations are patentable because they are a mixture of diverse

\textsuperscript{118} Mgbeoji, Global Biopiracy, supra note 7 at 140.
\textsuperscript{119} Correa, supra note 39 at 45.
\textsuperscript{120} Ibid. Emphasis added.
\textsuperscript{121} Ibid.
\textsuperscript{122} Ibid.
components. Modern pharmaceuticals fall within this class. However, it should be noted that the “use or commercialization of any of the components of a combination or preparation (isolated or in different combinations or preparations) would not constitute infringement”.  

It is also noteworthy that “many indigenous medicines are obtained through fractional distillation, purification or concentration”. These processes, if novel or non-obvious, can be patented. However, methods of treatment and diagnosis are not patentable due primarily to lack of novelty and the fact that they are not industrially applicable. Additionally, the importance of such methods to population health precludes patentability. Thus, many indigenous medical practices, which provide efficient and cost-effective primary healthcare in the community, and which are “generally accessible and affordable to people of all strata, particularly those living in poor and isolated regions,” cannot be patented. The exclusion of methods of treatment and diagnosis from the ambit of patentable inventions is in the best interest of the public, and ought to be maintained in both the biomedical and alternative contexts.

Although indigenous therapies that fall within extracts, formulations and combinations arguably meet the requirements of reproducibility and industrial application, there are profound concerns regarding these formal limitations established by the patent system. The requirement of reducibility (or reproducibility) is complicated when we examine indigenous therapies in the broader context of indigenous epistemology. As discussed in chapter 3, indigenous medical providers have historically administered herbal therapies as part of a broader regimen, in which the pure pharmacological effect of the herbs is only one part of the therapeutic regimen. The herbal plants have “cultural and spiritual significance in and of themselves”, and the arguments proffered by some scholars suggest that the bottling and dispensing of drugs and medications as strictly commercial items diminishes this significance. It is important to recall that indigenous therapies are administered according to the practitioner’s subjective evaluation

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123 Ibid at 48.
124 Ibid.
125 Ibid.
126 Ibid at 49-50.
127 Ibid at 49.
128 Oguamanam, supra note 39 at 177.
129 See generally ibid; see also Bratspies, supra note 83.
of the patient’s condition and needs, rather than on the basis of standardized prescriptions. Hence, therapies may vary for different individuals with the same condition.

Thus, a number of scholars committed to the interests of Southern nations contend that the patent system by its very structure is antithetical to the nature of indigenous medicine. The argument within this school of thought is that to make patents applicable to indigenous therapies is to destroy the foundations of medical pluralism.\(^{130}\) Oguamanam, a commentator on the issue, contends that:

Because IPRs, especially the patent regime, privilege the Western scientific or biomedical model, they constitute a potential threat to the sustainability of traditional medicine and associated aspects of indigenous cultural practices and the desire for medical pluralism on a global scale.\(^{131}\) …

The Western scientific and industrial system, supported by conventional intellectual property, is not flexible enough to accommodate alternative accounts of knowledge. Traditional therapeutic systems constitute alternative conceptions of health and healing. Protective schemes that do not reify one knowledge system over another enable humanity to maximize the immense strength and benefits that are inherent in its diversity.\(^{132}\)

Similarly, Rebecca Bratspies highlights the very significant compromise that biodiversity-rich communities may have to make in order to patent their knowledge. According to the author, members of these communities may need to break down the essence of their traditional culture into distinct classes of property in order to avail themselves of the existing property rights system.\(^{133}\) By implication, the IMP who creates a herbal pharmaceutical that is truly novel and inventive by even the standards of the patent system must dissociate his or her personalized art of healing (involving life style changes, prayers, incantations, and a combinatory therapeutic regimen) from the herbal preparation in order for it to meet the standards of reducibility and reproducibility of the patent system.

\(^{130}\) Oguamanam, supra note 39 at 31, 190, and 219-220; Bratspies, ibid at 19.
\(^{131}\) Oguamanam, ibid at 31.
\(^{132}\) Ibid at 219-220.
\(^{133}\) Bratspies, supra note 83 at 19.
4.4.3. The Public domain (or Common Heritage of Humanity) Narrative

There is an assumption among some schools of thought on the indigenous knowledge and IP debate that indigenous knowledge of therapeutic plants is the common heritage of humanity and belongs to the public domain. This argument originates from the common belief that indigenous knowledge of plant resources is communal property in originating communities. According to this argument, indigenous medicinal knowledge is generated, preserved, shared and disseminated from generation to generation by members of the community. Hence, the knowledge is considered free for public use.\textsuperscript{134} The public domain or common heritage argument is incompatible with the ‘novelty’ and ‘inventiveness’ requirements of the patent system. These latter criteria require that the information in the product sought to be patented must be original and non-obvious.

A related problem is the fact that the patent system emphasizes an individualistic creative process opposed to the communal collaborative process, which the creation of indigenous knowledge supposedly involves. Along this line, indigenous medicinal knowledge is often categorized as either ‘shared’ by community members or ‘inherited’ from one generation to another. Given the tenor of these arguments, indigenous knowledge of therapeutic plants has generally been consigned to a non-creative category of knowledge identified as unscientific, unoriginal and public domain material. Cast in this light, some scholars have easily reached the conclusion that indigenous knowledge has no place within the intellectual property system. Unfortunately, this argument ignores the collaborative process involved in the creation of ‘scientific’ inventions in the West, where researchers and scholars come together as a research community to invest knowledge, resources and time in a new invention. Such collaborative production of knowledge is common in many Southern communities. However, also common in today’s Southern communities is the case of the indigenous medical practitioner who, as lead researcher and inventor in a research team, invests in and produces an NHP that meets the criteria of novelty and inventiveness. These practitioners belong to an evolving class of IMPs who have been trained as healthcare providers through formal processes in an established indigenous healthcare centre. In this case, the practitioners pay for the knowledge and education they receive. Even in situations where the knowledge is handed down transgenerationally,

\textsuperscript{134} Ibid.
practitioners have been able to produce a truly novel NHP from the received knowledge. All four practitioners interviewed in this aspect of the research in Nigeria fall within the classes described here.\textsuperscript{135}

One practitioner, a medical sociologist, is part of an international medical institution known as the \textit{Pax Herbal Clinic and Research Laboratories}. The institution, which originated in the rural community of Ewu in Nigeria, has branches in several Nigerian states as well as in Togo, Benin Republic, Senegal, Ghana, the United States and the United Kingdom. Part of the objectives of the institution is to train new indigenous healthcare providers and biomedical practitioners in the practice of indigenous medicine. This institutional arrangement defies the common assumption that indigenous medicinal knowledge is always transgenerational.\textsuperscript{136} Today, the institution boasts of a number of medicinal products created from special, carefully researched and formulated recipes.\textsuperscript{137} The products bear NAFDAC registration numbers having been certified as safe and effective for public use. Considering that the products are not the result of ‘mere knowledge of the workings of a specific plant or plants’, they easily meet the criteria of novelty and inventiveness, and \textit{Pax Herbal Laboratories} can be deemed entitled to IP rights over the recipes.

A second practitioner who holds a degree in Microbiology received his training under the tutelage of his grandfather for over 15 years. While this practitioner’s general style of practice and the medicinal materials he uses may be drawn from the medical tradition he learned from his grandfather, the NHPs he produces in collaboration with other practitioners are the products of independent research. When asked whether he has special recipes not known to other practitioners in his field, he replied:

\begin{quote}
We have special recipes. It is very different from other herbals or other preparations probably prepared by the common man or the person who doesn’t have knowledge of herbals.\textsuperscript{138}
\end{quote}

\begin{footnotes}
\item \textsuperscript{135} Iyioha, \textit{International Research}, supra note 5.
\item \textsuperscript{136} \textit{Pax Herbal Clinic and Research Laboratories}, online <http://www.paxherbals.net/index.php?option=com_content&view=article&id=249&Itemid=200195>.
\item \textsuperscript{137} See \textit{Pax Herbal Clinic and Research Laboratories}, online: Product Categories <http://www.paxherbals.net/index.php?option=com_virtuemart&page=shop.browse&category_id=1&Itemid=200002&TreeId=1>.
\item \textsuperscript{138} Iyioha, \textit{International Research}, supra note 5.
\end{footnotes}
The practitioners usually obtain a NAFDAC registration number for medicinal products that they have invented from special recipes. This particular practitioner confirmed that some of his products and those he has contributed to producing have NAFDAC registration numbers.\(^\text{139}\) As will be recalled, most practitioners who submit their NHPs to the regulatory agency withhold some information on the products as a means of protecting what they consider an invention. Practitioners who do not invent new products through special recipes simply practice indigenous medicine based on a tried and proven system of knowledge. A number of practitioners in this category are inheritors of the medical tradition. The third practitioner who is a household name in the city of Benin and the fourth practitioner who has practiced indigenous medicine for nearly six decades are both inheritors of the indigenous medical tradition as well as independent producers of medicinal products, whose formulas are not duplicated in the public domain.

The common counter argument from proponents of the originality of indigenous medicine is that states have sovereign power to control plant genetic resources under their territories. The argument proffered by these scholars is that plant genetic resources are not within the “commons” as recognized under international law or any other known jurisprudence.\(^\text{140}\) Resources of the “commons” are public goods, which should be distinguished from plant genetic information resident within the borders of a sovereign state.\(^\text{141}\) While the concept of the commons has often been used to refer to such things as “air” or “outer space”, the equation of plant resources to such intangible concepts is a “misnomer”.\(^\text{142}\) Chika Onwuekwe has argued that such an equation “undermines the concept of sovereign control of natural resources (renewable and non-renewable) within a country’s territory” and “advances the capitalist ideology” of wealth accumulation.\(^\text{143}\) Other scholars sympathetic to the interests of biodiversity-rich communities worldwide have also asserted that “plant genetic resources and their human custodians are located within defined territories of sovereign states”.\(^\text{144}\)

\(^{139}\) See \textit{ibid.}
\(^{141}\) \textit{Ibid.}
\(^{142}\) Onwuekwe, \textit{ibid} at 69.
\(^{143}\) \textit{Ibid.}
\(^{144}\) Oguamanam, \textit{supra} note 39 at 161.
within the national borders of a state, the doctrine cannot be applied to plant genetic resources, which exist within national borders. The Convention on Biological Diversity reaffirms this point in Articles 3 and 5(1), which provides that states have sovereign rights over their natural (biological) resources.

While this argument counters the charge that indigenous therapeutic knowledge is public domain material, this study contends that the national sovereignty argument should not be the first line of defence to counter the supposition that indigenous knowledge belongs to the public domain. While proponents of this argument have successfully established the private ownership of indigenous knowledge by biodiversity-rich communities, yet the argument has eclipsed a few major points in the debate. First, it is important to note that the argument is effective only against international biopiracy. It is ineffective against biopiracy at the national level where local industries may simply claim a right to an indigenous innovation on grounds that it is part of a national heritage, which the industries have a ‘right’ to benefit from. This local appropriation poses problems to IMPs as much as does international biopiracy. As noted by a Nigerian IMP, “generally, no herbal traditional professional discloses full details of his or her medicinal constitutions … to NAFDAC officials…”¹⁴⁵ Of course, NAFDAC officials are local personnel. Thus, the reservations that IMPs have about disclosing trade secrets reflect distrust for both local and international researchers.

A substantive argument against the public domain assumption, which captures a different version of reality from that commonly analyzed through the national sovereignty argument by both Western and Southern scholars alike, is that indigenous therapeutic knowledge is a specialized form of knowledge, which in many societies is known to only a well-trained class of professionals who form a closed group. Other members of the society rarely have access to the specialized knowledge of this group. Holders of this knowledge guard their skills as a highly priced possession. Employing a diverse range of methods from trade secrets to communally upheld legal sanctions, the knowledge holders pursue their art in the understanding that the success of their profession is dependent on their knowledge being kept out of the public domain.

¹⁴⁵ Interview conducted with Ehinoma Aiguobarueghian, a Nigerian IMP: Iyioha, International Research, supra note 5.
Fundamentally, the scholarship has largely failed to distinguish between the basic knowledge that some societal members may have of the uses of a particular plant resource from the expert knowledge of the uses, composition, formulation and administration of the same plant resource, which is held by only a few in the community. Furthermore, the scholarship has often ignored the fact that indigenous societies are not homogenous. As diverse as the societies, so are the patterns of knowledge and systems of property ownership that exist in these societies. The scholarship has considerably failed to acknowledge the existence of multiple and quite diverse property systems. It is notable that only a few writers have highlighted the lack of homogeneity in the property regimes of many indigenous societies. For example, Mohammed Khalil has noted the diversity in indigenous property regimes, and identifies that knowledge is not always communally held in indigenous communities.\(^{146}\) The author notes that knowledge of medicinal plants is often a subject of much secrecy.\(^{147}\) In discourses on indigenous knowledge, the communities are often represented as homogenous entities within which members share the supposed public domain knowledge of therapeutic plants.

A small-scale qualitative study conducted in Nigeria reveals that this not the case among a sample of NHP users in an urban town and three rural communities. The study was conducted with the use of questionnaires to obtain the opinions of users of NHPs regarding their knowledge of the constituents of the products. Essentially, the underlying legal question was whether indigenous medicinal knowledge is public domain material. The questionnaires were distributed to respondents at University campuses, public centres, markets and shopping malls, and healthcare centres in Benin City and the Ogwa, Ewu, and Ekpoma rural communities, which are located in Edo State, Nigeria. The questionnaires were distributed in both biomedical hospices and indigenous healthcare centres among staff and healthcare consumers to account for any biases that might have been held by any one of these two professions. While the three rural communities are not homogenous, they are representative of the typical Nigerian rural community. A total number of 220 questionnaires were returned. The questionnaires asked four IP-related questions:


\(^{147}\) Ibid at 242.
1. Have you ever used herbal medicine or indigenous medical products?
2. If yes, who prescribed it? Was it self-prescribed, prescribed by a family member or a friend, a herbal practitioner or a medical doctor?
3. Were the ingredients used in the preparation of the herbal medicine known to you?
4. If yes (or if you had a vague idea of the ingredients), would you have known how to administer it without the herbal practitioner’s instructions?

The results were calculated based on the percentage of responses to each question. On the question of usage of indigenous medicine, 71% of respondents had used a natural health product (see chapter three for more information regarding usage of indigenous medical services and products and the reasons for usage). The outcomes of the research are represented in the tables and figures below:

**Table 4.1: Prescription or Administration of Indigenous Medicine**

<table>
<thead>
<tr>
<th>If you have used herbal medicine or indigenous herbal products, who prescribed or administered it?</th>
<th>Percentage of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self</td>
<td>16%</td>
</tr>
<tr>
<td>Family member/Friend</td>
<td>51%</td>
</tr>
<tr>
<td>Herbal Practitioner</td>
<td>28%</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>5%</td>
</tr>
</tbody>
</table>
Among the 71% of respondents who had used a natural health product, 16% had prescribed it for themselves, while 51% indicated that a family member or friend had prescribed the product. The product was prescribed by an herbal practitioner and a physician in only 28% and 5% of the cases respectively. It was important to obtain information about the prescriber so as to use this information to measure the responses regarding whether or not the subjects knew the constituents of the medicinal products.
Figure 4.2: NHP Consumers’ Knowledge of the Constituents of the Products

<table>
<thead>
<tr>
<th>Knowledge of Constituents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question</strong></td>
</tr>
</tbody>
</table>

Thus, as shown in figure 4.2 above, while 39% of respondents knew the constituents of the products, 75% of this figure had either prescribed it for themselves or had it prescribed by a family member or friend. Therefore, it can be inferred from the data that knowledge of the constituents came from their buying or collecting the raw materials for the medicines locally by themselves or through the assistance of friends or relatives. Indeed, in a few cases, respondents expressly indicated that the materials were “collected” by a family member.
Further evidence of the secrecy that surrounds the practice of indigenous medicine was provided when respondents were asked whether they would support medical integration, coverage of NHPs under the national health insurance scheme, and a role for IMPs in primary/community healthcare delivery. Among the reasons provided by the respondents for their support of these initiatives were the following comments represented in box 4.2 below:

**Box 4.2: Evidence of Secrecy**

It will help to discover many potent indigenous medicines. The practitioners of indigenous medicine will be encouraged to open up to sources of the drugs/herbs to government.

By making known to orthodox medicine the kind of plants they use for treatment.

They [IMPs] should work in collaboration with conventional medicine providers and … they should make their ingredients known.

They can help to teach people how [these] herbs can be used.

They [can] contribute positively by giving proper information to the community.

[By] giving information about the little they know about herbs and their therapeutic effects.
The research outcomes, including the comments reproduced in box 4.2 above, clearly contradict the more common perception that indigenous medicinal knowledge is so pervasive in originating communities that it does not deserve intellectual property protection. As indicated in figure 4.3 above, even where the constituents of the products were known, 60% of respondents conceded that they would not have known how to administer the product without the guidance of a qualified IMP.
4.5. Colonialism and the TRIPS Agreement

Discussions of the TRIPS agreement have had an underlying narrative of unfair negotiations between parties in vastly different positions of power. This narrative has its foundation in the arguably linear process by which the Agreement came into existence. The academic analyses reveal a ‘bargaining’ process in which the technical knowledge of the issues at stake and the benefits of higher IP protection were on one side of the bargaining table. Additionally, the contents of the Agreement as examined above reveal a body of law skewed to favour one ideological and cultural philosophy over all others.

Accounts of the creation of the TRIPS Agreement are often captured by scholars sympathetic to the struggles of most Southern countries as part of four interlinking narratives depicting an unequal power relationship: 148 (i) the TRIPS Agreement is considered a product of bargaining, 149 “in which the Agreement was considered the product of a compromise between developed and less developed countries”; 150 (ii) the Agreement is regarded as a product of “coercion” and “imperialism” and “an unfair trade document” imposed by the “developed world” on “less developed countries”; 151 (iii) the Agreement was for “developing states” “a first complete multilateral trade negotiation” 152 and as such “developing countries” “did not understand the importance of intellectual property protection during the TRIPS negotiations”; 153 (iv) “developing countries” are said to have consented to the Agreement on the basis of “self-interest” in order to benefit from the technological knowledge of the West. 154 These accounts, analyzed alongside the requirements for the grant of patents laid out in the Agreement, are often analogous to the history of colonialism and imperialism. Scholars sympathetic to the experiences of Southern states have emphatically highlighted this connection.

150 Yu, supra note 148 at 371.
151 Ibid at 373; Gervais, Intellectual Property, Trade and Development, supra note 58 at 5.
153 Yu, supra note 148 at 375.
154 Ibid. See also Gervais, Intellectual Property, Trade and Development, supra note 58 at 6.
The intellectual property and indigenous knowledge debate is cast as a replay of historical global power hierarchies.\textsuperscript{155} For example, Olufunmilayo Arewa argues that the global power hierarchies “evident at the negotiating table” in the international arena “reflect longstanding power hierarchies” between cultures.\textsuperscript{156} Linking this hierarchical relationship to the history of colonialism, the author contends that the hierarchies of power led to certain types of knowledge that were concentrated in the “Third World” being deemed public domain resources that were freely appropriable.\textsuperscript{157} The TRIPS Agreement echoes this treatment of non-Western forms of knowledge.\textsuperscript{158}

Mgbeoji makes a similar connection linking past imperialist relations between the global North and South to the current appropriation of indigenous knowledge through Western IPRs. While observing that very few academics have addressed the gap in the scholarship regarding the absence of discourses on the imperialist nature of the patent regime, the author contends that beyond being an “affirmation of a racist hierarchical ordering of cultures”, colonialism was also “a violent imposition of foreign legal norms and institutions on conquered peoples and cultures”.\textsuperscript{159} Among different indigenous communities, the narrative is similar. For African peoples, the patent system can be interpreted as an aspect of a linear colonial agenda to refashion non-Western ideals along European concepts on the “Western hypothesis that indigenous peoples had no pre-existing institutions worthy of respect”.\textsuperscript{160}

The appropriative elements of the patent system provide further evidence of the ties between imperialism and the patent system. The first appropriative element is the “sociocultural”, which relates to “the cultural and gendered denigration and denial of the intellectual input” of indigenous farmers and breeders in the development and creative use of plants.\textsuperscript{161} Under this first element, indigenous knowledge of therapeutic plants is commonly

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\textsuperscript{156} Ibid at 159.
\textsuperscript{157} Ibid.
\textsuperscript{158} Arewa also observes that the Agreement is relatively inflexible and has the potential to exacerbate existing disparities in technological and scientific capacity. Due to the globalization of the intellectual property system under TRIPS, local communities “have far less flexibility to craft intellectual property frameworks to help develop technological capacity”: ibid.
\textsuperscript{159} Mgbeoji, “Beyond Patents”, supra note 65 at 4. See also Mgbeoji, Global Biopiracy, supra note 7 at 82.
\textsuperscript{160} Mgbeoji, “Beyond Patents”, ibid at 4.
\textsuperscript{161} Mgbeoji, Global Biopiracy, supra note 7 at 87.
\end{flushleft}
regarded as unoriginal, non-inventive, and unscientific. According to Mgbeoji, biopiracy within this element is to be “understood as part of the cultural war with non-Western peoples, cultures, and epistemological frameworks” in which “traditional and non-European peoples” were held to be “inferior to Europeans in their intellectual capacity”.\(^{162}\) Much like the impact of colonization on customary laws and policies of conquered peoples, this perception continues to facilitate through extant IPRs the rejection of the innovations of non-Western peoples.

The second appropriative aspect of biopiracy is the “mechanisms” employed by powerful Western nations in establishing international agricultural research centres and gene banks for the genetic resources of the South.\(^{163}\) According to Mgbeoji, this process involves the transfer of “an enormous quantity, quality, and diversity of plant life forms from the South into gene banks strategically located in several countries of the industrialized North”.\(^{164}\) The logic behind this transfer has been attributed to the principle of “Common Heritage of Mankind”, which legitimizes an insidious, “asymmetrical” and “illegitimate” appropriation of plant genetic resources.\(^{165}\) The transfer of the South’s plant genetic resources without an acknowledgement of the intellectual contributions of knowledge holders in the development of the resources is again evocative of the colonial experience in which the human and natural resources of African and Southern nations fed development in the West. The third and final aspect, which Mbgeoji argues is the most “apparently legitimate”, is the patenting of plants and products of indigenous knowledge through the Western IP regime.\(^{166}\) The successful patenting of plants and products of indigenous knowledge has primarily been effected through the “deliberate lowering of the threshold of patentability” in the patent law regime\(^{167}\) such that minor modifications of resources and inventions originating from the South are deemed to be patentable discoveries in the North.

On a similar note, Rebecca Bratspies identifies a connection between the inglorious historical relationship between the global North and South and the indigenous knowledge debate. Bratspies equates the rush to exploit biological resources in Southern states with the extravagant claims of ownership made by outsiders coming to the “new world” during the Age

\(^{162}\) Ibid.
\(^{163}\) Ibid at 88.
\(^{164}\) Ibid.
\(^{165}\) Ibid.
\(^{166}\) Ibid at 88.
\(^{167}\) Ibid.
of Discovery.\textsuperscript{168} Using this analogy to draw a nexus between biopiracy and colonialism, Bratspies acknowledges the fact that because most of the world’s remaining biodiversity exists within the territories of indigenous peoples, issues of sovereignty, identity, colonialism and exploitation inevitably underlie the discourse on the protection of indigenous knowledge.\textsuperscript{169} By defining property to exclude the resources of indigenous peoples while including what is developed from those resources, this vision of property reconstructs the cycle of dependency that was at the heart of colonialism, an era when the word “\textit{res nullius}” meaning the “unowned thing” was used to describe newly discovered foreign lands.\textsuperscript{170} Thus, as Bratspies has aptly noted, the root problem appears to be definitional: how is “property” to be defined? The foregoing discussion of the requirements of the patent system reveals that the patent system is designed to protect specific forms of ‘property’. However, there is evidently a lot of dissension on the subject of what constitutes innovative ‘property’ under the patent regime. The next section examines this issue as part of the convoluted question on what constitutes scientific innovation.

\textbf{4.6. Science, Law and the Construction of Innovative Knowledge}

Science – as conceived and understood in Western academe – is central to the indigenous knowledge controversy. It plays a supervening role in the construction of knowledge systems and has a central function in the determination of what constitutes protectable intellectual knowledge. The discussion of the role of science here is geared specifically to unravel how Western science functions as an instrument for determining which innovations or to use a value-neutral term, ‘creations’ can have juridical status under the Intellectual Property Law regime (IPL). As noted at the outset, what constitutes knowledge and property in international patent law today is a set of science-based legal norms drawn from the Western legal tradition that governs IPL at the international level.

As discussed in chapter three, science plays a major role in the formulation of health policies.\textsuperscript{171} Western science supposedly thrives on objectivity, rationality and universality even

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\footnotesize
\textsuperscript{168} See generally, Bratspies, \textit{supra} note 83.
\textsuperscript{169} \textit{Ibid.}
\textsuperscript{170} \textit{Ibid} at 23.
\textsuperscript{171} See generally chapter 3, \textit{supra}. See also Oguamanam, \textit{supra} note 39 at 18.
\end{flushright}
though its claims to neutrality and universality have often been questioned.\textsuperscript{172} The universality of science has been challenged based on notions of the relativity of science. It has been argued that “what is considered science is dependent on the culture/worldview/paradigm of the definer”.\textsuperscript{173} Other scholars have observed that “all scientific knowledge is always, in every respect, socially situated”\textsuperscript{174} and “heavily influenced by cultural factors”.\textsuperscript{175} These observations may be garnered from Thomas Kuhn’s, \textit{The Structure of Scientific Revolutions}, which establishes the fluidity and multicultural nature of scientific paradigms.\textsuperscript{176} Kuhn’s work projects the cultural nature of scientific knowledge as a discourse contingent on the culture and historical situation of an observer or investigator than on a defined method.

Conceptions of the term ‘science’ today conjure images of the high-tech, laboratory-based or mechanistic results of Western science. While these versions of the meaning of ‘science’ are valid, it is important to acknowledge that conceptions of science – as a body of knowledge determinable by its procedural form as much as by its content – are not fixed and cannot be reduced to one cultural system represented by the Western viewpoint. Oguamanam argues that “because we can no longer take the objectivity of science for granted, we can equally not take for granted its claim to universality”.\textsuperscript{177} As highlighted in chapter two, the history of the dominant conception of Western science and its influx into other World Systems reveals that Western science is as cultural and particular as indigenous therapeutic knowledge systems, which like biomedicine continuously strive towards empirical results as new medical questions arise. In fact, in its claim to universal relevance and adoption by non-Western cultures, biomedicine reveals its actual historical and philosophical origins. To employ Baronov’s description, “in universalizing its scientific form, biomedicine particularizes its actual development”.\textsuperscript{178}

\textsuperscript{172} Oguamanam, \textit{ibid} at 18.
\textsuperscript{176} Thomas Kuhn, \textit{The Structure of Scientific Revolutions} (Chicago: University of Chicago Press, 1970).
\textsuperscript{177} Oguamanam, \textit{supra} note 39 at 19.
The current debate on whether products of indigenous therapeutic knowledge meet the Western scientific criterion of innovativeness further calls the universality of science into question. At the root of the epistemological controversy between the global North and South on the patenting of indigenous therapeutic knowledge is the fact that the patent system is rooted in the Western scientific knowledge system, which requires that knowledge, to come within the legal protection offered by the patent system, must be scientifically reducible. Specifically, the patent system is designed to prioritize certain forms of knowledge over others. For example, without the exact scientific details about the chemical compositions (and their interactions) operative in a given plant-based medicinal invention, knowledge of the workings of the plant and creative compositions based on extracts from the plant are not patentable according to the present rules of the patent system. For the purpose of further analyses below, let us call this ‘Invention Type A’. On the other hand, knowledge of the genetic components and active ingredients (and their interactions) which underlie the workings of a plant and creative chemical compositions based on extracts from the plant are patentable. Let us call this second example ‘Invention Type B’.

Jim Chen casts the former knowledge (Invention Type A), which often represents the manner of presentation of ‘indigenous therapeutic knowledge’, as “an ethnobiological tale”, which he argues can be “easily severed from the chemical and genetic information that inspired it”.179 Chen differentiates indigenous knowledge from biological knowledge using the categories of memes and genes. A meme is a “unit of cultural transmission” such as “tunes, ideas…ways of making pots or of building arches”.180 As a “sociological” unit, the meme is an “ethnobiological tale”, which is “easily severed from the chemical and genetic information that inspired it”.181 On the other hand, the gene is the biological information itself that is found within the specimen. Chen equates indigenous knowledge or an “ethnobiological tale” with a meme and asserts that only genes “may qualify for protection as a form of intellectual property”.182

Chen also employs what he terms the “layered model of information platforms” to enunciate the supposed incommensurability between indigenous knowledge and genetic

179 Chen, “Biopiracy”, supra note 38 at 22.
180 Ibid.
181 Ibid.
182 Ibid.
information. Chen’s “layered model of information platforms” consists of three layers: physical, logical and content. These three layers, Chen argues, correspond to the biological categories of ‘phenotype’, ‘genotype’ and ‘meme’. According to Chen, each specimen of a plant or animal represents the “physical sublayer”, while the genetic information in the DNA of each specimen constitutes the logical sublayer. The human knowledge, which determines the possible applications of genetic information, forms a “uniquely soft form of biological content”. Chen analogizes the distinction between phenotypes and genotypes with that between biological specimens (as physical chattel) and biological specimens as sources of genetic information. Chen asserts that the plant or seed itself is mere chattel, while the genetic information it embodies is “conceptually independent”. Thus, he contends that “genetic information resembles a nonrivalrous public good in that a single use does not preclude independent use by a different party”.

A number of misconceptions are inherent in this argument. These misconceptions originate from the basic impressions which Western scholarship creates of indigenous forms of knowledge. Fundamentally, the (mis)conception in Chen’s assertion is founded on the belief that indigenous therapeutic knowledge is *simpliciter* the banal knowledge of how a specific medicinal plant is used and applied, knowledge that is believed to inhere in the common man on the streets of any indigenous community. The argument that indigenous therapeutic knowledge begins and ends with knowledge of ‘what a plant does’ in whatever form it is reified, is fundamentally false. It stems from the schism which Western scholarship creates between the results of innovation generated from the laboratory and the same innovation created by a conscientious IMP who lacks the high-tech tools of the Western scientist, but produces a product that is in many ways equivalent to that from the laboratory. The asymmetry between these two products is only traceable to the fact that the indigenous product is often free of the industrially simulated chemicals of the Western pharmaceutical.

On this account, Bratspies observes that “there is an unpleasant dichotomy between defining the products of laboratory research as intellectual property” subject to the full

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183 *Ibid* at 6.
185 *Ibid* at 10.
186 *Ibid*.
187 *Ibid*. 
protection provided by TRIPS and formal domestic law, while “characterizing the uses and experimentation of indigenous peoples as “traditional knowledge” excluded from these protections”. 188 Bratspies asserts that indigenous medicines are the work of countless farmers and indigenous healers “whose labour and ingenuity developed these products to maximize certain traits and minimize others”. 189 Indeed, “they are products of the very same selective breeding that in the laboratory setting gives rise to a patentable property right”. 190 This point has also been affirmed by Canadian activist Pat Mooney, who posits that “the argument that intellectual property is only recognizable when performed in laboratories with white lab coats is fundamentally a racist view of scientific development”. 191 According to Mooney, “[f]armers, gardeners, and herbalists use much inventive genius and more as they continually modify and develop new plant, animal and microbial products and processes”. 192

Incidentally, only a few scholars have highlighted this crucial point in the indigenous knowledge debate. In what is supposed to be a candid picture of the situation in the South, most of the scholarship from both Northern and Southern nations has tended to emphasize certain basic characteristics, such as communality (i.e. communal knowledge), innovative but intergenerational knowledge, communal ownership, etc., which are assumed to be traceable to all indigenous systems. The scholarship has failed to identify the multiplicity of knowledge systems and models of property ownership that exist in indigenous communities and Southern states in general. These knowledge systems differ in their levels of creativity and conceptions of innovations.

Many writings on the subject assume the supposed non-exclusivity of ownership of indigenous knowledge as a given. While it is arguable that the supposed non-exclusive ownership of indigenous knowledge does not automatically place it in the public domain, yet the idea that non-exclusive ownership is universal in indigenous communities gives false credence to the argument that indigenous knowledge belongs to the public domain or the Commons. Put plainly, the argument that indigenous knowledge belongs to the Commons is reified by the view that every member of an indigenous community is privy to the medicinal

188 Bratspies, supra note 83 at 21.
189 Ibid.
190 Ibid at 23.
192 Ibid.
uses of plants existing within the community. This subject needs further research to ascertain how different communities, both in the past and present, view the concept of indigenous knowledge. Data from such research will provide valuable information on the manifold forms in which indigenous therapies are represented.

Having conducted a small-scale study which was designed to investigate the existence of a different reality besides that depicted in the literature, there is at least some evidence to conclude that the common perceptions regarding the nature of indigenous medicine, especially as regards its supposed universality among biodiversity-rich communities, differ from those held by the subjects surveyed. The qualitative study, which as noted above involved the sampling of opinions of NHP users through questionnaires as well as interviews with IMPs, reveals that for societies with a large community of professional herbal practitioners such as Nigeria, where innovation and competition are vital to a successful and profitable practice, indigenous knowledge of medicinal plants – knowledge substantive enough to lead to the creation of a natural health product – is possessed by a close group of professionals.

On the subject of ‘innovation’ and ‘originality’, the practitioners were asked the following questions:

Question 1: Do you have ‘recipes’ or ‘formulas’ for your medicines? If yes, how different are they from a preparation made by simply mixing up the leaves or roots of a specific medicinal plant?

Question 2: Can a lay person or a non-professional produce the same mixture that you have prepared and packaged as a marketable product?

In answer to these questions, one IMP had this to say:

We have special recipes. It is very different from other herbals or other preparations probably prepared by the common man or the person who doesn’t have knowledge of herbals. The reason is … if the quantity that I add to water or the quantity of salt or plants that I add to another plant is not measured in the [right] quantity or in a reasonable way, if the patient takes it, it will result in side effects or reactions.

In answer to the second question, he replied:

No, [a lay person] cannot because he doesn’t have the training, doesn’t have the knowledge and there is no way a lay man can produce and package the way we do it …
Another IMP remarked that community members know one, two or three plants or herbs for the
cure of a particular ailment. However, he included a caveat to this common perception:

As a professional, I have wider knowledge of herbs.

In the context of the specialized practice of indigenous medicine in Nigeria, an argument such
as Chen makes is easily deflated. Chen’s analysis fails to capture the diverse versions of reality
that emanates from a genuine and unbiased study of indigenous therapeutic knowledge systems.

It is also noteworthy that the practitioners are conscious of the relative similarity between
their products and those created in the laboratory. Indeed, as noted in the *Merrell Dow
Pharmaceuticals* case, there is usually no practical difference between the prior art and the
*newly* discovered art that is sought to be patented. It is necessary to reproduce the analysis of
the court on this crucial issue:

Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says:
“We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a
rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is
called quinine”. The Indian replies: “That is very interesting. In my tribe, we call it the magic spirit
of the bark”. Does the Indian know about quinine? My Lords, under the description of a quality
of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that
he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality
which makes it good for fever and that is one description of quinine.193

However, the court reasoned that it was possible that in different circumstances, the
Amazonian Indian could be said to be ignorant about quinine. According to the court:

If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not
know quinine under the description of a substance in the form of pills, and he certainly would not
know about the artificially synthesised alkaloid. I recognise that there is a distinction between
cinchona bark and terfenadine. The former is a substance occurring in nature and the latter is an
artificial product. This might have been relevant if the medicinal qualities of the bark had been
unknown and a person who discovered them had tried to patent the bark or the natural alkaloid. But
the distinction is not material to the present question, which is essentially an epistemological one:
what does it mean to know something, so that it can be part of the state of the art? The quinine
example shows that there are descriptions under which something may in a relevant sense be
known without anyone being aware of its chemical composition or even that it has an identifiable
molecular structure. This proposition is unaffected by whether the substance is natural or
artificial.194

Furthermore, the court asserted that “[t]he Amazonian Indian who treats himself with powdered bark for fever is using quinine, even if he thinks that the reason why the treatment is effective is that the tree is favoured by the Gods. The teachings of his traditional medicine contain enough information to enable him to do exactly what a scientist in the forest would have done if he wanted to treat a fever but had no supplies of quinine sulphate”.

The House of Lords did consider counter arguments against its position. As argued by counsel for the appellant in that case, it is possible that the patent law simply has its own “specialised epistemology”, which like Chen’s argument, recognizes only the specific language form of chemical compositions. The court disagreed with this reasoning on the contention that Section 2(2) of the Patents Act of 1977 “does not purport to confine the state of the art about products to knowledge of their chemical composition. It is the invention which must be new and which must therefore not be part of the state of the art. It is therefore part of the state of the art if the information which has been disclosed enables the public to know the product under a description sufficient to work the invention”.

Beyond the moral issues that arise from a candid evaluation of the absence of any difference between Invention Types A and B above, the argument that indigenous therapeutic knowledge is always communal and publicly held is simply incorrect, and must be refuted by empirical research-based scholarship. Madhavi Sunder traces this erroneous conception to the supposedly innocuous analyses of James Boyle’s in his work, Shamans, Software & Spleens: Law and the Construction of Information Society. Sunder argues that the concept of ‘traditional’ knowledge, and the associated concept of the public domain, is a recent development. Crediting James Boyle with the invention of the concept of the public domain, Sunder observes that the focus of Boyle’s work was on the “dark side of intellectual property” where Boyle attempted to show that IP rights could deplete the “cultural commons” and the world’s cultural heritage.

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195 Ibid at 91.
196 Ibid at 88-89.
197 Ibid at 89.
199 Sunder, supra note 48 at 3.
environmentalism”, a movement which “illustrated how third world peoples are disproportionately disadvantaged by IP law, which historically has not recognized their cultural contributions”.

According to Sunder, “by reifying the negative and focusing needed attention on the other side of intellectual property, Boyle invented the public domain”. Sunder argues that while indigenous communities and Southern peoples benefited from the attention to the cultural commons, Boyle’s invention of the public domain was a double-edged sword. Thus, while the concept of “cultural environmentalism” led to the invention of indigenous knowledge as a political-legal category, the same concept has “obscure(d) the inventiveness” of indigenous knowledge. Sunder asserts that the reification of the public domain may have the “unintended effect of congealing traditional knowledge as the opposite of property, presenting poor people’s knowledge as the raw material of innovation – ancient, static, and natural, rather than as intellectual property – modern, dynamic, scientific and cultural invention”. Conceived in this way, indigenous knowledge holders may only be compensated for conserving biodiversity and providing the raw materials for Western innovation, but they are not recognized as innovators or as deserving of IPR privileges in their own rights.

Sunder appeals to legal decision-makers to recognize “contingency, bias, and unreasoned orthodoxy in the legal definitions that begin to appear...as natural”, arguing that in many cases, the only distinction between the creativity of a product from the South and that from the North is the packaging and its availability in the market. On similar grounds, Gervais expresses apprehension that as products of indigenous knowledge evolve, they may come to resemble the derivative work. The “perverse” result will be the application of the IP system against the original work by the progenitors of the derivative work. This crucial point, which is one of a number of problems at the root of the charge of biopiracy, invalidates Chen’s argument that a single use of genetic information does not preclude independent use by a different party.

200 Ibid at 4.
201 Ibid.
202 Ibid.
203 Ibid at 5.
204 Ibid at 5.
205 Ibid at 12.
206 Ibid at 17.
While Chen’s argument on its face may appear to have some validity, it fails to address the fears of indigenous innovators because its foundation—the assumption that the final use to which the genetic information is put by pharmaceutical corporations is significantly different from the prior art of the indigenous innovator—is fundamentally false. The House of Lords in *Merrell Dow Pharmaceuticals* affirmed this when it asked what was new about the newly discovered chemical composition in terfenadine.\(^{208}\)

Arguments such as those made by Chen are often conditioned by perceptions of what knowledge is universal or valid and what constitutes property, perceptions which are inherently culture-specific. These arguments are also conditioned by rapid globalization and capital accumulation, which distorts the way in which health is conceptualized.\(^{209}\) The pursuit of capital and private property above all other considerations conflicts with the practice of indigenous medicine as a therapeutic system that purports to affect the individual and the community at multifaceted levels. The TRIPS regime with its central focus on innovation for wealth succeed(s) because of certain assumptions about medicine and health in the Western society.\(^{210}\) Summarily:

(1) The determinants of health and illness are assumed to be almost entirely biological, having little or no relation to the socioeconomic circumstances. Solutions to health problems are therefore seen to lie entirely in the purview of medical treatment, while broader questions about social change towards health promotion are ignored. (2) (m)edicine is presented as a science—and therefore assumed to be all but infallible. More importantly, medicine is seen as capable and competent of producing a set conclusion, one that is purely ‘scientific’ and completely removed from the broader social setting. (3) Medicine is inherently assumed to be good for the health and well-being of society—the only problem being there is not enough of it go around. Moreover, insufficient access, as a result of market restraints or other causes, is assumed to be solvable through the normal processes of democracy and pressure politics.\(^{211}\) Problems of health care are thus normatively represented purely as science-based, generally ignoring that there are problems that are intertwined with socioeconomic circumstances and capital interests.\(^{212}\)

This very illuminating summation of the assumptions held by the progenitors of the TRIPS Agreement reveals why opponents of the arguments of the South can easily disregard the socio-cultural context in which biodiversity-rich communities situate their knowledge and

\(^{208}\) *Merrell Dow Pharmaceuticals*, *supra* note 87 at 83.

\(^{209}\) Mykitiuk and Dagnino, *supra* note 54 at 311.


\(^{211}\) Mykitiuk and Dagnino, *ibid* citing Lesley Doyal, *ibid* at 13. Emphasis added.

\(^{212}\) Mykitiuk and Dagnino, *ibid* at 311.
innovations. In this context, there is no separation between memes and genes or between phenotypes, genotypes and memes.

The unfortunate consequence of the pro-West definition of ‘patentable property’ validated by the current legal regime is that indigenous therapeutic knowledge, much like the practice of indigenous medicine, lacks legal protection. While being perceived as raw materials for Western innovation, the patent regime creates a set of rules that necessarily expels such materials from the ambit of law and its protective umbrella. Essentially, indigenous knowledge systems are being filtered through new “culturally determined systems” instituted by a few “self-appointed arbiters of the ‘normative’ bases of global regulatory regimes”.213 Notably, the construction of indigenous knowledge as raw materials for Western development engenders “a model of benefit sharing”214 instituted by the Convention on Biological Diversity215 in which biodiversity-rich states are expected to receive some monetary compensation for the use of their knowledge in drug formulations in the West. Thus, rather than address the concerns of indigenous peoples regarding how the law can be applied to utilize their innovative and productive knowledge, the prevailing legal order emphasizes technology transfer, foreign direct investment, access to Western production, and equitable sharing of benefits.216

Bratspies has also questioned the definition of property in the indigenous knowledge controversy. The author observes that when the interests and assets of an entire group are, by definition, not embraced within the “protective mantle” called property, “it ought to prompt exploration of some hard questions”.217 One such question seeks to know on whose terms the concept of property is defined. Evidently, conceptions of property and of what is protectable by law are determined through the ideals of Western science. Bratspies contends that the international community needs to rethink the very idea of property, and asserts that these questions should provoke a rethinking of how a “bounded vision” of the right to property has hindered “the development of a full-fledged right to culture, and has trapped indigenous peoples

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214 Sunder, supra note 48 at 12-13.
215 Convention on Biological Diversity (CBD), entered into force on 29 December 1993.
217 Bratspies, supra note 83 at 5.
in a seemingly unending cycle of dispossession and exploitation”.\textsuperscript{218} The dispossession is fostered through the definition of property to include the products derived from the intellectual resources of indigenous peoples while excluding the intellectual resources themselves.\textsuperscript{219}

Vandana Shiva, physicist and environmental activist, also criticizes the role of reductionist science in the lack of recognition of indigenous knowledge as intellectual property.\textsuperscript{220} Shiva links the rise of scientific reductionism with the domination of women and non-Western peoples.\textsuperscript{221} The diverse knowledge systems of these groups of people were not regarded as “legitimate ways of knowing”.\textsuperscript{222} In this light, “reductionist biology” may be cast as a carefully designed paradigm and as “an expression of cultural reductionism”, which “devalues” non-Western cultures.\textsuperscript{223} In the process of devaluation, the fragility of the explanatory and conceptual power of scientific reductionism is offset “by its ideological power as well as its economic and political backing”.\textsuperscript{224} These accounts of the reductionism and cultural specificity of Western science contrast sharply with Chen’s perceptions of indigenous knowledge.

What is particularly intriguing in assertions like Chen’s “ethnobiological tale” is that “innovation” is hinged solely on a narrowly constructed idea of what ‘science’ implies and requires. Under the extant regime, the common trend is that indigenous therapeutic knowledge – regardless of how creative or phenomenal – cannot be patented as long as it is not expressed in the language of DNAs, genes, and scientific formula. Essentially, science is often construed as the language of the patent system. This has been upheld by the US courts, which have also expanded the scope of patentable subject matter through the ‘creation’, rather than the ‘interpretation’ of patent law provisions.\textsuperscript{225} Such ‘created interpretations’ categorize indigenous knowledge as innovative once they are expressed in formulaic language. In the case study of the Nigerian farmers who developed an insect-resistant cowpea briefly discussed in the introduction, the patent regime did not recognize the inventive processes that resulted in the

\begin{itemize}
    \item \textsuperscript{218} Ibid at 5.
    \item \textsuperscript{219} Ibid at 23.
    \item \textsuperscript{220} Shiva, supra note 39 at 24.
    \item \textsuperscript{221} Ibid at 24.
    \item \textsuperscript{222} Ibid.
    \item \textsuperscript{223} Ibid at 25.
    \item \textsuperscript{224} Ibid at 29.
    \item \textsuperscript{225} See Mgbeoji, \textit{Global Biopiracy}, supra note 7 at 32 and 88.
\end{itemize}
insect-resistant cowpea; however, the regime was employed to protect the same invention so long as it was framed in the culturally-specific language of science.

4.7. Options for Southern Countries

It was noted in the concluding section of chapter three that many IMPs are making changes to their practice in the interest of reaching out to a larger population. The changes encompass a slow, but gradual acceptance of the need to standardize and package medications for sale. The evidence from Nigeria reveals that many practitioners have devised a way to retain an individualized form of practice while standardizing their medicines. According to Bishop Magnus Atilade, a Nigerian physician and qualified chiropractic and head of the Council of Physicians of Natural Medicine and the National College of Alternative Medicine in Nigeria, IMPs are interested in producing medicines at a commercial scale.226 Atilade notes that “the future is in mass production to be able to take care of many patients”.227 Thus, the medicines – in the words of Atilade – need to be “formulated”.228 However, in this process, there remains a continuous agitation for the institutionalization of IP rights for natural health products. This concluding section examines how the reservations regarding biomedical standardization and the absence of intellectual property protection could be addressed in the interest of the growth and development of NHPs and the indigenous healthcare sector.

4.7.1. Extant Proposals

The literature is replete with numerous recommendations and proposals regarding how the demands of indigenous knowledge holders may be addressed. In spite of the seemingly unending list of recommendations, policy changes have been slow in coming. It is not exactly clear that further theorizing and recommendations will significantly alter the current state of affairs. However, it is imperative for governments of nation-states to begin to weigh the available options against newer recommendations; and based on decisions reached, they need to take decisive steps towards ameliorating the difficulties experienced by their peoples. A starting

227 Ibid at 35.
228 Ibid.
point should be an evaluation of the dominant viewpoints regarding how indigenous therapeutic knowledge might be protected.

Two dominant schools of thought on the possible mechanisms to be employed in protecting indigenous therapeutic knowledge may be deciphered from the scholarship. There appears to be a third school of thought which lays emphasis more on compensation for indigenous knowledge than on mechanisms for protecting the knowledge. One school of thought, promoted by Ikechi Mgbeoji, Daniel Gervais, and Rebecca Bratspies, contends that indigenous therapeutic knowledge is protectable through the Western intellectual property system, more specifically, the patent system. According to Bratspies, bringing traditional knowledge within intellectual property should not be a difficult task given the broad language of the World Intellectual Property Organization (WIPO) Convention. This is because the Convention specifically includes language designed to extend protection beyond the listed categories of intellectual property, to all “intellectual activity in the industrial, scientific, literary or artistic fields”. Bratspies further suggests that a “negative” or “positive” interpretation could be adopted to modify the TRIPS Agreement to include products of indigenous knowledge. In the former case, “traditional knowledge would remain part of the global commons, but so would works derived from that knowledge”. In the latter case, “the international community could redefine property so that indigenous knowledge is not categorically excluded”.

The second school of thought, represented by scholars like Vandana Shiva, Doreen Stabinsky, Stephen Brush, and Walter Reid, asserts that the patent system cannot adequately protect indigenous therapeutic knowledge. Shiva rejects the idea that intellectual property rights are capable of protecting indigenous knowledge systems on the ground that “while

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231 Bratspies, *supra* note 83 at 18.
232 Ibid at 26.
233 Ibid.
bioprospecting fees could be used to build scientific capacity” for Southern nations, “what is actually being built is a facility for the corporation”.\(^{235}\) She also rejects intellectual property systems on the reasoning that they are destructive to environmental sustainability. Shiva argues for the development of an “alternative economic paradigm which does not reduce all value to market prices and all human activity to commerce”.\(^{236}\)

A third approach emphasizes the need for monetary compensation for the owners of indigenous knowledge. This viewpoint is supported by the Convention on Biological Diversity, which provides for benefit sharing agreements between the holders of the knowledge and Western bioprospectors. Some authors, including Doris Long and Chika Onwuekwe\(^{237}\) favour a compensatory scheme in which Southern nations would earn royalties from Western companies for the exploitation of their knowledge and resources. For example, Long argues that monetary compensation will provide a major resolution to the controversy over indigenous knowledge resources. However, this argument fails to address broader public health and development issues arising from the indigenous knowledge discourse. Linking indigenous peoples’ economic independence to the proprietary benefits to be derived from royalties paid to them by Western pharmaceutical corporations and researchers, the author’s argument does not acknowledge the importance of exploring options that recognize the need for a development project that will prevent the reliance of most Southern countries on the North for economic and medical progress. Within the second school, there are calls for national governments to adopt sui generis systems carefully designed to fit the nature of the knowledge that they seek to protect.\(^{238}\) A number of strengths and limitations are inherent in the above positions. In examining these positions, it is necessary to discuss the strengths and limitations of applying patents to protecting the products of indigenous therapeutic knowledge.

The patentability of indigenous knowledge is a much-contested assumption. However, some scholars contend that indigenous knowledge can be accommodated within the patent

\(^{235}\) Shiva, ibid at 76.

\(^{236}\) Ibid at 77.


regime in a modified system that recognizes the inherent validity of different cultures.\textsuperscript{239} On this note, Gervais proposes the building of “cross-cultural bridges” in this area and advocates for flexibility in protecting indigenous knowledge through the modification of existing Western IP tools.\textsuperscript{240} With the cross-cultural theme at the centre of her work, Rosemary Coombe sues for a system of “cross-cultural” global dialogue between all stakeholders in the debate.\textsuperscript{241} She argues for “alternative understandings of human progress and an “alternative vision of intellectual property rights” beyond those of the neoliberal market logic that has so far dominated the TRIPS discussion.\textsuperscript{242} Coombe contends that only when indigenous peoples are full partners in this dialogue, with “full juridical standing”, and only when their customary laws and worldviews are recognized as fundamental contributions to “resolving local social justice concerns” will the international community be engaged in anything that can be genuinely termed a dialogue.\textsuperscript{243}

\textbf{4.7.2. The Strengths and Weaknesses of the Patent System}

When we transcend the specificities of the above arguments and proposals regarding whether or not indigenous knowledge can be accommodated within the IP system, we are confronted with certain consequences entrenched in the different options espoused by scholars. Patents bestow the right to apply the enforcement power of a state to prevent unauthorized persons, for a given number of years, from making mercantile use of an invention.\textsuperscript{244} The life of a patent as guaranteed by the TRIPS Agreement is twenty years. These elements of the patent system constitute some of the greatest strengths of the system.\textsuperscript{245} Patents secure the pecuniary interests of the inventor for the specified period, during which the inventor is expected to recoup the

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\textsuperscript{240} Gervais, “Traditional Knowledge and Intellectual Property: A TRIPS-Compatible Approach”, \textit{ibid} at 144-146.
\textsuperscript{241} Coombe, \textit{supra} note 239.
\textsuperscript{242} \textit{Ibid}.
\textsuperscript{243} \textit{Ibid}.
\textsuperscript{244} Fritz Machlup, \textit{An Economic Review of the Patent System – Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee of the Judiciary} (United States Senate, 85\textsuperscript{th} Congress, 2\textsuperscript{nd} Sess., Study No. 15) at 2.
\textsuperscript{245} Some scholars might argue that the life-span of a patent does not fit with the nature of indigenous knowledge, which is said to subsist in originating communities for generations. This point is taken into consideration in the final analyses and suggestions made below.
\end{flushleft}
money expended on research and development of the invention. This security of tenure constitutes a powerful incentive for drug manufacturers and at least some IMPs.

More than 80% of indigenous Nigerian healthcare providers utilize herbal products in their practice. These providers have always recognized the need to protect the secrets of their creativity and practice. As noted above, IMPs have had to rely on trade secrets. It is considered a serious offence for a student or “trainee” under the tutelage of an IMP to disclose the constituents of a natural health product to anyone considered an outsider. However, as already noted, trade secrets have become very inefficient given the ease of reverse engineering. The futility of trade secrets and consequential lack of protection for indigenous medicinal innovations constitutes a barrier to the regulation of NHPs in Nigeria. This is a major barrier to medical integration. An efficient patent system can assure IMPs that they would not lose their source of livelihood by providing data about the constituents of their products to aid the regulation of NHPs. A successful integration of medical systems requires a well-regulated indigenous healthcare paradigm. Thus, the success of the NHP regulation process in Nigeria is dependent on assurances that the patent system can provide.

The patent system appears to be the most attractive option for IMPs whose inventions can meet the criteria of the system. In spite of the fact that indigenous herbal practice is holistic in nature, a successful accommodation of indigenous knowledge within the patent system is possible. As revealed in interviews with IMPs in Nigeria, indigenous medicine can and is often practiced holistically while pre-packaged and processed natural health products are dispensed according to standardized protocols. It is important to emphasize that this system of practice has in no way diminished the agitation for the extension of intellectual property protection over NHPs. The intellectual property debate remains a current issue between indigenous and biomedical practitioners in Nigeria. Thus, the IMPs’ gradual accommodation of the Food and Drug Agency’s regulations within their private practice may be interpreted as one way in which the practitioners are drawing attention to their readiness for the protection offered by the conventional IP system.

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247 Chen, supra note 38 at 24.
248 Akunyili, supra note 26 at 2 and 3.
249 See Oguamanam, supra, note 39 for a different perspective on this argument.
A successful accommodation of NHPs within the patent system will make the system more “culturally-neutral”.\(^{250}\) A culturally-neutral system ensures the harmonization of different bio-cultural innovations under a single system, which if well-designed, “could at least in theory assist countries in adding value to their genetic resources”.\(^{251}\) This is a loftier objective than the proposition requiring Southern countries to sell their resources as raw materials to be processed elsewhere. Following this suggestion, intellectual property rights (IPRs) have been cast as a prerequisite for the international transfer of new biotechnologies to Southern states, in which case pharmaceutical companies will charge license fees that reflect the costs of innovation.\(^{252}\) Support for this arrangement is provided by Article 16 of the *Convention on Biological Diversity*, which requires parties to the Convention to facilitate the transfer of technologies to other parties under the fair and most favourable terms. However, this arrangement appears to hold out a double-edged sword. The International Institute for Sustainable Development has observed that the overall effect of strong IPRs will be to inhibit technological transfers because in a free market, patents restrict the number of people who could otherwise freely make, use, sell or import the protected products and processes. This will invariably have the effect of reinforcing North-South inequalities.\(^{253}\)

While weighing the relevant arguments on the strengths and weaknesses of the patent system, it is important to note that the decision regarding the best juridical protection for herbal medicines and other products of indigenous therapeutic knowledge has a direct and significant impact on access to medicines for indigenous populations. The patent system is expensive and complicated, and has implications for drug prices. The socio-economic costs of IP legislation can significantly inflate the costs of medical products. Interestingly, in its recommendation of access and benefit sharing agreements between knowledge holders and bioprospectors to aid the legitimate development and patenting of plant genetic resources by the latter, the *Convention on Biological Diversity* appears to have overlooked this crucial point.

\(^{251}\) IISD Trade and Development Brief, “The Trips Agreement and Biodiversity” Series No. 8 at 4.
\(^{252}\) *Ibid.*
\(^{253}\) *Ibid.* Although this argument is persuasive, it may also be argued that technological transfer may be the ultimate option if Southern states are to end their reliance on Western R&D because technologies are crucial to developing home-grown resources. Nevertheless, the validity of this option is hinged on the ability of parties to reach a fair agreement, which would reduce the overhead costs of drug production for Southern states.
As Hanns Ullrich has observed, the CBD’s rules on access and benefit sharing do all but improve its operation because the provisions “mistreat rather than foster the golden goose”.254 This implies that the exclusive rights that will be obtained by bioprosectors over the patented outcomes of the research will influence costs and profits; “the higher the costs of an innovation, including the costs of patenting, and the more public or private taxes are levied on potential profits, the higher the profit potential itself must be”.255 Indeed, high patent costs and processing fees, and the costs of benefit-sharing arrangements will eventually lead to higher costs of medicines produced by the North and exported to countries of the South. Ultimately, these medicines are largely unaffordable by citizens of biodiversity-rich nations. Furthermore, small domestic firms which have to operate on the same stringent patent standards as the big pharmaceutical companies might be affected.256 Ullrich argues that advocates of a strong patent system must realize that small home industries will be harmed.257

It is important to consider carefully the socio-economic costs of IP legislation, which can significantly inflate the costs of medical products. Statistics on the impact of patent protection on access to medicines are alarming. For example, a 200% increase was recorded in the costs of medicines after the 1979 introduction of pharmaceutical product patents in Italy. Comparison of drug prices between India and countries where patent protection exists revealed that drug prices were up to 41 times higher in countries with patent protection.258 On the overall, patented medicines – whether from indigenous knowledge or modern pharmaceuticals – will likely result in increased costs. Therefore, since integration encompasses coverage for both medical products and services, if current TRIPS regime is adopted wholesale in Southern nations, it is likely that integration will have entrenched an expensive health products market, thereby complicating present difficulties in the healthcare sector.

Nevertheless, in spite of the likelihood of IPs to increase costs of medicines, there remains a strong argument in favour of the choice of patents. Patents are the most feasible option for the protection of products of indigenous therapeutic knowledge. A compelling reason for this is that

255 Ibid.
256 Ibid at 26. See also Criticism of Natural Health Products Bill C-51 Mounts, supra note 3.
257 Ibid.
the patent system has ascended to a level of importance in the international community, and given the configuration of global economic, technological and political power, a drastic reform of the system may not be feasible in the near future.\textsuperscript{259} It is also unlikely that the global South can make a new IP system binding in international law.\textsuperscript{260} Hence, indigenous peoples need to seek options within the framework of the international law on patents and promote “interpretations suitable to their aspirations”.\textsuperscript{261} Rosemary Coombe reinforces this argument when she observes that “any new alienable right…is only as valuable as the position its holder occupies in the market”.\textsuperscript{262} As intellectual property involves questions of economic interest, competitiveness and market power, it is doubtful how far a new alienable right will go to protect indigenous communities.\textsuperscript{263}

The above arguments are compelling. In fact, proposals for \textit{sui generis} systems that differ drastically from current IPRs may face difficulties because there is little likelihood that the international community will recognize an IPR model that radically falls below the minimum standards of the Western IPRs. Given that the indigenous knowledge debate is championed by South states, the question is whether these countries have the requisite economic and political power to impose a new IP system on the rest of the world. While the CBD and recent documents prepared by the Secretariat of the World Intellectual Property Organization under the auspices of its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore suggest that states have some flexibility in the choice of a \textit{sui generis} model for the protection of plant genetic resources and products of indigenous knowledge, the aspirational language of the CBD and the WIPO documents signifies that states need to exercise caution in the design of such regimes.\textsuperscript{264}

Thus, realistically, any viable proposal should tilt towards the application of the current patent system to indigenous therapeutic knowledge. This proposal is reinforced by the foregoing argument that there exists little tangible difference between the products of indigenous therapeutic knowledge and its Western counterpart. However, the pertinent question

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\textsuperscript{259} Mgbeoji, \textit{Global Biopiracy}, supra note 7 at 171.
\textsuperscript{260} Ibid at 165.
\textsuperscript{261} Ibid at 175.
\textsuperscript{262} Coombe, supra note 239 at 7-8.
\textsuperscript{263} Ibid.
\end{footnotesize}
is how biodiversity-rich countries can adopt the patent system without a significant impact on the nature and affordability of natural medicines. For, as Bratspies has noted, the protection of indigenous knowledge “will involve more than bringing a new form of knowledge within the scope of intellectual property law”.265 The problem lies in the conceptual differences between indigenous and western innovations, or to employ Bratspies’ description, in the unpalatable choice faced by indigenous peoples: they may either remake their knowledge in the image of the rights claimed and recognized within the dominant society and break down the essence of their traditional culture into distinct classes of property, or “deny themselves access to existing intellectual property protections”.266

One way of interpreting the concerns expressed by Bratspies’ is that scientific evidence of industrial application and reducibility which are requirements for patentability may be deemed “culturally discriminatory”267 by some knowledge holders. Oguamanam contends that this requirement threatens the “cultural essence”268 of the indigenous medical paradigm. The question is whether innovators in indigenous communities are willing to make such a compromise. One IMP interviewed in Nigeria expressed a preference for “an outstanding” scheme to “protect [the] intellectual property of herbal medicine”.269 Another practitioner was clearly of the opinion that “there must be an appropriate provision for intellectual property rights” for indigenous medicines.270

4.7.3. The Future: Possible Options

Taking into consideration the expectations of the practitioners and the totality of the foregoing analyses which favour the adoption of patents, it is expedient to have a resolution based on a dual initiative at the national and international levels. First, states of the global South will certainly benefit from a simplified and uncomplicated patent system that is reformed to meet the needs of the specific community. At the national level, a modified patent regime can be

265 Bratspies, supra note 83 at 18.
266 Ibid at 19.
268 See Oguamanam, supra note 39 at 33.
269 Iyioha, International Research, supra note 5.
270 See Adodo, “Orthodox Medicine and Traditional Medicine”, supra note 31 at 12. In the statement, the author made the provision of IP rights for indigenous medicines a precondition to the disclosure of indigenous knowledge to the regulatory agency (at 12).
designed to allow affordability, easy administration, and ensure a simplified application process. A simplified and low-cost initiative will help reduce the costs of acquiring patents. Indeed, national governments have the necessary political power to initiate and implement this process in the best interests of their citizens. Contrary to popular notions, the modern state is in the best position to accomplish this task. As Mykitiuk and Dagnino have noted:

Contrary to claims that the state has been marginalized by globalization, the importance of the state in creating national policy has been strengthened, even as globalization has fundamentally altered the latter’s direction.\textsuperscript{271}

The Nigerian government for several years has exercised this political power in denying patents to pharmaceuticals in the interest of lowering costs for its citizens. The exclusion of pharmaceuticals from patentability in that country has been based on the rationale that patents may prevent easy access to drugs at competitive prices in Nigeria.\textsuperscript{272} With the emergence of the TRIPS Agreement and the World Trade Organization’s (WTO) mandate that all member nations must have operative patent systems in all fields of technology including pharmaceuticals, Nigeria has expressed the intention to review the \textit{Patents and Designs Act}. On this note, the National Office for Technology Acquisition and Control (NOTAP) in Nigeria has stated that the Act will be reviewed to make it TRIPS compliant.\textsuperscript{273}

When the laws are reviewed to permit the patentability of pharmaceuticals, it is expected that the Act will incorporate the standards of the international patent system as embodied within the TRIPS Agreement. Therefore, indigenous therapeutic knowledge will encounter the same difficulties under the Nigerian patent regime as it has encountered under the international patent system. A new amendment to the Act is unlikely to review this provision in favour of indigenous knowledge as currently defined. This is because NOTAP has deferred to the provisions of the Convention on Biological Diversity (CBD), which provides for benefit sharing between indigenous knowledge holders and Northern countries.\textsuperscript{274} However, such an outcome

\textsuperscript{271} Mykitiuk and Dagnino, \textit{supra} note 54 at 310.
\textsuperscript{273} \textit{Ibid} at 5.
\textsuperscript{274} \textit{Ibid}.
can be avoided if the Nigerian *Patents and Designs Act* is amended to recognize NHPs that meet the minimum requirements of the patent system.

Furthermore, in its bid to simplify the patent system, the Nigerian government has ensured that patents for inventions are not examined for novelty at the time of filing. This system, known as the *Deposit System*, was adopted because of the limited availability of technical expertise in the area of patents examination. The system was also adapted to reduce the financial burden associated with the process of examination. Notably, in the deposit system, the courts are empowered to declare the patents invalid only upon a future challenge by a person or persons with a stronger title to the patent. The Nigerian state will benefit from a reformed IP system, which – while not discounting the provisions of TRIPS – represents the best interests and aspirations of its people. Amendments to the *Nigerian Patents and Designs Act* must reflect not only Western-styled high tech-innovations, but also products of indigenous therapeutic knowledge.

The second arm of the dual proposal addresses the debate at the international level. This aspect of the debate – which marks the international appropriation of indigenous knowledge – is perhaps the most problematic because of the “territoriality” principle within patent law. The territoriality principle states that patents are not enforceable outside the country in which they are granted. Thus, patents granted to protect products of indigenous knowledge within a state are ineffectual outside the boundaries of the state and at the international level, where biopiracy primarily occurs. To counter this, it is necessary to have an international patent registry to record patents granted at the national levels. In recent times – in fact, as recent as February 2010—after the first draft of this study was written, a relatively similar suggestion was brought to the attention of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO).

This Committee after its fifteenth session held in December 2009 had invited Member States and observers to submit draft papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources. The papers were to be made available before February 12, 2010 for circulation and consideration in the next session of the Committee. In the summary document containing the “revised list of options” for the protection of genetic resources, it was recommended that:
The Committee could consider the creation of a dedicated international information system on disclosed genetic resources as prior art in order to prevent the erroneous grant of patents on genetic resources. This was submitted at the ninth session as an alternative proposal for dealing with the relationship between intellectual property and genetic resources.\textsuperscript{275}

Notably, Graeme Dinwoodie has made a suggestion to counter the territoriality principle. He advocates for “incremental” and reciprocal recognition of national \textit{sui generis} systems “on an ongoing basis” through an international treaty by the international community.\textsuperscript{276} Dinwoodie advocates for a system whereby member states of the WTO would “deny the grant of industrial property rights in their own country based upon the recognition of rights, accorded by a foreign nation”.\textsuperscript{277} Dinwoodie’s proposal evidently requires the draft of an international treaty that would make domestic countries/courts subject to the jurisdiction of foreign laws. This implies that domestic courts would be bound to reject patents in their home countries based on laws passed in foreign jurisdictions. Dinwoodie recognizes the choice of law problems implicated in his proposal and suggests that the international treaty would displace the “intrusion upon sovereignty” of other countries.\textsuperscript{278}

While this proposal for countering the territoriality principle is credible, it is doubtful whether Northern nations would accede to a treaty that would make them subject to the laws of other nations. A country like the United States with high stakes in the TRIPS Agreement is unlikely to accede to such a treaty. Take for example the fact that the US is yet to ratify the \textit{Convention on the Rights of the Child}. It would not be unprecedented for the US to reject such a treaty. While the rejection of such treaty by the United States does not affect the validity of the treaty, yet the United States’ patent regime arguably poses the most problems for countries seeking to prevent biopiracy. Therefore, any such treaty – to be truly successful in addressing

\begin{footnotes}
\footnotetext[277]{\textit{Ibid} at 10.
\footnotetext[278]{\textit{Ibid} at 12.}
\end{footnotes}
biopiracy – should ideally bind the United States. An international patent registry, which simply re-registers patents granted at the national level, serves to place other countries on notice that a particular invention or (combinations of) indigenous therapeutic knowledge which have been put to inventive use is prior art in a foreign state. In effect, this registration process may be deemed to satisfy the requirement of ‘publication’ as outlined in section 102 of the US Patent Law:

Beyond these proposals, the ultimate decision regarding the best approach to protecting indigenous therapeutic knowledge is one that must be weighed against some important questions, which states and policymakers in biodiversity-rich societies must consider. These questions include: (1) what is the overriding interest of the state in the protection of indigenous knowledge? To protect the local natural health products market from internal biopirates? Or is international biopiracy the most pressing concern? Alternatively, the state could consider whether its paramount interest lies in developing the indigenous healthcare system and successfully integrating it into its national healthcare delivery system; (2) is the state in a position to initiate and implement an amended patent system that suits the interests of its people? If not, will recourse to the framework of existing IPRs result in an unaffordable market for natural healthcare products and further entrench the existing inequities and healthcare disparities? If the state can pursue patent reform, then it may consider whether a reformed patent system for products of indigenous therapeutic knowledge can promote innovation without necessarily entrenching capital accumulation.

These types of questions are at the heart of the debate and can help states determine which agenda they should pursue. If the choice is patent reform, then amendments to the law would need to address the main issues of concern to practitioners, which include the criteria for patentability and the length of the patent regime. A reformed patent law would largely retain the basic framework of the current patent regime in order to comply with the minimum requirements of the TRIPS Agreement. Thus, the derivative products must meet the requirements of novelty and inventiveness to be eligible for patentability under the reformed law. This means that the products created from an IMP’s knowledge of therapeutic plants must:
1. Comprise of a constituent whose medicinal quality and relevance for the treatment of a given medical condition was previously unknown;

2. Neither the medicinal quality of the product nor its composition is obvious to the average indigenous healthcare specialist in the field; or

3. Include a mixture of diverse constituents, the exact combination of which must not be of common usage within the relevant community. The combination must not have been previously published or commercially produced by another practitioner.

4. However, where another practitioner discovers that the same combination may be applied for the treatment of other medical conditions, it may be deemed to have met the requirements of novelty and inventiveness.

5. Finally, a product should be entitled to patent protection whether or not it is chemically processed. The TRIPS requirement of ‘industrial applicability’ for patentable products fails to recognize the epistemic differences between indigenous and Western forms of knowledge. Thus, this suggestion aspires to remove the technicality imposed by the TRIPS Agreement in this area. As long as the product can be shown to have met all other criteria, it should be protectable.

Another issue of concern to practitioners is the tenure of a patent right. Ideally, states should consider extending patents for products of indigenous therapeutic knowledge beyond the 20 years minimum requirement established by the TRIPS Agreement. This amendment would ensure that IMPs have an extended period to exploit a product derived from indigenous therapeutic knowledge, especially when the knowledge from which the product was derived can be shown to be a long-time family secret. In this case, as well as in situations where the product is the result of collaborative efforts by two or more IMPs, the patent rights may be jointly held by the family or the group. The patent may be managed by the lead inventor or all members of the group in the case of a group invention or by the family member whose efforts led to the synthesis and production of the product, or by some other method agreed upon by all rights-holders.

It is important to note that a number of products of indigenous knowledge might not meet these reformed standards. In such a case, a state may decide to grant some form of certificate of recognition and/or a registration number (akin to that granted by the NAFDAC) to products that
do not meet the standards suggested above. A certificate of recognition would simply serve as a notice to foreign bioprospectors that the resources or materials contained in a given product are recognized as originating solely from within the boundaries of the nation-state. This protective mechanism would be utilized only in cases where the resources used in the production of the product can be traced geographically to a particular community or nation-state. While the certificate of recognition would not confer monopoly rights on the holder, it would serve to bar foreign appropriation of the resources of the given community – especially where the certificates are recorded in the international patent registry suggested above.

In the overall, irrespective of what scholars think is best for the affected communities certain realities are indisputable: that indigenous peoples, interests, and traditions are at the centre of a globalizing world – a position that largely induces change. The ultimate decision in this controversy rests with the knowledge holders themselves. Where represented by states, the state must evaluate how various recommendations are likely to affect the health economy and the healthcare of the citizenry. It is in the best interests of Southern peoples and states to choose a course which ensures greater access to essential medicines and other therapeutic resources.
CHAPTER 5. GOVERNING PLURALISM – MODELS OF INTEGRATION AND GOVERNANCE REGIMES

There is no doubt in my mind that pain and suffering can be relieved by alternative medicine. Sometimes the law leads society in a certain direction, but often times societal behaviour leads the law...it is a matter of the law eventually catching up...and I am hopeful the legislators will do that...they...are not there yet regarding the types of alternative treatment expenses you seek.

Justice Miller, Davar v. The Queen

5.1. Introduction

The last two chapters examined regulatory impediments to medical integration. As observed, these impediments include the statutory prohibition of the practice of medicine by persons who do not hold a medical licence, the fragmentary regulation of indigenous and alternative medicines in Nigeria and Canada, disciplinary actions against physicians who practice integrated medicine for allegedly falling below conventional medical standards, and the lack of financial support for users of indigenous and alternative medical systems. The chapters examined how controversies surrounding the interpretation of ‘scientific validity’ and of ‘innovative property’ under the intellectual property law regime constitute major impediments to the regulation and integration of indigenous and alternative medicines within national health systems in Nigeria and Canada. This chapter introduces the first part of the reform initiatives that are necessary for addressing the above impediments. The chapter provides an overview of three processes necessary for achieving medical integration while discussing the relevance of a theory of governance to the objective of medical integration. As part of the latter discussion, the chapter examines current theories of health governance and their affiliation with different models of integration.

Generally, three independent processes may be identified in the journey towards medical integration: institutional and legislative reform engineered by the state, negotiation and dialogue among practitioners and between practitioners and the state on issues relevant to

medical integration, and where necessary, contestation with the state initiated by consumers and practitioners. Contestation involves a challenge of laws and policies that are considered unfair or prejudicial by patrons and practitioners of indigenous and alternative medicines. As noted in chapters one and two, the primary processes for building an integrated healthcare system involve legislative and institutional reforms by the state. These initiatives will involve changes to the configuration of the policymakers in healthcare institutions as well as reform of healthcare laws and policies. The processes of policymaking and administration, and the operation of laws and policies in combination are represented by the term ‘health governance’. Hence, most of the discussion in the next chapter – including the legal issues and principles arising from proposed changes to current systems of health governance – falls under institutional and legislative reform. However, beyond these two reform initiatives, the movement towards medical integration would also benefit from negotiation and dialogue between the state and IMPs as well as between IMPs on matters of regulation and organization of the professional bodies.

The first section of the chapter summarily discusses dialogue, negotiation and contestation, highlighting why they are necessary for achieving medical integration. Following this discussion, section II examines three models of medical integration: co-option (or co-optation), co-existence (or parallel practice) and systemic integration. The section highlights the connection between these models of integration and current theories of governance, contending that models of integration are created by the institutional and legal frameworks that govern healthcare practice in a given society. By implication, co-option and parallel integration are outcomes of two different institutional approaches to governance. These approaches to governance are themselves based on specific theories of how health systems should be organized and managed. Section III discusses the importance of a ‘theory’ of governance to medical integration and then examines the micro-governance and stewardship theories of governance which are associated with the coptative and parallel models of integration. The chapter concludes with the argument that the chosen theory of governance in a given society must effectively integrate the realities and needs of legal subjects.

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2 See generally Ireh Iyioha, “In Search of Law’s Residence: Towards the Creation of a Mosaic Healthcare State” (2009) 24:2 Canadian Journal of Law and Society 251 where the processes of negotiation, dialogue and contestation were first outlined [‘Iyioha, “In Search of Law’s Residence’”].
5.2. The Journey towards Integration: Negotiation, Dialogue and Contestation

Negotiation and dialogue entail open communication between practitioners and the state as well as between practitioners themselves on key issues involving associational and professional organization, regulation and standardization, and scope of practice, amongst others, critical to the legal recognition of a healthcare system. Negotiation and dialogue are critical to the process of integration because of the dissension that occasionally exists between and within indigenous and alternative medical professions. This dissension is often based on the reluctance of the professionals of one school of practice to be organized under and controlled by the professionals of another school. The imperatives for negotiation and dialogue in the integration process are further discussed under section 6.4 of chapter six.

Contestation, on the other hand, involves a legal challenge of laws and policies which are deemed to be unrepresentative of certain legitimate interests. In the present context, the interests sought to be protected are the rights of consumers and practitioners of indigenous and alternative medicine to utilize, practice and be reimbursed through state health insurance programmes for using and administering these forms of medicine. A legal action against the state may be ignited by the failure of the state to authorize and regulate the practice of some indigenous medical systems, the non-inclusion of indigenous healthcare services and products within state health insurance programmes, or legislative denial of reimbursement to consumers who use indigenous medicine. As a matter of convenience, contestation is further discussed under sections 6.5 and 6.3 of chapter six where the need for an expansion of informed consent rules as well as the imperatives for legislative amendment of national and provincial laws on reimbursement for medical expenses are addressed.

Generally, negotiation, dialogue and contestation are important to medical integration for two major reasons: the dominance of the scientific and biomedical paradigm on the one hand, and the reality that the Westphalian state is the extant institutional order, which – regardless of its failures in delivering its post-colonial promises – continues to have considerable influence over the lives of the governed in some formerly colonized Southern states, on the other hand. In the former case, while consumers’ dependence on indigenous medical systems (IMS) in Southern states and the growing consumer movement towards alternative therapies in North
America are compelling factors for medical integration, the political “pressure from organized Western medicine” marginalizes indigenous medicine, excluding it from policy discussions, official systems and national healthcare strategic plans. Thus, practitioners of IMS will need to negotiate through the complications imposed by organized medicine in their pursuit of legitimacy.

In this regard, there exists a “fundamental tension” within the state authority regarding whether or not to bypass its historical allegiance to biomedicine and embrace non-allopathic systems in response to consumers’ movement towards IMS. This tension arises from the conflict between the state’s mandate to protect the public and the obligation to respond to consumer demand for indigenous therapies. Merrijoy Kelner et al. have argued that the state, “in order to maintain its legitimacy”, must respond to the growing consumer demand for “increased choice of healthcare modalities”. This is particularly important because of the weight citizens attach to participation in decision-making processes. Canadian case law as seen in chapter three reflects the growing frustration of users of alternative medicine; such mounting frustration is not a positive account of the healthcare decision-making process. Regardless of the weaknesses of the modern state, the state – as noted in the second major reason for negotiation, dialogue and contestation – is primed to address consumer concerns.

The state’s responsibility to address the discrepancy between extant law and consumer expectations is two-fold. First, the state must ensure that the goods and services that patients value are accessible; of course, this will be based on the necessary trade-offs between “relative costs and health benefits”, safety concerns, patients’ values about prevention and treatment, the values society holds regarding equality and fairness as outlined in the constitution, and the available healthcare resources. The second responsibility of the state is to regulate the professional groups seeking entry into the mainstream system. However, the grant of legal

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5 Ibid.
6 Ibid at 80.
recognition through formal regulation is often predicated on the existence of a dialogic relationship between the state and the professional group. Thus, every professional group has to “enter into a special relationship, or a ‘regulative bargain’ with the state”.

Indeed, it has been noted that, “professions have arrived at their current position through struggle and negotiation with the state as well as within and between their own organizations and with other groups”. Negotiations with other professional groups are necessary to delineate the boundaries of legitimate practice within each professional group. At this stage, practitioners and the state are able to come to an agreement on the medical areas within which each group can have professional jurisdiction. While some alternative health professional groups might resent the scope of practice boundaries imposed by the state on alternative medical professions, many alternative health professions remain willing to accept this imposition as a condition to formal state recognition. This is because “state control is not only necessary for the professions; it constitutes part of their legitimacy and power”. However, it must also be noted that professions and their relationships with the state cannot be analyzed in isolation from the social context within which they are entrenched. This is because the social structure shapes the nature of professional developments, and this in turn influences the way the state responds to these developments. In the context of the present discussion, this implies that the consumer movement towards integrated healthcare has influenced the growth of indigenous medicine as a healthcare paradigm or profession in its own right; the movement could also be instrumental to state recognition.

However, although consumer interest has influenced the mainstreaming of the integrated medicine debate and to possible future integration by states, indigenous and alternative medical systems remain reliant on the state – and not simply the consumer ‘force’ – to thrive as

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9 Ibid at 80.
10 See M.H. Cohen, Complementary and Alternative Medicine, Legal Boundaries and Regulatory Perspectives (London: John Hopkins University Press, 1998) at 109-110 where he describes the scope of practice boundaries imposed by the state as “reductionistic” and “problematic” (at 109). According to the author, “scope of practice rules reflect the notion that the enterprise of healing can be carved into neatly severable and licensable blocks” (at 109).
11 Kelner et al., supra note 4 at 80.
13 Ibid.
recognized health professions. Evidently, there is a symbiotic relationship between the state and the social contexts of a medical paradigm, and this is apparent in the context of indigenous medicine and the consumer movement that has lifted it to the fore of healthcare discourses. Kelner et al. have noted that the realization of the professional aspirations of ‘complementary and alternative medicine’ practitioners will depend on the “outcome of a political contest between the public, the state and the established healthcare professions”. The health professions will need to dialogue and negotiate with the government from a united position.

5.3. Governing Medical Pluralism: Models of Integration

The extent to which a state sanctions or limits the development of a plural healthcare market is often manifested in the legislations and policies governing medical practice. However, beyond the influence of law and policy, the healthcare institutional ordering is often dependent on other factors such as the type of relationship that exists between biomedicine and the state and “the kind of privileges which this position has accorded to doctors in terms of income, status and opportunities”. These two factors – law and policy on the one hand and the nature of the relationship between biomedicine and the state on the other hand – have a co-efficient relationship, in which one influences the other. The nature of the state’s relationship with the biomedical profession often shapes the laws and policies that govern medical practice. At the same time, biomedicine’s relationship with the state and its position of dominance has been strengthened by the “historical, legal position of biomedicine”, which has mapped the boundaries of what constitutes legitimate or illegitimate medical practice.

An understanding of these factors explains the governance structures that exist in different medically pluralistic communities. For example, Murray Last suggests that three governance structures are discernible from world medical systems. These are the exclusive, tolerant and integrative systems. The exclusive system involves centralized state control with ‘alternative’ practitioners largely outlawed. This system is said to exist in countries such as

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14 Ibid at 80 and 87.
15 Sarah Cant and Ursula Sharma, A New Medical Pluralism? Alternative Medicine, Doctors, Patients and the State (London: UCL Press, 1999) at 127 [‘Cant and Sharma’].
16 Ibid at 113.
17 Ibid.
France and the United States. The tolerant system does not outlaw ‘alternative’ practitioners. However, ‘alternative’ practitioners operate outside the state system and are forbidden from identifying themselves as doctors. This system supposedly exists in Britain and Germany. In the integrative system, biomedicine is privileged by the state while ‘alternative’ medicine is legally recognized as well. The integrative system is assumed to be operative in India, China and the “Third World”.

It is important to note that Last’s typology of world medical cultures does not accurately depict the reality in different societies today. For example, the United States presently operates what is more or less an ‘accommodative’ system rather than a “tolerant” system. While legal actions are brought against unlicensed healthcare providers for the unlicensed practice of medicine (and this is to be expected even in an integrative or integrated system), the US now licenses a wider range of alternative healthcare groups and mandates (at least in some states) state insurance regulators to include a broader range of licensed practitioners within standard insurance plans. Several US statutes now permit physicians to administer an alternative (non-allopathic) therapy provided the patient is not harmed by the chosen therapy. Similarly, while indigenous medical practice in India and China have the backing of the states, only the Chinese medical system fits at least some of the core characteristics of an integrated medical system. The Indian medical system fits within neither the simply tolerant category nor the integrative system. India operates what could more appropriately be described as the ‘parallel or co-existence’ model. This model of governance guarantees the legitimate co-existence of multiple forms of medical systems within the society.

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19 Ibid.
20 Ibid.
21 See chapter three, supra for a discussion of some of the legal reforms on the issue of alternative healthcare financing in the US.
22 See chapter six infra for a discussion of these statutes as well as the problems with the framing of the law.
23 Note, however, that China’s integrated medical system is hierarchical considering that biomedicine continues to be the dominant system which sets the standards of medical practice.
The ‘parallel’ or ‘co-existence’ model is one of three approaches to integrating medical systems identified by Tartaryn and Verhoef. The other approaches are the co-optation and systemic models. The first two approaches – co-optation and parallel integration – generally represent the current attitudes of states to medical pluralism; only China appears to be practicing what is more or less a systemic model, without the non-hierarchical relationship between biomedical and indigenous providers that comes with systemic integration. Again, it is important to emphasize that each of these approaches or models is a corollary of the type of healthcare laws and policies in a given province or state. In other words, they are outcomes of the state’s approach to governing the healthcare system. The following sub-sections examine co-optation, parallel and systemic integration.

5.3.1. Co-optation

Co-optation (or co-option) involves the delivery of indigenous and alternative therapies by a biomedical healthcare provider after empirical evidence has established the efficacy and safety of the therapies. An example of co-optation is the reimbursement of physicians for the provision of acupuncture for pain control, while traditional Chinese medicine (TCM) practitioners, trained in the practice of acupuncture are not. Co-optation has been described as the easiest route to medical integration. Perhaps, this is because of the simplicity of the process of co-optation; it merely involves assigning conventional physicians to the task of delivering medical therapies that belong to other paradigms. However, while this approach is convenient for medical practitioners and the state, it has a number of shortcomings, which render it “morally and ethically” indefensible.

First, co-optation is “conceptually and pragmatically” dangerous because each healthcare system brings with it a distinct and sometimes elaborate knowledge and philosophy of health.

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25 This point is further discussed under theories of governance below.
26 Tartaryn and Verhoef, supra note 24 at VII.101.
27 Ibid at 101.
28 Ibid.
29 Ibid.
and illness, which places the therapy in a very different setting. Second, co-optation has the tendency to “stifle” the development and knowledge acquisition of indigenous health systems that may eventually evolve to be “more robust and effective” than the biomedical system, which restricts disease etiology and treatment to biological theories. Fundamentally, co-optation is a hierarchical model of integration, which excludes indigenous medical providers from their fields of expertise. Evans Willis and Kevin White have identified some historical instances, such as the cases of anaesthesiology, x-rays, acupuncture and chiropractic, where healing practices previously considered unorthodox were incorporated into orthodox medicine and the original practitioners were shut out.

Co-optation, therefore, holds out specific risks, alongside some benefits, for the state, patients and even the biomedical profession. For the state, co-optation may mean a convenient and simplified administration of diverse healthcare modalities through one well-established and regulated profession. It means that the state can deliver a more comprehensive healthcare package, and perhaps with less resources. However, Fran Collyer contends that ‘integration’ (by which she means the availability of alternative medicine through private markets) may escalate healthcare costs for consumers, third-party contributors and governments. According to the author, integration has occurred only at the level of products, services, and techniques and this implies that there has been co-option of CAM rather than an “amalgamation of philosophies or knowledges”. The author asserts that “there is already sufficient evidence that, at the national level, market-based healthcare systems have higher costs than those which are publicly delivered and financed, and that the intensification of private sector involvement in healthcare offers little long term benefit to the nations themselves”. While Collyer’s argument holds true for consumers who pay out-of-pocket for alternative medical care, it is noteworthy that the ‘integration of products, services and techniques’ on which the author bases her analysis of ‘medical integration’ is not the same as the “integration of medical systems” properly defined.

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30 Ibid.
31 Ibid.
34 Ibid at 94.
35 Ibid.
For some patients, co-optation may simply ensure easier access to alternative therapies. However, this same benefit can be disadvantageous when we consider that some patients patronize indigenous practitioners primarily because of their interest in the philosophical underpinnings of the treatment. Thus, as Ian Coulter as well as Tartaryn and Verhoef have acknowledged, co-optation will have the effect of stripping indigenous therapies from their cultural-philosophical environment.\textsuperscript{36} Since indigenous therapies are administered within a distinct philosophy of health and healthcare, which may have an impact on the efficacy of the interventions,\textsuperscript{37} the patient may not have obtained what was truly desired when he or she receives an indigenous therapy from a biomedical practitioner who is untrained in the unique paradigm of treatment administered on the patient. Therefore, co-optation is not necessarily the best for patients who have a philosophical interest in indigenous medicine. This is because it can lead to the administration of indigenous medicine outside its cultural-philosophical context thereby diminishing the very meaning of the treatment for the patient.

Co-optation could also mean a “revitalization of the orthodox market system”, in which biomedical practitioners through “clever marketing and acquisition strategies” employ indigenous therapies in expanding their scope of practice and attracting more consumers.\textsuperscript{38} In this instance, biomedical practitioners ensure that indigenous therapies are “amenable to a high production, high profit system”, which enables companies to expand their markets into new services and products, thereby “extending their reach beyond the established boundaries of the healthcare system”.\textsuperscript{39} However, this will engender a concomitant loss of autonomy for indigenous medical practitioners (IMPs) within the healthcare system.\textsuperscript{40} Indigenous medical providers will eventually be made redundant within the healthcare system. More importantly, it will make little sense to adopt the co-optation model in countries, such as Nigeria, that are faced with a human resource crisis and are in dire need of more healthcare workers.

\textsuperscript{37} Ibid.
\textsuperscript{38} Collyer, supra note 33 at 95.
\textsuperscript{39} Ibid.
\textsuperscript{40} Ibid.
5.3.2. Co-existence or Parallel Model

The second approach to regulation is the co-existence model. While indigenous and alternative medicines are regulated by the state under this model, these systems primarily exist as privatized healthcare systems. Under this model, different medical systems operate separately within their distinct boundaries and the “focus is on whether and how” practitioners of different systems of medicine can collaborate with each other in terms of referrals, inter-professional communication, etc. The co-existence approach has several shortcomings. It engenders inter-professional isolation and mistrust, stifles knowledge-transfer between medical systems, and places tension between practitioners and consumers who use both systems.

The co-existence model, which presently operates in Nigeria, has more profound shortcomings than Tartaryn and Verhoef have identified in their work. In Nigeria, indigenous healthcare products and services “are presently marketed like any other commodity, on principles wholly determined by market trends”. While biomedical services and products are now subsidized by the government through the National Health Insurance Scheme, indigenous healthcare services and products are paid for on a fee-for-service or out-of-pocket basis. It is common knowledge that out-of-pocket expenditure on healthcare in the long-run puts healthcare out of the reach of the average citizen. The outcome will be no different for those who utilize indigenous medicine for their everyday healthcare needs.

The co-existence model has none of the hallmarks of integration properly defined, which include state funding for research, coverage in a state/national health insurance scheme, clearly defined educational training within accredited or recognized state institutions, legislative recognition via different statutes, and incorporation within a broad range of health policies. The “biomedical profession has all of these hallmarks, which places it in a position of authority,” and without which indigenous medical practitioners within the co-existence model may be viewed as occupying a position outside the health system. Simply stated, “these hallmarks are often the denominator of legitimacy, professional influence, and therefore,
hierarchy”. This type of hierarchical system poses several problems – especially for the patient who relies primarily on indigenous medicine.

A major problem with the system relates to its privatized nature. An ungoverned, privatized healthcare system can lead to increased healthcare costs for the consumer. Indigenous medicine, as a privatized system of healthcare, is accessible to only those who can afford it because the scale of prices is unregulated by the state. While there are reports that indigenous medicine is cheaper than its biomedical counterpart in some societies, it is also true that the scale of prices varies based on the medical condition or the service rendered, and equitable access may be jeopardized for consumers who rely on it for all their healthcare needs, and who have no form of insurance to cover at least some of their expenses. Korean herbalists are reported to have resisted the introduction of insurance coverage for “traditional medicine” because the profit margin of herbal medicines when paid out-of-pocket is estimated to be between 100% and 500%. The co-existence model will ultimately place indigenous healthcare out of the reach of consumers.

Another primary problem associated with the co-existence model relates to the absence of state regulatory schemes for a significant number of alternative healthcare services or of close monitoring of alternative healthcare products by food and drug agencies. Consumers of an unregulated healthcare system are unprotected against the “vagaries” and “imperfections” of the healthcare market. According to economic theory, a perfect market is one where there is complete equilibrium in the transmission of information between buyers and sellers. The healthcare market is described as imperfect because consumers often cannot access information regarding the quality of health products since the exercise of their judgment is dependent on test results, quality assessment and the professional judgment sometimes required before

46 Ibid.
49 McNamara et al., ibid.
Thus, beyond reinforcing the limited access to healthcare for patients who pay for it on a fee-for-service basis, the co-existence model is likely to endanger patients, especially when the indigenous healthcare products and services are unregulated.

These important considerations drive the thesis of this study: that state governance of healthcare pluralism must be comprehensive. State governance that involves integration of indigenous medical systems at all levels of the healthcare system achieves subsidization of costs, equitable access (including financial and geographical access), quality monitoring, and acceptance of indigenous medicine as a unique healthcare paradigm through legislated assurances. The next section examines the systemic model of integration. This model of regulating medical pluralism aptly captures the ideal nature of medical integration.

5.3.3. The Systemic Approach

Medical pluralism, as noted in chapter two, denotes the existence in a single society of different medical systems founded on differing philosophies. The deliberate attempt to make the different systems work together in the same clinical context leads to the concept of medical integration. This study defines an integrated system of healthcare as one in which practitioners of different medical systems work collaboratively and across healthcare paradigms in the same clinical context for better health outcomes. This healthcare system, which reflects the best approaches from different systems of healthcare, is primarily concerned with the content of healthcare. In other words, integrated medicine is first and foremost about the type of healthcare provided within a system.

Medical integration has been defined in different ways. Each definition produces a particular relationship between biomedicine and indigenous medicine, which may be hierarchical, non-hierarchical or simply non-collegial. For example, Cant and Sharma define integration as a clinical system “where biomedical and alternative practitioners collaborate or

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50 Ibid.

51 This has been achieved in the United States (in the state of Washington). In a 2002 study, the impact on alternative healthcare expenditure of a 1996 Washington State law which mandates all health plans to cover “every category of [licensed] provider” was evaluated against the total cost of out-of-pocket health expenditures previously recorded. The results showed an impressive lowered cost of care. See W.E. Lafferty, et al. “Insurance Coverage and Subsequent Utilization of Complementary and Alternative Medicine Providers” 12:7 (2006) Am J Manag Care. 397.

52 See Obi Aginam, “From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World” (2002) 3 Chicago Journal of International Law 102.
work alongside each other in a variety of institutional arrangements”.

As noted by the authors, the integration of medical cultures “does not itself do away with medical hegemony”. Where the integration takes place within existing public health institutions, the non-biomedical practitioner may simply appear to have been “tacked” on to the “organization of the state-run clinic or health promotion scheme”.

However, where the integration, which is the admixture of knowledge about different healing systems, takes place at all levels of the healthcare system, “what knowledge and technology will be borrowed from whom will depend very much on what is accessible, what is deemed “effective” and on what is regarded as attractive to patients”. This latter conception of integration reflects the systemic model, which involves non-hierarchical integration at all levels of the healthcare system. Boon et al. have also provided a definition which identifies integration as “an interdisciplinarity, non-hierarchical blending” of biomedicine and alternative healthcare that provides a “seamless continuum of medical decision-making and patient-centred care”. These features – interdisciplinarity and non-hierarchical synthesis of therapeutic approaches – may be identified within the systemic model of integration.

Systemic integration facilitates integration at the different levels of the healthcare system, from the consumer, provider, and clinical levels to the policy level, and lays emphasis on the inter-dependence of healthcare systems. It incorporates experiential evidence, clinical efficacy and academic knowledge to provide an integrated healthcare system that balances the needs of consumers and practitioners and recognizes the “fiscal efficiencies and humanitarian benefits of health promotion and disease prevention”. Systemic integration therefore answers the call by population health experts for a redirection of healthcare spending into preventive initiatives rather than invest resources into the “fiscally inefficient” system of palliative care. The most important benefit of this approach is its potential to expand the healthcare domain, and therefore

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53 Cant and Sharma, supra note 15 at 160-161.
54 Ibid at 183.
55 Ibid at 183-184.
56 Ibid at 184. Emphasis supplied.
58 Tartaryn and Verhoef, supra note 24 at VII.102.
59 Ibid.
60 Ibid at VII.94.
improve access to healthcare. The systemic model of integration represents an ideal healthcare system, offering comprehensiveness in healthcare delivery, freedom of choice for consumers who prefer indigenous medicine, and obviating the problems inherent in other models.

As outlined in the next chapter, the ideal of medical integration, which the systemic model captures accurately, is achievable primarily through institutional and legislative reform – specifically, through a progression from an existing political will largely influenced by consumers’ interest to an orchestrated design at each level of the healthcare system. To achieve this, it is necessary to reconceptualize existing power structures within the policymaking process. The next section discusses how the restructuring of governance might assist in this process.

5.4. Medical Integration and Theories of Governance

Historically, health policymaking and health systems regulation and management were viewed as the tasks of ‘government’. Today, the term ‘health governance’ aptly captures these tasks – not as responsibilities of government but as shared goals that may or may not be backed by formal authority. Dodgson, Lee and Drager define health governance as “actions and means adopted by a society to organize itself in the promotion and protection of the health of its population”. Another definition offered by public health scholar, Scott Burris, is that governance involves “the management of the course of events in a system”. Governance also denotes “the policing of social relations, environmental conditions, and the allocation of resources essential to well-being”. Health governance – “the management or administration of health systems and population health – necessarily involves formulating laws and policies to achieve specific health outcomes”.

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61 Ibid at VII.102. Emphasis supplied.
65 Ibid.
66 Iyioha, “In Search of Law’s Residence”, supra note 2 at 252. Indeed, as some scholars have noted, health governance is crucial to achieving specific policy objectives in healthcare delivery: see generally Nasreen Jessani and Christina Zarowsky, Governance and Public Health: IDRC Supports Global Initiatives, online: International
Health governance is crucial to medical integration because of the significance of laws and policymaking to health systems. The most crucial step towards the creation of an integrated health system involves law and policymaking, which creates an acceptable environment for collaboration between practitioners. Presently, the laws and policies in place and the organization of roles and powers within the healthcare system place biomedicine above other healthcare systems. Indigenous medical practitioners “are seldom included in the ranks of policy makers, not even when the policies in question concern grassroots or community healthcare matters, an area in which indigenous practitioners are greatly skilled”. The relevant health laws and policies “are often skewed to legitimize the allopathic system, with perfunctory allusions to indigenous medical practitioners”. Indigenous healthcare practice becomes more or less a privatized healthcare system governed by private actors and market forces.

Medical integration is diametrically opposed to this hierarchical organization of governance. The establishment of an integrated health system relies very much on both the support of the state as well as of private actors. Hence, the idea of governance as better suited to private management or as the responsibility of states alone is antithetical to the concept of medical integration. Recent scholarship reveals that scholars are moving away from this narrow conception of governance. While earlier interpretations of ‘governance’ have confined the duties associated with the term within the conceptual walls of the nation-state, emerging conceptions of ‘governance’ are acknowledging that “states do not have monopoly over governance”.

Thus, governance may now be understood as “the institutions, processes and traditions that determine how power is exercised, how decisions are taken, and how citizens have their say”. Evident in these emerging definitions of health governance is the notion that the policymakers are as important to the process of decision-making as are those affected by the

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Iyioha, “In Search of Law’s Residence”, supra note 2 at 256.

Ibid.


decisions. This fact reflects the importance of an inclusive system of governance, which seeks collaboration between state/conventional and non-state/non-conventional actors in the business of healthcare management. Therefore, healthcare governance intersects with the concept of medical integration in the context of logistics: the question is how should health systems be organized or administered to achieve a truly integrated medical system? This question requires an operable theory on which health systems governance is based. For example, the co-optative and parallel models of integration discussed above are outcomes of specific systems of governance. Each of these systems of governance is founded on a certain theory of how the healthcare system should be organized.

The next subsection examines the linkages between systems of governance and models of integration. The subsection begins with a discussion of why the development of an ideal theory of governance is crucial to the establishment of an integrated healthcare system.

5.4.1. Why Theory is Critical

Theory is critical to the integration project because of its role in ensuring that institutional reforms are grounded in factual situations. Simply stated, theories reflect “reason informed by experience”. For example, the pluralistic nature of healthcare and the socio-cultural worldviews and economic realities of many African states like Nigeria counter a monolithic governance of healthcare through restrictive or exclusive healthcare policies or through private initiatives. The healthcare situation in Sub-Saharan Africa does not lend itself to a simple public-private bifurcation. The healthcare situation in many African states is pluralistic and may be more appropriately divided into “organized” and “non-organized” categories. Indeed, as Freedman et al. have observed, the healthcare choices the peoples of “low- and middle-income countries” are faced with are not simply between a private healthcare system that offers “a broad menu of high-quality services” and a public system that provides essential services at

71 A. Seidman and R.B. Seidman, State and Law in the Development Process: Problem-Solving and Institutional Change in the Third World (New York: St. Martin’s Press, 1994) at 64.
72 Ibid.
little or no cost.\textsuperscript{74} Rather, citizens of all strata of society “are confronted with a bewildering array” of healthcare choices and sources, including “medicine peddlers”, indigenous healers, physicians and specialists, and “civil servants setting up private practices of wildly uneven quality”.\textsuperscript{75} This chaotic system requires government supervision. In fact, as observed by Freedman et al., the decline of “government supervision systems” is an important contributing factor to the “marketization of health services.”\textsuperscript{76}

As noted in chapter two, this situation has been identified as one of the leading causes of the failures of the healthcare initiatives of private international agencies in Sub-Saharan Africa.\textsuperscript{77} The incongruity between the World Bank and International Monetary Fund’s (IMF) neoliberal health policies for Sub-Saharan Africa on the one hand and that part of the continent’s socio-economic and cultural worldviews on the other hand resulted in the failures of the health initiatives in the 1990’s, and this compounded the problems of Sub-Saharan African health systems.\textsuperscript{78} The World Bank proposals offered solutions to Sub-Saharan African healthcare systems on the assumption that a public-private divide was essential in ensuring efficiency. Within this divide, the private sector was deemed the most efficient sector to meet the needs of population health, while the public sector was relegated to the reactive role of intervening when there was market failure.\textsuperscript{79} Fundamentally, these neo-liberal policies attempted to radically restructure the existing socio-economic lifestyle of the people. The objective of a viable theory of governance is to avoid this pitfall.

Since models of integration are not distinct from the institutional frameworks within which they exist, the theory that undergirds the governance of a healthcare system must reflect the dominant norms of the society affected as well as ensure that the resultant model of governance is effective. For example, the theory underlying the co-optative model of integration is based on a philosophy of insularity in which the government is deemed the sole provider of public goods and services based on criteria established by biomedical policymakers. As is further discussed in the next sub-section, this theory is similar to that offered by the

\textsuperscript{74} Ibid.
\textsuperscript{75} Ibid.
\textsuperscript{76} Ibid, citing Bloom and Standing, \textit{Pluralism and Marketization in the Health Sector}, supra note 73.
\textsuperscript{77} See \textit{ibid}; see also Colleen O’Manique, \textit{Neoliberalism and AIDS Crisis in Sub-Saharan Africa: Globalization’s Pandemic} (New York: Palgrave Macmillan, 2004) at 53.
\textsuperscript{78} Ibid, Freedman et al. at 39.
\textsuperscript{79} Ibid.
stewardship model of governance. In examining the different theories of governance, the subsection contends that the utility of the theories of governance is determined by how closely they reflect societal realities and how well they can improve the experiences of societal members.

5.4.2. Theories of Governance

5.4.2.1. Micro-governance Theory

There are different conceptions of health governance in the academic literature, and while a number of studies on global health governance have emerged in recent years, it is arguable that the academic literature on the subject of health governance, at least at the national level, still needs further development. One conception of governance that is reflected in the parallel or co-existence model of integration is the “micro-governance system”, which discounts the role of the state in favour of non-state actors playing a dominant role in the governance of the healthcare system. The micro-governance theory largely emphasizes the imperfections of the modern state and promotes a healthcare system primarily governed through private initiatives. Scott Burris proposes a micro-governance theory termed “nodal governance”, as a strategy for improving population health. Burris rejects the hierarchical organization of governance within the Westphalian state and advocates for a bottom-up approach to healthcare governance exemplified through the nodal governance theory. Asserting that the goal is to make governance count positively towards reducing health inequalities, Burris states that nodal governance focuses on “how governance happens – how power is yielded – at specific points within a system”.

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81 See generally Burris, “MicroGovernance”, supra note 64.

82 Ibid at 337.

83 Ibid at 344.

84 Ibid at 337.
The theory of nodal governance is “first a description of how resources are mobilized and power exercised in social systems”. According to Burris, this concept of governance “raises essential normative questions about democratic decision-making”. Within this theory, “governance is a social adaptation accomplished in significant part through the creation and operation of nodes”. Burris’ theory effectively emphasizes that non-governmental bodies and institutions can govern healthcare outside the Westphalian state system. It also credits the bottom-up approach to governance with the capacity to resolve inequity in the healthcare system.

Burris’ arguments are important in any thesis – such as that submitted here – that endorses the utilization of local (human and material) resources in generating change within a system. However, the author concedes the existence of some gaps in the nodal governance theory when he notes the difficulties encountered when powerful private actors are in control of a system. An example may cited of the role of private-for-profit international pharmaceutical corporations in the creation of the TRIPS Agreement. Burris acknowledges that health governance through private actors such as pharmaceutical companies (or in the case of indigenous and alternative medicines through powerful medical research institutes) could produce unfavourable results for consumers, who may have little or no power to challenge the companies in cases of price increases or profiteering. Burris acknowledges that the millions of people affected by the TRIPS Agreement “lacked the resources to mobilize sufficient opposition to stop TRIPS (though they have since been instrumental in building a network aimed at limiting its effect)”.

The author’s observation is legitimate and underscores the importance of state oversight in healthcare governance. Another example discussed in subsection 5.3.1 above relates to the failed initiatives of the IMF and World Bank in the 1990’s. These institutions dictated the trend of policymaking during this period. The policies adopted by the institutions emphasized private governance of health systems and discouraged government interference. The initiatives outlined by the two financial institutions constituted a micro-governance approach to healthcare governance.

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85 Ibid at 344. Emphasis added.
86 Ibid.
87 Ibid at 341.
88 Ibid at 346.
By its very nature, integrated medicine is opposed to a micro/nodal governance theory that accords limited significance to the importance of macro-governance by the state. The inputs of a diverse range of actors within the healthcare system are essential for the success of an integrated medical system. This system of medicine can only thrive under a state that functions effectively as a regulator, limiting the excesses of private actors and regulating the private healthcare market. The state has a crucial responsibility to govern the currently privatized indigenous healthcare market in the interests of consumers. This responsibility extends to protecting consumers from unscrupulous private actors for whom the popularity of indigenous medicine has become profitable business. Thus, the micro/nodal governance theory, especially when over-extended, is not a feasible method for health systems management. Its utility is also limited in the context of medical integration because an integrated healthcare system requires both government support and the collaboration of private actors.

Burris suggests another limitation in the nodal governance theory when he notes that the micro-governance theory may be perceived as unjust. He observes that the theory conforms “to a neo-liberal model of self-help, purporting to extend self-determination but in fact extending governmental control (through its funding of the local intervention) while shifting the burden of responsibility for change onto the shoulders of the dispossessed themselves”. Burris’ response to this problem is “to simply promote and operate microgovernance within a broader framework that also recognizes the need for substantial change in the world outside the community”. Ironically, this response essentially shifts the conceptual boundaries of the micro/nodal governance theory to the type of composite governance framework represented by the integrated health governance theory proposed here. Essentially, Burris’ response captures the importance of a multifaceted initiative towards health systems governance which the micro-governance theory by itself fails to achieve.

89 Ibid at 352.
90 Ibid.
5.4.2.2. Stewardship Governance (Macro-governance)

Another conception of governance is the ‘stewardship governance’ model\textsuperscript{91} which, as noted above, offers a theory of governance that is conducive to the co-optative model of integration. Stewardship governance is a macro-governance system which denotes top-down governance by state authorities. There are different conceptions of ‘stewardship governance’ in the scholarship. Some scholars use the phrase simply to denote government regulation, while others have used the term in a different sense to refer to private industry initiatives as a substitute to state supervision.\textsuperscript{92} While the scholarship on ‘stewardship’ is inconsistent, it is at least apparent that the term is employed to denote either a pattern of leadership of specific public or private organizations, bodies or societies or simply a system of leadership within organizations of government.

In the area of health governance, conceptions of stewardship often fall within the second category in which stewardship denotes a certain pattern of leadership of a branch of government. The World Health Organization (WHO) provides some clarity to the meaning of stewardship in the context of health governance. According to the WHO:

\begin{quote}
Governments should be ‘stewards’ of their national resources, maintaining and improving them for the benefit of their populations. In health this means being ultimately responsible for the careful management of their citizens’ well-being. … Stewardship encompasses the task of defining the vision and direction of health policy, exerting influence through regulation and advocacy, and collecting and using information.\textsuperscript{93}
\end{quote}

Thus, stewardship governance in the context of health systems conceives the state as an agent of the citizenry and therefore responsible for the regulation and delivery of healthcare. As Saltman and Ferroussier-Davis have noted, most definitions of this theory in relation to the role of the state in healthcare delivery describe stewardship governance as “a particular type of governance linked with agency theory and the concomitant role of the state as an agent for its

\textsuperscript{91} Saltman and Ferroussier-Davis, supra note 66; see also Marc Saner and Jakes Wilson, “Stewardship, Good Governance and Ethics” Policy Brief No. 19 (Ottawa, Canada: Institute on Governance, 2003), also online: Institute on Governance <http://iog.ca/sites/iog/files/policybrief19.pdf> [‘Saner and Wilson’].

\textsuperscript{92} Ibid, Saner and Wilson at 1.

Within this conception, the state exclusively is expected to play the role of regulator and instigator of social change.\textsuperscript{95} In light of its theory on how systems should be governed, it is not clear to what extent the stewardship model of governance allows, or is structured to accommodate, contributions from outside the state system.\textsuperscript{96} The stewardship model of governance may discount or limit the contributions of both non-conventional actors and the citizenry to health systems governance. As Saner and Wilson have noted, while this interpretation of stewardship may be “sensitive” to the citizen’s interest in outcomes, it “does not emphasize the need for engaging rather than just listening to citizens”.\textsuperscript{97} These attributes make this model of health governance inapposite for an integrated healthcare system. Within this approach to governance, the state and the biomedical profession may deliver alternative forms of medicine that fit within criteria established by biomedical professionals. Given the collegial relationship between the state and biomedicine, a co-optative approach might be deemed the best model for delivering integrated healthcare to the populace. Furthermore, while indigenous and alternative medical professionals may still practice within such a system, they do so in isolation from the state-governed healthcare system.

Another reason for the disutility of the macro-governance theory (as aptly captured by the stewardship model of governance) for integrated healthcare is what Saltman and Ferroussier-Davis have termed the gradual “de-sovereignization of the state”, which is a consequence of “regionalization” and “globalization”.\textsuperscript{98} Globalization and regionalization, according to the authors, “can potentially diminish the ability of states to design and implement desired regulatory strategies”.\textsuperscript{99} For example, there are concerns that “in some post Soviet transitional and developing countries the state is not strong enough to impose its will once it has adopted a strategy”.\textsuperscript{100} According to the authors, this problem is particularly serious in the health sector,
“where public revenues and providers may be severely constrained, encouraging parallel sources of private funding and service delivery”\textsuperscript{101}

Indeed, as outlined in chapter one, the problems of resource and fiscal constraints are at the heart of the proposition for medical integration. In some countries of the South, including countries in Africa, the private sector has assisted the government in alleviating some of the hardships resulting from both acute shortage of healthcare resources and technologies, and financing difficulties. Of course, the costs of the ‘assistance’ are often passed to healthcare consumers. Nevertheless, the contributions of the actors are significant as they are sometimes made in communities or zones with poor access to healthcare resources. For example, the establishment of the Pax Herbal Clinic and Research Laboratories in rural Ewu in Nigeria has alleviated some of the healthcare difficulties faced in the past by community members. The clinic, which (as earlier noted) has branches in several Nigerian states as well as in Togo, Benin Republic, Senegal, Ghana, the United States and the United Kingdom, has 200 hundred regular staff, 70 casual staff, 600 accredited healthcare providers, 30 medical personnel, 10 scientists, 20 zonal distribution depots\textsuperscript{102} in the country, 27 NAFDAC approved products\textsuperscript{103} in Nigeria and 5 FDA approved products in the United States.\textsuperscript{104}

A private initiative of this nature functions best when the actors have the support of the state within an integrated system of governance. For example, beyond the endorsement necessary to grant popular legitimacy to the initiative, the clinical products have to be regulated, and this as well requires legal and institutional settings that are accommodative to the initiative. There have been meetings between the directors of the Pax initiative and the director of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC), and as noted above, several of the natural health products produced in Pax Research laboratories have been certified by the NAFDAC.\textsuperscript{105} While the government could further support such initiatives in other ways discussed in this and the next chapter, the current symbiotic relationship between the state and the Pax initiative has contributed to the growing legitimacy of the latter.

\textsuperscript{101} \textit{Ibid.} Emphasis added.
\textsuperscript{102} This figure was obtained from communications with the project director of the clinic, Fr. Anselm Adodo. The website presently shows 16 zonal distribution depots: See \textit{Pax Herbal Clinic and Research Laboratories}, online <http://www.paxherbals.net/index.php?option=com_content&view=article&id=249&Itemid=200195>.
\textsuperscript{103} \textit{Ibid.} The website currently shows 21 NAFDAC approved products.
\textsuperscript{104} \textit{Pax Herbal Clinic and Research Laboratories}, online, \textit{ibid}.
\textsuperscript{105} See \textit{ibid}. 
Authors, Saltman and Ferroussier-Davis conclude that while there are positive elements in the stewardship behaviour of some states, “one cannot as yet point to a fully fledged embodiment of the stewardship model at the national level”.\textsuperscript{106} It is important to state categorically that this is primarily because the real experiences of legal subjects or actors in the modern state do not accommodate such an ambitious model of governance. The socio-economic realities that societies, especially in post-colonial states, are faced with require a balancing of efforts from different sectors and actors – states, financial institutions, healthcare institutions, research laboratories, research institutes, biomedical and indigenous/alternative medical providers, amongst others.

Nevertheless, when we move beyond the shortcomings of the stewardship theory, we find an important conceptualization of the state in the authors’ thesis. Saltman and Ferroussier-Davis implicitly accept the malleability of the modern state as a given. This view, which is espoused in this study, contradicts most of the legal theory scholarship on this point. The authors, like Boaventura De Sousa Santos,\textsuperscript{107} conceive the state structure, not in the static and hierarchical lenses through which some schools of legal theory view the state, but as a flexible system which can be ‘configured’ to achieve specific healthcare goals. In the context of medical pluralism, the specific configuration of state authority or state governance determines the nature of its national health system; that is whether the national health system is integrated/inclusive, exclusive or adopts the parallel or co-existence approaches. In other words, the state can produce any of the constellations – integration, co-existence, co-optation, or exclusion\textsuperscript{108} – based on the manner in which it governs its healthcare system.\textsuperscript{109} Applying this perspective to the foregoing discussion on the ideal governance model suitable for medical integration, the outcome is that while present configurations of state governance – through micro- or macro-governance theories – are ineffective for the creation of an integrated healthcare system, the state can restructure its

\begin{footnotes}
\item[106] Saltman and Ferroussier-Davis, supra note 66 at 736.
\item[107] See generally Boaventura de Sousa Santos, Toward a New Legal Common Sense: Law, Globalization and Emancipation 2d ed. (London: Butterworths, 2002).
\item[108] Summarily, ‘integration’ involves the concurrent and collaborative practice of different systems of medicine; ‘co-existence’ denotes the mere existence of different systems of medicine within the same society - the systems could complement or compete with one another; ‘co-optation’ involves the provision of services belonging to one medical system by practitioners of another system who are deemed by the laws of the state to be more qualified to provide the services; and ‘exclusion’ refers to the existence of only one formally recognized medical system within a given society - non-biomedical groups are largely prohibited from practicing medicine: see generally Tartaryn and Verhoeof, supra note 24 and Cant and Sharma, supra note 15.
\item[109] See generally Iyioha, “In Search of Law’s Residence”, supra note 2.
\end{footnotes}
system of health governance into a form suitable for achieving the desired goal of integrated healthcare.

Given the gradual decline of the state’s power to effectively provide public goods, the state needs to apply its inherent ability to reconfigure its approach to governance towards creating a participatory and equitable system of health governance which would encompass state authority, private actors and consumers. As is the case with attempts to reinterpret nodal/micro-governance theory to include the community outside the state, there are attempts to broaden the meaning of stewardship governance to include “the roles and relations of government, industry, and the public”.\textsuperscript{110} In the new approach to stewardship, according to Saner and Wilson, stewardship would be viewed –

\begin{quote}
[n]ot just as a set of practices but rather as a governance process – one in which government, industry, and citizens may be involved, whereby the responsibilities of each of these groups can be determined, and decisions can be made regarding the appropriate kinds of mandatory or voluntary measures required to achieve a particular goal.\textsuperscript{111}
\end{quote}

As noted under the discussion of nodal/micro-governance above, the attempt to redefine different theories of governance to atone for the inherent limitations of the theories only further emphasizes the shortcomings of the theories. Rather than extend fixed ideas on governance beyond their given labels and intended meanings, a broader, independent notion of governance can be developed to address the realities within communities and health systems as well as to resolve the limitations in extant theories of governance.

5.4.2.3. Other Concepts of Governance Combining Micro- and Macro-governance – Theoretical and Practical Limitations

The emerging literature on health governance highlights other categories of actors as key players in health systems governance while advancing a collaborative approach to governance as between this expanded category of actors.\textsuperscript{112} These actors include non-governmental organizations (NGOs), charitable foundations, and business associations carrying out business

\textsuperscript{110} Saner and Wilson, \textit{supra} note 91 at 4.
\textsuperscript{111} \textit{Ibid}. Emphasis added.
\textsuperscript{112} See Hein and Kohlmorgen, \textit{supra} note 80 at 16.
activities related to that of the healthcare sector. Other actors already identified in previous chapters of this study are international pharmaceutical corporations and international bodies such as the WHO whose policies tend to be geared towards co-operating with provincial governments and the civil society, rather than with national governments. While bearing a superficial semblance to the integral approach herein proposed, these forms of collaborative ‘governance’ evoke the same problems, amongst several others, pertaining to the integrity of policies and objectives already outlined in chapter two.

For example, multi-national pharmaceutical corporations may be more interested in controlling the international market for pharmaceuticals than in improving the healthcare system of a given community through approaches that can best address the problems in those communities. As discussed in chapter two, these corporations being primarily private-for-profit enterprises are generally more interested in addressing specific diseases that plague Northern nations rather than those prevalent in many African countries or Southern states.

Furthermore, in addressing the healthcare needs of a given province, it is expected that an international body, such as the WHO, would adopt mainstream approaches or strategies that are generally based on conventional medical opinions about what works in health systems management or development. The role of IMPs as a vital part of community-based initiatives remains de-emphasized in the global approaches to health governance that are being initiated in different Southern communities.

A further concern with the current formulations of global health governance has to do with the type of interactions, if any, that exist between the state and non-state or global actors. The concern here lies with the extent to which the objectives and practices of the global/non-state actors can be said to be truly integrated with those of governments and their societies towards achieving a shared goal. Current conceptions of governance often depict a relationship between global/non-state actors and local actors at the state or community level in which governments are now being “by-passed” in preference for direct negotiations with local actors.

According to Hein and Kohlmorgen:

113 Ibid.
114 Ibid at 16-17.
115 Ibid.
116 See ibid where the authors make a similar point.
117 See generally Hein and Kohlmorgen, ibid.
These interfaces [between global actors and actors on the national and local level] are slowly changing their character. Formerly, they primarily consisted of negotiations between at least formerly sovereign governments and international organisations, the results of which were, of course reflecting the asymmetry of power relations in the field of international politics. Now, they are assuming an increasingly complex structure. This includes various types of actors on either side, interacting across borders without the implications of governments and institutions of global governance and do not aim solely at supporting governments but at reaching specific goals in fighting diseases or poverty – if necessary in cooperation with local actors against the respective state agencies.

The circumvention of national or state governments is problematic and raises the issue of decontextualized governance which is at the fore of the central arguments in this study – that health governance is continuously being modelled along *global* or international ideals that have worked favourably for Northern nations without due consideration to the needs of particular societies. Policies are being framed at the international level advancing global approaches to resolving what are believed to be the core healthcare problems of most Southern countries. Yet, governments are best equipped with knowledge of what the healthcare priorities of the members of their constituencies are, and would have significant input into how those needs can best be addressed. Thus, these other approaches to governance that purport to embrace state and non-state actors or aspire towards a more inclusive system of governance through collaborations between international and local actors raises questions as to both the objectives of the global/non-state actors and the propensity for success of their initiatives.

Doubts can legitimately be raised as to the possibility of success of these approaches to governance because at the very core of the different approaches is a disconnection between what the global, transnational or non-state actors believe about the conditions of living as well as the available resources in a given community, and what might indeed be best for the community. Thus, these top-down or internationalized approaches reflect “conflict of interests”, already identified in chapter two, between the different actors that are supposed to be part of a collaborative approach to governance. As Hein has observed in the context of a framing of ‘health’ as a “*global* public good” to be delivered (as Millennium goals) at the local level through policies formulated at an international or global level:
This [the formulation of global policies which directly aim at results at the local or individual level], however, raises the question, how these activities[of global organizations] interact with national institutions in the field of health and their responsibility for national health governance. The problems at hand basically refer to the control of resources which include knowledge, technology, intellectual property rights, financial resources to solve health problems but also the allocation of financial resources to different aims. The problems imply conflicts of interests between many different types of actors like nation states with different interests, enterprises, civil society organisation, corporate interests of international organisations, various actors at the national and local level, representing interests of various elite and poor groups as well as institutional interests at different levels.118

Hein further highlights a key problem – already highlighted in previous chapters – with the efforts of global actors in local health governance where this involvement bypasses the national government:

…[T]he dynamics of global health governance can also be seen in a more pessimistic perspective: Interests of powerful actors tend to distract the attention of the global public from issues where health could be promoted by local means like improving the quality of water and sanitation towards issues in which pharmaceutical companies and their home countries have a primordial interest.

This observation highlights the much-emphasized importance of the government in the success of the type of integral governance proposed in this study. Governance—global or local—without interaction, integrity of goals, and a synchronization of objectives would be futile against the healthcare challenges faced in underserved societies.119 It is on this and other grounds discussed above that this study proposes a system of integral governance herein denoted as the Integrated Governance theory for health systems.

118 Wolfgang Hein, “Global Health Governance and National Health Politics in Developing Countries. Conflicts and Cooperation at the Interfaces” in Hein and Kohlmorgen, supra note 80 at 55. The first emphasis is in the original while the second is of the present author.
119 See Walter Eberlei, “Poverty Reduction Strategies Between Global Governance and National Politics” in Hein and Kohlmorgen, supra note 80 at 71 where the author asserts in the context of global health governance: “In the long run, there will be no meaningful or effective Global Governance without cooperating National Governance Systems based on constitutional and participative rule”.

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CHAPTER 6. INTEGRATED GOVERNANCE

The role I would like to play in the Nigerian healthcare system is that of a struggle for the full recognition of the indigenous medical practitioner devoid of constant harassment of law enforcement agents. *Judging from the political history of Nigeria, this would not be possible unless there are indigenous medicine practitioners who can get elected into the various parliaments of the nation.*

E. Aiguobarueghian (2009)*

Alternative medicine and malpractice law are an awkward fit. The issues of what the appropriate standard of care in alternative contexts is, and how to determine it, go to the heart of this question.

C. Feasby (1997)¹

6.1. Introduction

The acute shortage of healthcare resources and medical personnel in the 1960’s and 70’s led the World Health Organization (WHO) to show a marked interest in national indigenous healthcare systems in the African region. The situation influenced the WHO to produce a series of Reports detailing the promising role of indigenous medical providers as key human resources in healthcare delivery.² These Reports emphasized the critical role indigenous medical systems (IMS) can play in the delivery of primary healthcare. In recent Policy Reports, such as the Traditional Medicine Strategy 2002-2005,³ the WHO has reiterated the contributions of indigenous medicine to national healthcare delivery and population health.

In its *Traditional Medicine Strategy* 2002-2005, the WHO promotes the integration of indigenous and alternative medicines into national health systems. The policy is aimed at facilitating the development of national health policies on indigenous medicine and drafting

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national guidelines for indigenous medicine through the development of international standards, technical guidelines and research methodologies. Other objectives of the policy include promoting rational evidence-based use of indigenous medicine, advancing research into indigenous medicine through the promotion of clinical research on the safety and efficacy of indigenous medicine and managing information exchange on indigenous medicine.\(^4\) However, although the WHO acknowledges the plurality of medical systems through these and other detailed policies and programs on the development of indigenous medicine, it has not established a “binding” legal regime that can effectively govern indigenous medicine.\(^5\)

Thus, while the WHO continues to struggle with a dual vision – continued allegiance to Western biomedicine on the one hand, and engineering policies for the recognition of indigenous forms of medical care on the other hand, it has been critiqued for not employing its treaty-making power under Article 19 of its constitution to establish a legally binding regulatory convention on indigenous medicine for the global health community.\(^6\) The argument is that in spite of its broad conception of health and healthcare and the expansive nature of its indigenous medicine policy, the WHO has failed to “explore the possibilities in international law for advancing that policy”.\(^7\) However, it is not clear whether a legally binding instrument for implementing its policies on indigenous medical systems (IMS) will have a significant impact on the status of indigenous medicine worldwide. The existence of such an instrument might simply indicate a legitimate intent on the part of the WHO to ensure that national healthcare systems, especially in the global South, are sustainable.

Nonetheless, the WHO’s policies have influenced several initiatives at the national level where it has raised considerable awareness on the importance of policy guidelines and regulatory frameworks for indigenous medicine. Several WHO member states, including Canada, Nigeria, the United States, the United Kingdom, India, Australia, and China have established guidelines for regulating at least some indigenous and alternative medical services and products. However, in accordance with the WHO’s fixation on legitimacy through

\(^4\) Ibid.
\(^6\) Ibid at 95.
\(^7\) Ibid at 100.
“scientific validation’ or Western-style empiricism”, these regulations often focus on the clinical and experimental aspects to the neglect of the public health aspect of indigenous medicine. As suggested in chapter three, while focusing on the clinical and experimental medical aspects of indigenous and alternative medicines, governments need to ensure that public health research also addresses the “social, cultural, political, and economic contexts” of indigenous medicine to “maximize” its contribution to health systems worldwide. However, even where statutes or regulations formally recognize indigenous medicine as an integral part of the national health system, they do not provide binding principles regarding the practice of indigenous medicine. For example, most statutes on indigenous medicine (often known as ‘Traditional Medicine Acts’) do not mandate the inclusion of indigenous medicines into national formularies nor do they outline guidelines for standardizing the practice of indigenous medicine.

Similarly, national and provincial health Acts and most healthcare-related statutes do not clearly articulate the role of indigenous medical systems (IMS) in national or provincial healthcare delivery. It is also not surprising that these national or provincial laws have no provisions that directly incorporate IMS into healthcare delivery. For example, the informed consent provisions under Ontario’s Health Care Consent Act, 1996 and Nigeria’s National Health Act, 2008 do not include indigenous medicine among the alternative therapies to which patients are entitled. While some provincial medical practice Acts in Canada now redefine medical malpractice to limit the liability of physicians practicing alternative medicine, such provisions – as will be contended in this chapter – have not eradicated the existing hierarchies between biomedicine and IMS. Furthermore, existing medical practice laws do not permit referral between medical systems, except on limited grounds and to a limited class of alternative providers. Thus, while a binding legal instrument issued by the WHO could facilitate the

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8 Ibid at 100.
9 The clinical aspects include issues of safety, efficacy, rational use and mechanisms of action.
11 Health Care Consent Act, S.O. 1996, c. 2, Schedule A.
12 National Health Act, 2008 LFN (SB.50) ['National Health Act '].
13 See section 6.5 infra, for a discussion of the physician’s duty to disclose ‘alternative’ medical options and the interpretation of this duty in the context of ‘alternative indigenous medicine’.
15 See chapter 2, infra, for a fuller discussion of this.
necessary harmonization of national or state medical practice laws and existing regulations on indigenous and alternative medical systems, it remains necessary to address how the content of such laws and regulations may be structured.

This chapter takes on the challenge. The importance of standardizing current health law and policy frameworks to address the atypical (legal and ethical) issues that arise from integrated medical practice has not been at the fore of the scholarship on integrated medicine.16 These issues arise partly because of the prohibitive and/or restrictive nature of most laws governing medical practice. These laws prevent or limit the practice of alternative medicine, and by extension constrain the development of an integrated health system. Also unacknowledged and unaddressed is the central role that a standardized system of laws, as part of a state’s health governance regime, can play in bridging the gap between transplanted legal and institutional norms that often fail to meet established objectives for population health and pragmatic, evidence-based strategies for meeting consumer needs.

Thus, this chapter examines the current fragmentary state of laws on indigenous and alternative medical systems and analyzes how legal and institutional reform implemented at the six levels of the healthcare system can bring about a more cohesive body of healthcare laws and policies that could facilitate medical integration.17 The analyses will emphasize the relationships between all six levels – consumer, healthcare practitioner, healthcare clinic, healthcare institution, professional healthcare organization and health policy levels – and particularly between the first five levels and the policy level. The policy level is critical to the agenda of medical integration because of the state’s key role in health systems legitimization. The six levels in combination create a tripartite picture of the healthcare system comprising the consumer, the medical establishment and the state.


17 These levels, as identified by Tataryn and Verhoef, include the consumer, healthcare practitioner, healthcare clinic, healthcare institution, professional healthcare organization, and health policy levels. As noted in chapters one and five, Tataryn and Verhoef’s outline of the systemic model of integration at every level of the health system reflects an ideal healthcare system, and the integrated theory of governance set out in this chapter proposes methods for resolving the legal issues implicated at each level: D.J. Tataryn and M.J. Verhoef, “Combining Conventional, Complementary and Alternative Health Care: A Vision of Integration” in Perspectives on Alternative and Complementary Health Care: A Collection of Papers Prepared for Health Canada (Health Canada, 2001) [‘Tataryn and Verhoef’].
In this relationship, the establishment of an integrated healthcare system (achieved partly through the state’s interest in incorporating consumers’ interest in IMS into its health policies) necessarily mandates a reconstitution of the state’s approach to health governance. Health governance, it will be recalled, is not limited to law and policymaking. It also involves the implementation and interpretation of laws and the organization of roles within the administrative setting; and covers matters related to the composition of decision-makers and the protocols involved in the decision-making process.\(^\text{18}\)

The sections of this chapter examine how the state can achieve such institutional reform. Specifically, the chapter examines how the state’s implementation of an ideal governance theory can aid in achieving medical integration while ensuring a participatory relationship

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\(^{18}\) See chapters one, two and three, *supra.*
between the public, healthcare professions and the state in health policymaking. The chapter proposes that such a theory has to be structured around fiscal, social, cultural, historical as well as medical realities. For example, the social and cultural landscape of the Canadian society requires a long overdue focus on integrated medicine given that most Canadian immigrants from diverse cultures use alternative medicine as a vital part of their healthcare regimen. Furthermore, millions of Canadians are turning to alternative forms of care to address chronic and terminal conditions that are not amenable to biomedical treatment. According to Health Canada, 74% of Canadians use ‘complementary and alternative medicine’, while 71% use natural health products.19

Similarly, economic and historical realities in Southern states such as Nigeria, as well as Cameroon and Ghana, provide a strong case for integrated medicine. As noted in the introductory chapter, Africa faces a human resource in health crisis and is in critical need of healthcare workers. Moreover, indigenous medicine is an integral part of the healthcare traditions of most African peoples, and the fact that more than 80% of the members of these societies rely on indigenous medical systems for their daily healthcare needs has as much to do with the scarcity of resources as with the peoples’ resolute belief in the strengths of holistic medicine. As stated in chapter one, Canada has laws and judicial precedents that serve as pointers to areas in which policy reform is needed. These legal resources are also prognostic and comparative tools for analyzing legal trends in a Southern state like Nigeria considering that the Nigerian legal system is largely based on the British Common Law system. Thus, the analyses and recommendations in this chapter relate to both the Canadian and Nigerian healthcare systems.

The chapter explores the above propositions in seven sections. The sections generally analyze the legal issues and principles related to medical integration that are implicated at each level of the health system, while highlighting how a reinterpretation or amendment of these principles can assist in achieving medical integration. Section one addresses institutional reform and analyzes a system of integral health governance (denoted in this study as Integrated Governance) as a governance theory that targets reform at the six levels of the healthcare

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system. The analyses and discussions regarding reform at each of the levels begin in section two with a discussion of reform proposals at the health law and policy level. The analyses begin at this level because of the importance of policy and legislative reform to medical integration. Indeed, as observed in chapters one to three, the most significant reform initiative in the interest of integrated medicine is legislative reform. Decisions made at the law and policy level generally have an impact on other levels of the health system. Under the law and policy level, the section examines how national and state or provincial laws and policies can be amended in the interest of integrated healthcare. In the context of this discussion, the section examines four regulatory approaches for health systems including licensure, certification, registration and self-regulation. The section also examines patients’ claim for reimbursement of their expenses on alternative medicine and the constitutional arguments on which the claims are often founded.

Section three discusses reform at the practitioner level. The section examines the legal rules on scope and standards of practice within the context of medical negligence law. It also examines rules established by state medical practice laws, which govern medical practice in different states. The section analyzes how the law and the courts foster a hierarchical relationship between medical professions and providers through task prescriptions that are not founded on the needs of the patients or the expertise of the different professions. Notably, Canadian law grants primacy to biomedicine in the area of diagnosis. In fact, judicial interpretation of the standard of care in medical negligence has often been inclined towards allowing dual medical standards between biomedicine and indigenous medicine in the area of treatment than in diagnosis. Within the context of this analysis, the section discusses how a reformulation of these rules can facilitate medical integration.

Section four addresses reform at the consumer level and examines how the medico-legal concept of informed consent or informed choice can facilitate integrated healthcare. The section analyzes federal statutes on information disclosure as well as on consent to medical treatment and proposes an expansion of the doctrine of informed consent to accommodate integrated medical practice. Section five examines how tasks may be divided between practitioners through referrals at the level of the healthcare clinic. While discussing the nature of liability implicated in clinical referral, the section examines four integrated clinic organizations in two Canadian cities and a Nigerian community. Specifically, it analyzes the relationship between the organization of responsibilities within the clinical setting (that is, with respect to who
diagnoses, prescribes or treats) or the structure of the clinic itself and the type of liability that might arise from referral.

Section six summarily addresses reform at the level of the healthcare institution. It is noteworthy that the legal issues that arise at the level of the healthcare institution are similar to those that arise at the level of the healthcare clinic. Finally, section seven briefly examines the level of the healthcare organization. Reform at this level implicates legal issues similar to those arising at the practitioner level. The analyses are concluded at this level with a summary discussion of state medical practice laws which often place legal restrictions on the practice of medicine by non-biomedical experts.

6.2. Integrated Governance
Medical integration and its legal implications as discussed in this thesis are built upon the theory that medical integration or integrated healthcare thrives on an inclusive and participatory system of health governance. This system of governance is termed here as Integrated Governance, and perhaps more fittingly described as an integral approach to governance considering the emphasis of the theory on interaction between all levels of the health system and as between different actors. Integrated governance as propounded in this study differs theoretically and methodologically from that proposed by the NHS of the Isle of Wight, which has employed this term to describe an approach to governance in which the focus is on the “systems, processes and behaviours by which trusts lead, direct and control their functions”. Integrated governance, as employed in this study, emphasizes the interdependence between the state, healthcare professionals of the different healthcare systems, healthcare consumers, and relevant non-state actors. The integration of these actors, especially indigenous health professionals, into the healthcare delivery system can foster a non-hierarchical participation of the health professions in health policymaking. The idea of an integrated system of health governance is built upon the need to restructure existing power structures in the area of healthcare decision-making. Governance, as we have noted, ought to involve the institutional

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20 This is part of the meaning that the NHS Primary Care Trust in the Isle of Wight attaches to the term. The Trust employs the term to denote ‘systems, processes and behaviours by which trusts lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations’: see Integrated Governance Strategy citing the Department of Health (2006), online: NHS Isle of Wight <http://www.iow.nhs.uk/index.asp?record=1018>. This expression is employed within the limited framework of its definition to address the internal affairs of the NHS.
and communal processes that determine how decisions are made. In the area of healthcare, this conception of governance is designed to ensure that the healthcare decision-making process incorporates the inputs of the diverse range of actors involved in healthcare delivery. This system of governance avoids the hierarchical relationship that exists between the healthcare professions.

This study defines ‘integrated governance’ as a democratic and participatory decision-making and administrative process that incorporates the contributions of state officials, private actors, and consumer interests into healthcare management at every level of the health system in a manner that ensures interaction between the actors as well as between the levels of the health system. This model of governance harmonizes the regulatory and administrative processes (as well as the legal rules that support those processes) within a healthcare system with the needs of legal subjects. As discussed in chapter five, there are conceptions of governance that discuss the importance of a broader category of actors, including non-state actors, in the delivery of healthcare. These approaches, as contended in chapter five, have significant limitations in terms of the conflict that exists between the objectives of some private actors, such as transnational pharmaceutical corporations, and local communities, the lack of interaction between international actors and governments, and a de-emphasis on the role of government in facilitating the necessary interaction between actors. More importantly, while purporting to represent a collaborative system that recognizes the emerging role of non-state actors in health systems governance, these extant approaches to governance are yet to recognize the critical role of indigenous health specialists in primary healthcare delivery and the centrality of state law to creating a system that accommodates this category of actors.

Integrated governance, therefore, attempts to articulate the importance of an approach to governance that fosters interaction between actors, especially with policymakers at the local level, and recognizes the reciprocal relationship between citizen and law. By this, I mean the legal order as implemented by the state must make informed decisions that reflect the needs and experiences of societal members.21 These legal and policy decisions are themselves crucial to reform in the healthcare sector. Hence, any system of governance that bypasses this crucial relationship between law or state and citizen risks overlooking the true needs of the citizenry—

21 See chapter 2, infra, for a full discussion of the reciprocal relationship between law and society.
an outcome which reaffirms the problems of decontextualized governance. The theory of integrated governance in totality problematizes the propensity for global (and even state) healthcare actors to introduce international objectives into local communities without due consideration to the above dynamics. This integral approach to health governance consists of clearly defined characteristics which are designed to address the objectives of improved healthcare access, and if feasible, comprehensive and equitable healthcare delivery. I have developed the features of this theory based on insights from some of the theoretical and practical gaps in the current scholarship as well as in the practices of transnational corporations, international agencies and organizations that offer (foreign) aid in the delivery of health services and products to local communities. The features of the theory may be outlined as follows:

1. Democratic Governance:
   a. Representative governance that accommodates diverse actors and interests;
   b. Decentralization of (policymaking) power from biomedical actors to hitherto ‘unconventional’ healthcare specialists;
   c. Consumer/citizenship empowerment through recognition of their interests/values.
   d. Participatory governance through consumer/citizenship knowledge of, and input in, policies and policymaking processes.

2. Interactive Governance:
   a. Interaction between global/non-state actors and government;
   b. Interaction between non-state actors – a category inclusive of indigenous healthcare specialists – facilitated at every level of the health system, including the policymaking, practitioner, clinical, institutional, organizational and consumer levels.
3. **Non-hierarchical Knowledge Transfer:**
   a. Symmetrical exchange of information and knowledge transfer between actors (especially as between healthcare professionals of different medical systems);
   b. Eschews top-down relations (from the more powerful transnational corporations or agencies to local actors).

4. **Centrality of States/Governments to Healthcare Reform:**
   a. Governments possess knowledge of local needs and challenges;
   b. Governments are primed to make knowledge-based policy decisions founded on their understanding of the living conditions in their constituencies;
   c. Governments/state actors can engender legislative reforms to advance proposed healthcare objectives and create the desired health system.

5. **Prioritization of National or Local Resources:**
   a. Emphasizes the importance of harnessing local resources—human and material to eradicate dependence on foreign aid;
   b. Values transplanted knowledge where they do not conflict with local needs;
   c. Rejects legal, informational, and institutional transplants that are oppositional to the aspirations of, and realities (socio-economic, geographic, material, political, and cultural) within, the recipient community – except where such transplants positively advance a given objective.

The expanded category of actors within the integrated system of health governance represents the idea that solutions to a society’s healthcare problems do not reside with a specific class of professionals nor are they defined by an inherited ideology about how health systems should be governed. Rather, they are best defined through an approach to governance in which the perspectives of both diverse healthcare practitioners and healthcare consumers are incorporated into policymaking. The perspectives of healthcare consumers often reflect the specific realities, including the socio-economic, geo-cultural and the political, under which societal members exist. Being of itself a system that welcomes diverse perspectives (including those commonly termed alternative or non-conventional) about how best to address a people’s
needs – perspectives that are based on experiential evidence and drawn from actors (such as IMPs) who are cognizant of a community’s resources and needs – integrated governance represents an approach to governance that inherently recognizes the complex relations of socio-economic, geographical, political and cultural dynamics that shape the health and healthcare behaviour of legal subjects. As such, integrated governance envisions a reform of extant ahistorical laws and policies on healthcare to embrace a legal framework that reflects the above dynamics. Effectively, such a system of governance seeks to make laws and the administration of those laws fit with the social setting within which they are promulgated.

The current legal frameworks that govern medical practice in Canada and Nigeria legitimize the domination of medical practice by the biomedical profession. As explained in the preceding chapters, while the body of healthcare laws in these countries selectively make provisions for the recognition of (some) alternative medical systems, the level of recognition granted by these laws has not conferred alternative medical providers with the necessary legal and institutional status needed to thrive at the level of the biomedical profession. For example, while many alternative medical professions remain unregulated, the regulated alternative professions do not have the full institutional support of the state (in terms of funding for research, reimbursement for services, and enlisting in healthcare plans) to adequately address consumers’ needs and expectations. More importantly, the selective or perfunctory recognition granted to alternative medical systems in these states fail to address the population health implications of the marginal legal and institutional status of indigenous and alternative medicines.

In Nigeria, while the legal framework governing healthcare delivery in the country legitimizes indigenous medical practice, the totality of the laws, policies and institutions that govern healthcare are not structured to allow the type of systemic integration advocated by the country’s policymakers. For example, while the National Health Act recognizes indigenous medical practitioners as part of the national healthcare delivery system, other provisions in the Act as well as key healthcare policies and statutes in the country do not make provisions for shared tasks between the recognized health professions. The country’s health system is governed through this asymmetrical body of laws in a social context in which there is a limited

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22 This issue is addressed under sub-section 6.3.1 below.
access to health services. The provisions of the laws in totality do not address the economic difficulties encountered by healthcare consumers who pay out-of-pocket for healthcare; the geographical discrepancies in the availability of health services between urban and rural communities; the historical dependence of consumers on indigenous medicine because of its accessibility and dependability; and the cultural and philosophical interest of consumers in holistic healthcare delivery. In sum, the legal framework as it is simply reifies and legitimizes the often politicized notion that the development of, and unidirectional focus on, organized Western biomedicine is the best answer to a country’s healthcare problems, regardless of the socio-cultural and experiential factors that shape healthcare delivery within the country.\(^{23}\)

Integrated governance – as both an administrative theory and an account of how a given system can adapt its own resources towards meeting its needs – challenges this notion.

Beyond its emphasis on non-hierarchical governance as between the health professions, an integral aspect of the theory of integrated governance is its espousal of inclusive governance involving the incorporation of private actors into healthcare delivery. By recognizing the input of a diverse range of state and non-state actors in healthcare management, integrated governance acknowledges the limitations inherent in both public and private health governance and recognizes that neither absolute control of the healthcare system by the state nor over-privatization of the healthcare market is beneficial to healthcare regulation and integration. Santos acknowledges the problem inherent in such an over-extended concept of the state or of the market when he states that such “overreaching” claims have resulted in “unfulfilled promises and irredeemable deficits”.\(^{24}\) Fiscal and resource constraints limit the ability of the state to meet all the challenges of healthcare management. In the case of private management, the lack of government oversight may result in the escalation of healthcare costs and in the delivery of substandard care.

Thus, in the interest of achieving equitable healthcare delivery, integrated governance espouses the need for concerted efforts between the state (macro-governance) and non-state actors comprising indigenous healthcare practitioners, research institutes interested in developing both biomedical and natural health products (NHPs), health management

\(^{23}\) See chapter two, supra, where this issue is discussed.

\(^{24}\) See Boaventura de Sousa Santos, Toward a New Legal Common Sense: Law, Globalization and Emancipation 2d ed. (London: Butterworths, 2002) at 4 [‘Santos’].
organizations (HMOs) and health insurance companies willing to cover indigenous healthcare services, funding agencies, healthcare consumers, and other healthcare establishments (micro-governance). A co-efficient relationship between the macro and micro systems is crucial to achieving the specific health policy objective of medical integration. The distinctiveness of an integrated health governance framework is evident in its recognition of the co-dependency of the macro and micro governance theories. This implies that both state and non-state actors and initiatives (as represented by the macro and micro governance theories respectively) need to work together towards achieving health equity. Given the state of healthcare in most Southern countries, it is unlikely that one of these two models of governance can exclusively maintain a sustainable healthcare system for the populace.

It is important to clarify the description of this approach to governance as a ‘theory’ in this work. It is noteworthy that extant approaches to governance which are generally described in the literature as ‘theories’ or ‘models’ attempt to delineate specific notions of how a system should be organized and managed. These ‘theories’ or ‘models’ generally present an idea of what the progenitors consider to be the best approach to governance. In this work, ‘integrated governance’ represents a particular conception of how health systems should be organized and administered. It proposes that the perspective it embodies holds possible answers to a given social problem. To the extent that it is conjectural – that is, it predicts certain outcomes should its postulations or approaches be adopted – and considering that it contains principles for efficient governance (for example as regards its rejection of blanket legal transplantation), it can be considered a ‘theory’. Part of the recommendations of this theory is that in order to achieve medical integration, health governance will need to be conceived as a collaborative enterprise between diverse healthcare actors at every level of the healthcare system including the consumers, practitioners, healthcare clinics/healthcare institutions, healthcare organizations, and health policy/systems levels. This integrated approach to governance begets the systemic model of integration discussed in chapter five.

Although healthcare consumers have since initiated the process of medical integration through their use of biomedical and indigenous medicines, the final level, the health law and policy level, is the starting point for a formal, state engineered integrated medicine agenda. At

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this level, states can (re)formulate laws and policies to legitimize non-Western forms of healthcare, to allow for funding within national (and private) health insurance schemes, to encourage public and private funding of research and development of indigenous/alternative medicines, to stimulate the interest of private medical research institutes, amongst other initiatives. These initiatives, spearheaded by a state that embraces its (re)new(ed) role as a leader rather than as a subsidiary to private governance, will legitimize collaboration between practitioners of the healthcare professions, healthcare clinics/healthcare institutions and healthcare organizations.

6.3. Health Law and Policy Level

Health law and policy reform is perhaps the most fundamental step towards the creation of an ideal integrated healthcare system. This is because decisions at this level usually influence behavioural changes in other levels. Medical integration at the systems level generally “involves policy making that creates an acceptable environment for collaboration among practitioners”, and requires a harmonization of policy formulation and policy implementation. Laws and policies must reflect a positive governmental attitude towards integrated medicine. Legislative recognition of a particular indigenous therapy, coupled with other laws and policies that accommodate the new reality of medical pluralism, is a useful tool for mainstreaming indigenous healthcare paradigms. This is because legislative recognition creates a professional identity for the particular healthcare system upon which statutory recognition has been conferred and places it within the juridical circle of recognized health professions.

Integration at the health policy level would involve federal support and infrastructure. For example, the Canadian federal government is responsible for “guiding and facilitating the various healthcare organizations and professions in moving towards integrative care”. Part of this task is to provide an “overall vision of how integrative healthcare system might look, as well as clarify the logistical and fiscal responsibilities of the new system”.

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27 Ibid.
28 Ibid.
29 Ibid.
30 Tataryn and Verhoef, supra note 17 at VII.105.
31 Ibid.
6.3.1. National and Provincial Health Laws and Policies

The promulgation of a national law that entrenches indigenous and alternative healthcare systems into the national health delivery system is an uncommon but important first step towards the realization of medical integration. A law may be entirely dedicated to the agenda of integration. Alternatively, the agenda may be incorporated into specific national health legislations. The Chinese government “protects” indigenous medicine by incorporating it into the country’s constitution.\(^32\) Article No. 21 of the Constitution of the People’s Republic of China (1982) stipulates that “both modern medicine and traditional Chinese medicine must be developed”.\(^33\) China is the only country that has incorporated the agenda of integration into its national constitution. This step is strong evidence of the interest and intention of the government to develop its indigenous healthcare sector and maintain a legally binding policy on integration.

Similarly, the first steps towards the mainstreaming of indigenous healthcare in the Indian national healthcare system involved the direct expression of this agenda in the country’s National Health Policy of 1983.\(^34\) Bolstered by the conviction that governance of the indigenous medical sector would help achieve the country’s goal of health equity for all, the government established an independent department led by a government official whose mandate was to “facilitate, encourage, strengthen and promote development efforts and measures for recognition” of the indigenous medical sector nationally and internationally.\(^35\)

Law and policy reform may also be facilitated through necessary legislative amendments, the promulgation of laws or inventive judicial interpretation.\(^36\) Legislative amendments are necessary to facilitate the provision of different medical services under the same national scheme. The Indian healthcare system strives to provide different medical services under the


\(^{33}\) \textit{Ibid.} See also \textit{Anthology of Policies, Laws and Regulations of the People’s Republic of China on Traditional Chinese Medicine} (Beijing: The State Administration of Traditional Chinese Medicine of the People’s Republic of China, 1997).


\(^{35}\) \textit{Ibid.}

\(^{36}\) See sections 6.3.3, 6.4 and 6.5 for a discussion of inventive legal interpretation in the contexts of litigations on reimbursement for expenses on alternative medicine as well as on charges of medical negligence.
same national scheme. The institutional arrangement at the central level comprises the departments of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy established under the Ministry of Health and Family Welfare. Further mainstreaming of indigenous healthcare has occurred with the introduction of a number of Ayurveda and Unani drugs in the national reproductive and child health programme.

In Nigeria, formal recognition of indigenous medicines through legislation dates back to 1966 when the Ministry of Health approved research into the medicinal properties of local herbs. The research was conducted by the University of Ibadan, the country’s oldest university. A series of investigative and research committees were established through the 1970s and 80s to examine the regulation and standardization of indigenous medicine. The country established policies in the 1980s to register indigenous medical providers in the country, and in 1984 the Federal Ministry of Health set up the National Investigative Committee on Traditional and Alternative Medicine. In 1988, the Federal Ministry of Science and Technology established a committee to research and develop indigenous and alternative medicines. In 1992, the National Primary Health Care Development Agency Decree established the National Primary Health Care Development Agency. The Agency had a “broad mandate” on issues related to healthcare, including the authorization and support of traditional birth attendants and village health care systems through:

- paying special attention to and providing maximum support for the training, development, logistic support, and supervision of village health workers and traditional birth assistants, along with the relationship between those workers and their communities and the mechanisms that link those workers to other levels of the health system;
- paying special attention to the involvement of women and grassroots organization of women in the village health system.

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37 Lavekar and Sharma, supra note 34 at 91.
38 Ibid at 90.
40 Ibid.
41 Ibid citing S. Sule, Communication with WHO: National Traditional Medicine Development Programme (Nigeria: Federal Ministry of Health, 2000) [‘Sule, Communication with WHO’].
43 Nigeria, Legal Status of Traditional Medicine, ibid at 29-30.
Other initiatives taken by the country include the establishment of the National Traditional Medicine Development Programme in 1997 and the proposed promulgation of a Traditional Medicine Bill. Since the establishment of the National Traditional Medicine Development Programme, the Federal Ministry of Health has taken steps to create the National Technical Working Group on Traditional Medicine; developed policy documents on indigenous medicine, including the National Policy on Traditional Medicine, National Code of Ethics for the Practice of Traditional Medicine, the Federal Traditional Medicine Board Decree, and Minimum Standards for Traditional Medicine Practice in Nigeria; constituted Consultative Meetings of the Honourable Minister of Health with State Commissioners for Health and Local Government Chairmen (1999), and organized the Presidential Think Tank Forum (1999).44

A law, the ‘Traditional Medicine Council of Nigeria Act’, was proposed in 2000 to establish a regulatory council for indigenous and alternative medical systems. The mandates of the council were to facilitate the practice and development of traditional medicine; establish guidelines for the regulation of indigenous medical practice to control quackery, fraud, and incompetence; liaise with traditional medicine boards at the state level to ensure observance of policies and guidelines outlined in the Federal Traditional Medicine Board Act; establish traditional medicine clinics, herbal farms, botanical gardens, and traditional medicine production units in the country’s geopolitical zones; and collaborate with local and international organizations with similar objectives.45 There has been another attempt to establish a Traditional Medicine Act for the regulation of indigenous medical practice. The proposed law is expected to establish a council for the regulation of indigenous medical practice in Nigeria. The functions of the council would include establishing national guidelines for the regulation and practice of indigenous medicine; preparing and reviewing practitioners’ code of conduct; collaborating with relevant agencies within and outside Nigeria for the promotion of indigenous medicine; accrediting institutions that would train providers and conduct certificate courses on indigenous medicine; and promoting the establishment of model services on indigenous medicine such as clinics, schools, botanical gardens, drugs and manufacturing units in the country.

44 Ibid at 30.
45 Ibid.
While the above initiatives are laudable, it is noteworthy that the proposed initiatives and the mandates under those initiatives do not sufficiently address the needs of both the citizenry and the indigenous medical practitioners. While the government has outlined impressive objectives for the development of indigenous and alternative medical systems, these initiatives are not often reflected in key healthcare statutes in the country, which directly affect the provision of medical services and products to the citizens. For example, an amendment of the National Drug Formulary or the list of essential drugs under Nigeria’s National Health Insurance Scheme Act to include natural health products and other alternative medical products will indicate a clear intent on the part of the government to develop an integrated healthcare system. Although Nigeria’s National Drug Policy proposes to reduce the country’s “high dependence on foreign sources for finished drug products, pharmaceutical raw materials, reagents and equipment” through several methods including the “publication of a Nigerian Pharmacopoeia, incorporating a list of effective herbal medicines”, the Essential Drugs List recognized by the National Health Insurance Scheme does not include any herbal pharmacopoeia.46

Further, it is not evident that the consultative meeting between the Honourable Minister of Health and the State Commissioners for Health and Local Government Chairmen inaugurated in 1999 is a continuous practice, and more importantly, whether it included representative groups of consumers and indigenous medical practitioners whose interests supposedly constituted the agenda in those meetings. Decision-making within national and state health systems through ministerial offices, commissions, committees and meetings remain organized around physicians and biomedical practitioners. This arrangement prevents the participation of indigenous practitioners and consumers in the decision-making process. In chapter three, it was noted that healthcare decision-making in Ontario is governed primarily by the Physician Services Committee (PSC), Medical Directors, and the Health Services Appeal and Review Board. Similarly, the Nigerian National Council on Health (NCH), which is the highest health policymaking body in the country, is comprised of the Minister of Health (federal), Commissioners of Health (states), the Secretary of Health and Human Services in the Federal Capital Territory, and the Permanent Secretary of the Federal Ministry of Health who is the

46 See the National Health Insurance Scheme, online: <http://www.nhis.gov.ng/about.asp>.
secretary to the council. All of these officials are members of the biomedical profession. Their decisions do not often reflect the interests of non-biomedical actors.

Reform of this hierarchical ordering will necessarily require stakeholders in the indigenous medical sector to become involved and participate actively in the healthcare system. It is important to emphasize active participation because the Nigerian National Health Act makes provisions for the inclusion of “one representative each of the registered health professional associations including trado-medical practitioners” in the Technical Committee, which is the advisory body of the NCH.47 Although the inclusion of a representative of the indigenous medical sector in this national advisory body is commendable, it is doubtful that such a representative will be able to influence major policy decisions, especially since the final decision rests with the NCH. The inclusion of representatives of indigenous health professions in major decision-making bodies and councils where they can have direct input into decisions affecting the healthcare of the populace would ensure that the decisions taken by the administrators of the healthcare system are representative of the interests of societal members.48

In interviews conducted with Nigerian IMPs, the practitioners expressed a desire to be part of policymaking processes within the healthcare sector.

The practitioners were open to two methods of participation: through active membership within the decision-making bodies or by simply having their interests and inputs factored into health policy decisions. When asked what role he would like to play in the Nigerian healthcare system, one practitioner expressed an interest in playing a key role in the recognition of indigenous medical practitioners. According to the practitioner, this would prevent the constant harassment of practitioners by law enforcement agents. However, the practitioner was convinced that the proper approach to realizing this objective – “judging from the political history of Nigeria” – was to “elect” indigenous medical practitioners into “the various parliaments of the nation”.49 The political history of Nigeria, as highlighted in the practitioner’s statement, refers to the historical suppression of indigenous medical practice through political

47 Section 6(2)(l) of the Nigerian National Health Act, supra note 12.
and legal mechanisms which originated in the colonial era. It is important to highlight the practitioner’s implicit association of political dynamics surrounding the regulation and practice of indigenous medicine with the need to restructure the configuration of the policymakers. The practitioner clearly problematizes the historical-political trend regarding the prohibition and subsequent limitation of the practice of medicine, and in his view, there has to be a restructuring of policymaking bodies before the country can achieve medical integration. This critical statement reflects the postulations of integrated governance, which as I have outlined above, involve reorganizing the management of the health system based on historical-political as well as socio-economic dynamics.

Along this line, the practitioner also indicated an interest in an expanded category of decision-makers not limited to the usual class of biomedical practitioners. According to the practitioner:

> Slow as the steps being taken are (that is, for the integration of IMS and biomedicine), I am satisfied [that] integration will be meaningful if, and only if an independent body is made to administer the marriage. It must not be left in the hands of the existing conventional healthcare bodies.

The response of this practitioner reveals the growing interest among practitioners to have a neutral body of policymakers to make healthcare decisions for the country. Given the successes recorded by some integrated medical centres, such as the *Pax Herbal Clinic and Diagnostic Laboratories*, many practitioners and consumers are convinced that the inequities in healthcare delivery can be adequately addressed through medical integration facilitated by an independently constituted body of decision-makers. The interest of both patrons and practitioners of indigenous medicine in institutional and legislative reform is also evident in their agitation for regulatory statutes and intellectual property laws. For example, in 2006 there

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50 See chapter two, *supra*, where this history is discussed.
51 See the discussion of integrated governance in section 6.2, *supra*.
were two Traditional Medicine Bills before the Nigerian National Assembly: a private member bill sponsored by a private citizen and another introduced by the Federal Ministry of Health.\textsuperscript{54}

Another area for legislative reform is the category of healthcare workers recognized by the state as part of the human health resource workforce. For Southern societies experiencing a shortage of healthcare workers, legislative reform of national or state law provisions that outline mechanisms for increasing the healthcare workforce may be necessary. For example, section 43 of the Nigerian \textit{National Health Act} (NHA),\textsuperscript{55} which governs the training and management of human resources in the healthcare system, has no provisions indicating the possible contributions of indigenous healthcare providers within the national healthcare system. The same provision contemplates a possible importation of health workers from foreign countries.\textsuperscript{56}

While the state has expressed its interest in developing an integrated healthcare system through setting up the Presidential Committee on the Integration of Traditional Medicine into National Healthcare Delivery, legislative provisions such as section 43 of the NHA do not reflect this interest. Legislative recognition of the importance of indigenous healthcare providers to a country’s health systems workforce is crucial to the integration process. India appears to be pro-active in implementing its interest in harnessing indigenous healthcare workers into the national healthcare delivery system. In that country, “institutionally-qualified” indigenous providers have been placed in the primary healthcare system.\textsuperscript{57} The country also ensures that “general and specialized” indigenous treatment facilities are established in allopathic healthcare centres.\textsuperscript{58}

However, as already noted, the integration of the indigenous medical workforce into state and national healthcare delivery systems must be preceded by formal regulation.

\textbf{6.3.2. Regulation (Licensure, Certification, Registration and Self-Regulation)}

Generally, medical practice statutes in different jurisdictions whether in the North or South of the globe restrict the practice of medicine to a limited category of professionals who are recognized by the state as qualified to practice medicine. In Canada, provincial health statutes

\begin{footnotesize}
\textsuperscript{54} Valentino Buoro, “Interview with Bishop Magnus Atilade” (2006) 1:1 \textit{The Herbal Doctor (A Journal of African Medicine)} 32 at 35 [‘Buoro’]. Presently, there is one Bill before the House for the establishment of the Traditional Medicine Act. The Bill has since gone through the first and second hearings.

\textsuperscript{55} \textit{National Health Act, supra} note 12.

\textsuperscript{56} Sections 43(d) (ii) and 43(i), \textit{ibid}.

\textsuperscript{57} Lavekar and Sharma, \textit{supra} note 34 at 90.

\textsuperscript{58} \textit{Ibid}.
\end{footnotesize}
stipulate the category of persons who may practice medicine. As noted in chapter three, subsections 27(1) and (2) of the Ontario Regulated Health Professions Act (RHPA)\(^59\) prohibit a person who is not authorized by a health profession Act from performing any of fourteen controlled acts stipulated in the statute. These acts include diagnosis, treatment, and drug prescription, which are the major tasks of a healthcare provider.\(^60\) The regulated health professions include a broad range of conventional or allopathic health professions\(^61\) as well as chiropractic,\(^62\) massage therapy,\(^63\) naturopathy (‘drugless practitioners’),\(^64\) and traditional Chinese medicine and acupuncture.\(^65\) The regulated alternative health practitioners are generally limited to the tasks stipulated under the statutes regulating the given profession. In British Columbia, Section 13 of the Health Professions Act\(^66\) limits the practice of medicine to the designated health professions. The designated health professions include a broad range of conventional health professions\(^67\) as well as four alternative health professions including chiropractic,\(^68\) massage therapy,\(^69\) naturopathic medicine,\(^70\) and traditional Chinese medicine and acupuncture.\(^71\)

\(^{59}\) See Regulated Health Professions Act, S.O. 1991, c. 18.

\(^{60}\) However, section 35 exempts aboriginal healers and midwives from the provisions of the Act: see section 35(1), (2) and (3), ibid.

\(^{61}\) For a list of regulated health professions, see Ontario Ministry of Health and Long Term Care <http://www.health.gov.on.ca/english/public/program/pro/procol_dt.html>.


\(^{63}\) Massage Therapy Act, S.O. 1991, c. 27; the College of Massage Therapists of Ontario By-Law No. 11 (Code of Ethics); see other regulatory information online: College of Massage Therapists of Ontario <http://www.cmto.com/index.html>.

\(^{64}\) Drugless Practitioners Act, R.S.O. 1990, c. D-18.

\(^{65}\) Traditional Chinese Medicine Act, S.O. 2006, c. 27.

\(^{66}\) Health Professions Act, R.S.B.C. 1996, c. 183.

\(^{67}\) For a list of regulated professions, see B.C. Ministry of Health Services <http://www.health.gov.bc.ca/leg/>.


\(^{70}\) Naturopathic Physicians Regulation, B.C. Reg. 282/2008 (M242/2008); Bylaws of the College of Naturopathic Physicians, online: B.C. Ministry of Health Services and Professional Regulation <http://www.cnpc.bc.ca/rules.htm>.

\(^{71}\) Traditional Chinese Medicine Practitioners and Acupuncturists Regulation, online: B.C. Reg. 290/2008 (M250/2008); College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia Bylaws, online: B.C. Ministry of Health Services and Professional Regulation <http://www.ctcma.bc.ca/upload/091228%20Amended%20CTCMA%20bylaw%20without%20Schedules.pdf>
In Nigeria, section 17 of the *Medical and Dental Practitioners Act*\(^{72}\) criminalizes the practice of medicine by persons who are not registered medical practitioners. Section 17(1) provides that:

(1) Subject to subsections (6) and (7) of this section, if any person who is not a registered medical practitioner –

(a) for or in expectation of reward, practices or holds himself out to practice as a medical practitioner; or
(b) takes or uses the title of physician, surgeon, doctor or licentiate of medicine, medical practitioner or apothecary; or

(d) without reasonable excuse takes or uses any name, title addition or description implying that he is authorized by law to practice as a medical practitioner –

he shall be guilty of an offence.

Sub-section 6 of section 17 exempts from the above provisions IMPs who are recognized within their communities as capable of providing a system of medical care that originates from the given community within which the IMP practices. According to the sub-section:

Where any person is acknowledged by the members generally of the community to which he belongs as having been trained in the system of therapeutic medicine traditionally in use in that community, nothing in paragraph (a) of subsection (1) or paragraph (a) of subsection (2) of this section [the sections of the Act dealing with offences] shall be construed as making it an offence for that person to practice or to hold himself out to practice that system.\(^{73}\)

However, this exemption is further limited by sub-section 7, which stipulates that the medical acts that can be performed by IMPs do not extend to “any activity involving an incision in human tissue or to administering, supplying or recommending the use of any dangerous drugs”.\(^{74}\) These activities are similar to some of the controlled acts listed under subsections 27(1) and (2) of Ontario’s *Regulated Health Professions Act*.\(^{75}\)

These provisions generally seek to restrict medical practice to a limited category of practitioners. While Ontario’s *Regulated Health Professions Act* permits members of the medical, dentistry, chiropractic, optometry and psychology professions to diagnose, other

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\(^{72}\) *Medical and Dental Practitioners Act*, CAP M8 LFN 2004.

\(^{73}\) Section 17(6), *ibid*.

\(^{74}\) *Ibid*, section 17(7).

\(^{75}\) *Regulated Health Professions Act*, supra note 59.
practitioners of the healing professions may only “assess” a patient’s medical condition.\textsuperscript{76} Among the practitioners that are statutorily regulated, physicians are given the broadest freedom to diagnose, treat and make prescriptions.\textsuperscript{77} Alternative healthcare professions whether in Ontario, British Columbia, or in Nigeria may only practice within the specific medical areas stipulated in the governing laws and regulations.

Some commentators have critiqued legal rules that limit the practice of medicine to physicians and a few designated providers, while restricting the medical areas within which the designated providers can practice. One commentator argues that scope of practice laws are “reductionistic”, “problematic” and “reflect the notion that the enterprise of healing can be carved into neatly severable and licensable blocks”.\textsuperscript{78} It has also been argued that while regulatory laws aim to protect patients from harm and “overreaching practitioners”, healthcare regulation requires “rethinking” because the relevant legal rules on regulation “impose(s) constraints on integrative health care”.\textsuperscript{79} While the hegemonic position of physicians within the health system may serve to maintain the high standards often associated with the biomedical profession, biomedical hegemony has also contributed greatly to excluding indigenous and alternative practitioners from the health system. The hegemonic position of the biomedical profession within the health system may be addressed through the regulation and integration of alternative healthcare providers into state or national health systems.

Regulation may be effected through licensure, certification and registration. Licensing, certification and registration are methods of professional regulation, which monitor those who provide specialized services and place restrictions on how these services are provided.\textsuperscript{80} Generally, these methods of regulation ensure that healthcare providers are practicing within boundaries established by statute or the professional governing board.\textsuperscript{81} The regulation of

\textsuperscript{76} Ibid; see section 27(2) for the list of controlled acts. See also Medicine Act (Ontario), supra note 14.

\textsuperscript{77} Ibid.

\textsuperscript{78} Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 109.

\textsuperscript{79} M.H. Cohen, Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution (Ann Arbor: The University of Michigan Press, 2003) at 23 [‘Cohen, Beyond Complementary Medicine’].


\textsuperscript{81} Cohen, Beyond Complementary Medicine, supra note 79 at 23.
indigenous and alternative healthcare providers can increase patients’ access to alternative therapies that are safely, effectively and appropriately administered; it can also increase the “availability of a systematized framework that can be relied on” by clinicians, healthcare institutions, and insurers, and most importantly, the healthcare consumer.\textsuperscript{82} Furthermore, regulation constitutes a major step towards the systemic integration of biomedicine and indigenous medicine.\textsuperscript{83} States can adopt either licensure, certification or registration in the regulation of indigenous medical practice.

\textit{I. Registration}

The registration model has been noted to be the “least restrictive of these three models”.\textsuperscript{84} Registration usually involves guidelines that must be met by members of the profession.\textsuperscript{85} A registration status is granted upon successful compliance with the guidelines.\textsuperscript{86} According to McNamara \textit{et al.}, this model appears to be a preliminary step adopted “by a professional organization in its pursuit of certification or licensing, and ultimately, self-regulation”.\textsuperscript{87} In Nigeria, the \textit{Medical Rehabilitation Therapists (Registration, etc.) Decree of 1988} provides registration requirements for chiropractors and osteopaths.\textsuperscript{88}

\textit{II. Certification}

Certification, which is also known as “right to title/reserved title regime” is designed to protect the public from inefficient health services through the provision of a “quality signal”\textsuperscript{89} which notifies consumers of the educational or training standards, and the ethical guidelines, which practitioners must satisfy.\textsuperscript{90} It is noteworthy that certification does not generally prohibit non-
biomedically trained practitioners from providing the same healthcare services as biomedical practitioners; however, it restricts the title assigned to the profession to only the certified professional group.\textsuperscript{91} Thus, while certification guarantees easy entry into the market, “thereby protecting consumer choice”,\textsuperscript{92} a shortcoming of the system is that it may not eliminate the provision of services by incompetent individuals.\textsuperscript{93} This is a significant disadvantage where the costs and consequences of error are high.\textsuperscript{94}

Thus, while it is frequently suggested that medical error in indigenous medical practice is relatively low, it is important that issues of professional competence and the possibility of error be given serious consideration in the choice of regulatory models for indigenous medicine.\textsuperscript{95} For example, a regulatory scheme for invasive procedures, such as bone-setting and acupuncture, must address competence, training and/or education and other safety guidelines as may be required to protect patients. These therapies need to be regulated through an approach that supervises the services rendered by the practitioners.\textsuperscript{96}

\textbf{III. Licensure}

Licensure involves an exclusive scope of practice, which grants a medical professional the right to perform a set of controlled or specialized activities and the right to exclude others from performing those activities unless they are governed by a legislated authority.\textsuperscript{97} Only licensed professionals may use the professional title, ‘Dr.’.\textsuperscript{98} Licensure offers a higher degree of protection for the public than certification by barring incompetent and unethical practice.\textsuperscript{99} However, a serious disadvantage of this model over certification is that it raises the costs of services significantly, and these costs are often transferred to the consumer. Furthermore, since

\begin{itemize}
\item\textsuperscript{91} Iyioha, “Healthcare Systems Regulation”, \textit{supra} note 80 at 11.
\item\textsuperscript{92} \textit{Ibid} citing McNamara \textit{et al.}, \textit{supra} note 80 at 64.
\item\textsuperscript{93} \textit{Ibid}.
\item\textsuperscript{94} McNamara \textit{et al.}, \textit{supra} note 80 at 65.
\item\textsuperscript{95} Iyioha, “Healthcare Systems Regulation”, \textit{supra} note 80 at 11.
\item\textsuperscript{96} \textit{Ibid at} 11-12.
\item\textsuperscript{97} See McNamara \textit{et al.}, \textit{supra} note 80 at 65; see also R.G. Evans and W.T. Stanbury, \textit{Occupational Regulation in Canada} (Toronto: University of Toronto Press, 1980) at 2.
\item\textsuperscript{98} McNamara \textit{et al.}, \textit{supra} note 80 at 65. For example section 5 of the \textit{Alberta Nursing Profession Act}, R.S.A. 2000, c. N-8, restricts the use of the title “Registered Nurse” or “R.N.” to only registered nurses. Section 3(1) of the Act provides that: “subject to the provisions of this or any other Act entitling a person to practice a science, therapy or system of practice, a person is guilty of an offence who, not being a registered nurse or permit holder, engages in exclusive nursing practice.”
\item\textsuperscript{99} \textit{Ibid at} 66. See also Manitoba Law Reform Commission, \textit{Regulating Professions and Occupations} (Winnipeg: Manitoba Law Reform Commission, 1994) at 14.
\end{itemize}
only a limited number of professionals have the right to provide the healthcare service,\textsuperscript{100} licensure essentially reduces consumer access. Thus, the system primarily protects well-established practitioners who “control” the profession and “whose interests define the licensing boards’ agenda”.\textsuperscript{101} Furthermore, “licensing fails as an effective safeguard of public safety” and hence “increases barriers to professional entry”.\textsuperscript{102} This important point was observed by the 1994 Manitoba Law Reform Commission. According to the Commission:

Consumers who are denied access to a service (whether because of high prices or due to an inadequate supply or distribution of practitioners) are left with three unpalatable options: performing the service themselves ..., obtaining the service illegally … or going without the service entirely. Whichever option consumers select, they are unlikely to obtain the necessary service at acceptable levels of performance. In this case, ironically, although regulation may have succeeded in raising the quality of service offered by licensed practitioners, it may not have raised the quality of service actually received by the public as a whole and may have diminished it.\textsuperscript{103}

These issues are particularly important in the context of indigenous and integrated medical practice given that this system of medical practice sometimes lacks the type of scientific evidence necessary for regulation. Although these drawbacks are justifiable for practices “characterized by high cost of error…not fully compensable in damages, and for situations where there is reasonably high correlation between prescribed training inputs and desired service outputs,”\textsuperscript{104} a number of indigenous therapies, such as the mind-body and manipulative interventions,\textsuperscript{105} may not be amenable to this system of regulation.

\textbf{IV. Self Regulation}

Voluntary self-regulatory involves direct government regulation of a profession through a statute; it could also involve self-regulation by a profession through ethical codes of conduct.\textsuperscript{106} McNamara \textit{et al.} have noted that while many health professions that are regulated through

\begin{thebibliography}{99}
\bibitem{100} McNamara \textit{et al.}, \textit{supra} note 80 at 67.
\bibitem{101} Cohen, \textit{Beyond Complementary Medicine}, \textit{supra} note 79 at 17.
\bibitem{102} \textit{Ibid}.
\bibitem{103} Manitoba Law Reform Commission, \textit{Regulating Professions and Occupations}, \textit{supra} note 98 at 15.
\bibitem{105} Some examples of these therapies are reiki, therapeutic touch, hypnosis, counseling, meditation, and affirmations/suggestions.
\bibitem{106} Iyioha, “Healthcare Systems Regulation”, \textit{supra} note 80 at 13.
\end{thebibliography}
certification or licensing are also self-regulated, certification and licensing are not the same as self-regulation. Many indigenous healthcare systems are presently self-regulatory. In Nigeria, there are Traditional Medicine Boards as well as registered associations of indigenous medical practitioners in several states. These Boards oversee the registration, practice and conduct of indigenous medical practitioners in the states. Only registered members may join the professional association. There are also attempts to establish a College that would oversee research into indigenous medicine. The College would also be responsible for the training of indigenous medical practitioners as well as ensuring that there is a continuous process of growth and development in the field.

Indigenous medical practitioners who are registered by the Boards are required to have met certain standards of training before they are certified to practice in their respective fields. It is noteworthy that the various professional associations are established as corporate bodies having the powers of a company; their activities are guided by constitutions, which are often drafted by lawyers. Notably, most self-regulatory bodies have a code of conduct, which outlines the guidelines regulating practitioners’ conduct, the practitioners’ relationships with themselves and with their clients, and their duties to society. These codes of conduct are self-imposed and thus differ from those imposed by government or external regulatory agencies. The professional body also maintains a register of members, with entry requirements supervised by a committee whose functions may include “setting educational standards and instituting accreditation systems, promulgating ethical advice … and exercising some form of disciplinary function over members.” In Nigeria, the aforementioned associations have ethical codes of standards that regulate the conduct of practitioners and oversee the “discipline of erring members”. It is noteworthy that the Nigerian associations are not government funded. The running of the association is the financial responsibility of members.

107 State health ministries were required to set up ‘traditional’ medicine boards in 1994: Sule, Communications with WHO, supra note 41.
108 Buoro, supra note 54 at 33.
109 Ibid.
111 Stone and Mathews, supra note 16 at 132.
112 Ibid at 132.
113 Ibid.
114 Oyebola, supra note 110 at 232.
115 Ibid.
Self-regulation offers a number of advantages. It has a lower cost of administration and could be a more effective system because the practitioners are familiar with the services being rendered.\textsuperscript{116} The system may also better identify impermissible standards of practice. Furthermore, “self-governance” may better influence practitioners to comply with professional standards given that “peer pressure” and internally-imposed sanctions “may be a better motivator than a government watchdog”.\textsuperscript{117}

However, the system faces a number of weaknesses, such as the conflicting interests that exists between the interests of the self-governing body and that of the public. This is perhaps the most critical problem with self-governing bodies. While the associational interest to promote “collegiality” among members of the profession is essential to the underlying associational goal of enforcing professional standards, it might result in a professional attitude that is adverse to the interest of the public.\textsuperscript{118} For example, members may be reluctant to report the “incompetence” or “unethical” behaviour of colleagues”.\textsuperscript{119} To avoid this situation, it will be necessary to separate the regulatory and professional branches of the profession.\textsuperscript{120} The regulatory branch would have the responsibility to further the interests of the profession, while it remains a separate body from the professional group itself.\textsuperscript{121}

Self-regulation has had no major operational drawbacks in jurisdictions such as Britain\textsuperscript{122} or Nigeria.\textsuperscript{123} While the systems in those countries are not faultless, a “well-organized” self-regulatory system can certainly meet the standards of “efficiency” and qualitative healthcare delivery.\textsuperscript{124} However, it is necessary to have the regulatory and professional bodies established by statute. The legislative backing will confer the much-needed legitimacy on the bodies and positively influence public acceptance of the role of IMPs in healthcare delivery in the society.

\begin{thebibliography}{9}
\item[116] Iyioha, “Healthcare Systems Regulation”, supra note 80 at 13 citing McNamara et al., supra note 80 at 73.
\item[117] Ibid at 73; see also Manitoba Law Reform Commission, The Future of Occupational Regulation in Manitoba, supra note 90 at 40.
\item[118] Iyioha, “Healthcare Systems Regulation”, supra note 80 at 14 citing McNamara et al., supra note 80 at 73.
\item[120] Iyioha, “Healthcare Systems Regulation”, ibid at 74.
\item[121] Ibid. See also J.J. Morris, M. Fergusson, and M.J. Dykeman, Canadian Nurses and the Law, 2d ed. (Toronto: Butterworths, 1999) at 41.
\item[122] Stone and Matthews, supra note 16 at 133 (Stone and Mathews note that the system has “operated fairly successfully”).
\item[123] Iyioha, “Healthcare Systems Regulation”, supra note 80 at 14.
\item[124] Ibid.
\end{thebibliography}
Finally, it is important to emphasize the importance of (continuous) education and knowledge transfer in meeting the standard of qualitative healthcare delivery as part of a regulatory scheme. Healthcare providers of the different paradigms must learn to “keep an open mind about the other profession’s ability to deliver positive health outcomes to their patients”. Practitioners of both systems need to undergo some training in both biomedicine and indigenous medicine as educational training can facilitate the legitimization process. Indigenous medical systems “will benefit from being incorporated into clearly defined educational programmes within recognized state institutions”. Such institutions exist in China and India. Nigeria has also taken a crucial step in this process to establish a degree programme on integrated medicine at the Osun State University.

6.3.3. National and Provincial Laws on Reimbursement for Medical Expenses

Legal reform is also necessary where laws and policies make no provisions for reimbursing consumers for expenses on indigenous services and products which have become part of their medicine cabinets. Reform is particularly important in the case of statutes that provide some form of financial relief – especially tax credit – for medical expenses. For example, the majority of consumers have been unsuccessful in challenging the validity of section 118.2(2) of the Canadian Income Tax Act. As discussed in chapter three, the provision disallows the medical expense tax relief where the medical products and services are not prescribed by a medical practitioner or dentist and recorded by a pharmacist. Consumers who have incurred huge expenses using indigenous medicine have often argued that the non-inclusion of these forms of medicine into specific laws violates their Charter rights.

Hence, these consumers have employed the legal and constitutional concepts of medical autonomy, multiculturalism, freedom of conscience and equality to challenge the exclusion of indigenous therapies from health insurance coverage. To do justice to the issues raised by these concepts, it is important to examine the case law and the literature on the subject. There are two schools of thought on the rights of consumers to indigenous medicine and the place of integrated medicine within a country’s laws. One school represented by Marie Blanc and

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125 Iyioha, “In Search of Law’s Residence”, supra note 26 at 274-275 citing Tataryn and Verhoef, supra note 17 at VII.103.
126 Iyioha, “In Search of Law’s Residence”, ibid at 275.
127 Ibid.
Richard Haigh contends that multiculturalism and diversity mandate the recognition of ‘complementary and alternative medicine’ by the state. Failure of the state to include alternative medicine within national healthcare formularies, health insurance coverage, or the Canadian medical tax credit may therefore constitute a breach of sections 27 (multiculturalism clause), 7 (fundamental justice clause) and 15 (equality clause) of the Canadian Charter. The second view suggested by Olawale Ajai challenges these views. Ajai contests the constitutionality of medical integration based on the supposed interconnectivity between indigenous medicine and religion. Ajai contends that the freedom of conscience and secularity provisions of the Nigerian Constitution preclude the country from adopting a state religion.

6.3.3.1. Comprehensive Healthcare and the Constitution: The Case for a Constitutional Right to Integrated Medicine

Scholars have examined whether consumers can invoke the constitution to protect their interest in indigenous or ‘alternative’ therapies. For example, Mary Shaw examines the claim whether the exclusion of certain indigenous therapies from reimbursement under the medical expense tax credit constitutes discrimination against the users of the therapies and a violation of section 15, the equality provision of the Canadian Charter. Section 15(1) of the Canadian Charter provides that “every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.”

In Law v. Canada (Minister of Employment and Immigration), the Supreme Court of Canada outlined a three-step framework for determining a discrimination claim under section 15(1) of the Charter. According to the court:


A court that is called upon to determine a discrimination claim under s. 15(1) should make the following three broad inquiries. First, does the impugned law (a) draw a formal distinction between the claimant and others on the basis of one or more personal characteristics, or (b) fail to take into account the claimant’s already disadvantaged position within Canadian society resulting in substantively differential treatment between the claimant and others on the basis of one or more personal characteristics? If so, there is differential treatment for the purpose of s. 15(1).

Second, was the claimant subject to differential treatment on the basis of one or more of the enumerated and analogous grounds? And third, does the differential treatment discriminate in a substantive sense, bringing into play the purpose of s. 15(1) of the Charter in remedying such ills as prejudice, stereotyping, and historical disadvantage?130

Thus, according to the ruling in Law v. Canada, in the determination of a discrimination claim under section 15, the court must find that the impugned law draws a formal distinction between the claimant and others on the basis of one or more personal characteristics, and that this distinction leads to a differential treatment between the claimant and others.

In Chevalier v. Canada, the appellant claimed that section 118.2(2) of the Canadian Income Tax Act violated her equality rights under section 15(1) of the Charter on the ground that section 118.2(2) “as drafted, failed to take into consideration her treatment needs and thus excluded her from the medical expense tax credit scheme on the basis of her disability”.131 Justice Bédard dismissed the claim on the ground that “controlling the safety and efficacy of medication is a pressing and substantive objective”,132 which justifies the government’s interference with the equality rights of the claimant. This interference with the rights of the claimant is protected under section 1 of the Charter – the ‘reasonable limits clause’ – which guarantees the rights and freedoms set out within the Charter “subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society”.133

The Chevalier decision is based on the criteria laid out in Law v. Canada. According to the court, the law did not provide for the benefit claimed under s.118.2(2) as the legislative scheme did not purport to accommodate all medical expenses under the medical expense tax credit. The claimant could have had a chance of success if the legislative provision had purportedly covered all medical expenses and then excluded a group of patients who suffered from the same medical condition or shared some other personal characteristics (such as

130 Ibid.
131 Chevalier v. Canada, [2008] T.C.J. No. 5 [‘Chevalier’]. See chapter 3 infra for a full discussion of this case.
132 Ibid at para. 71.
133 Section 1, Canadian Charter of Rights and Freedom, Part I of the Constitution Act, 1982.
ethnicity or race) as the claimant. Then, the claimant could have used the non-excluded groups of patients covered under the scheme as a comparator group to demonstrate that the law indeed drew a formal distinction between the claimant and others on the basis of a personal characteristic as required under the first step in *Law v. Canada*.¹³⁴ In deed, the court expressly observed that the law did not “exclude individuals that suffered from the taxpayer’s medical conditions” from the benefit of the law “as she was allowed to claim expenses that otherwise fell within the scope of s. 118.2(2)”.¹³⁵ Rather, “the benefit differentiated on the basis of the type of product or service purchased rather than the type of disability suffered”.¹³⁶ Furthermore, it held that the taxpayer had failed to demonstrate differential treatment or discrimination. In any event, “had a violation been found, the provision was justifiable under s. 1 of the Charter”.¹³⁷

Similarly, the court applied the three-step criteria established in *Law* in rejecting the *Charter* claim of the appellant in *Noddin v. The Queen*.¹³⁸ In that case, the appellant who suffered from severe chronic pain challenged the denial of her claim for massage therapy expenses under paragraph 118.2(2)(a) of the *Canadian Income Tax Act*. The relevant law required that the health professional who administered the therapy must be one recognized to practice as such in the province in which the therapy was administered.¹³⁹ The therapy was administered in New Brunswick where massage therapists are unregulated. The court held that the law made no distinction with respect to the personal characteristics of the appellant. Rather, the distinction made by law was whether there was “some legislated assurance of competence of the person administering the service”.¹⁴⁰ The court stated that even if the first two elements of *Law v. Canada* had been satisfied, the denial of Ms. Noddin’s claim based on the absence of provincial legislation “could not be said to have the effect of treating her as less worthy of concern or respect, or in a way that offends her human dignity”.¹⁴¹ The court also rejected the

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¹³⁴ Elsewhere, I have argued that a claimant’s health status falls within the purview of ‘personal characteristics’ that can constitute the basis of a discrimination claim under section 15(1): Ireh Iyioha, “A Different Picture Through the Looking-Glass: Equality, Liberalism and the Question of Fairness in Canadian Immigration Health Policy” (2008) 23 *Georgetown Immigration Law Journal* 621.


¹³⁶ Ibid.

¹³⁷ Ibid.

¹³⁸ *Noddin v. The Queen*, 2004 TCC 687 [‘*Noddin*’].


¹⁴⁰ *Noddin, supra* note 138 at para. 8.

¹⁴¹ Ibid at para. 10.
argument that there was a distinction (and hence discrimination) based on province of residence.

As regards the distinction based on province of residence, Shaw suggests that while the Act does not on the surface make a distinction based on the province of residence, this is its effect. However, for an effects-based analysis to be successful in a Charter challenge, prior disadvantage has to be proven.\textsuperscript{142} While acknowledging that the formalism and technicality inherent in the standards of section 15 may frustrate a discrimination claim, Shaw contends that “effectiveness and economics ground a strong argument for the inclusion of some complementary/alternative therapies as fully insurable services under the public healthcare system, where they would also be available to those who cannot afford their cost”.\textsuperscript{143} Thus, irrespective of the outcome of the Charter analysis, “there is an important policy question about whether or not the medical expense credit should provide relief to Canadians who use alternative medicine, given its increasing importance as a primary health care tool”.\textsuperscript{144}

While this policy question should indeed be at the heart of the debate, one commentator has suggested that there is a sense in which the exclusion of alternative medicine from the medical expense credit may be interpreted as discriminatory. Richard Haigh contends that because alternative medicine is used by “well-defined segments of the population” (e.g. persons of a certain ethnic/national origin) “whose cultural values incorporate and rely on alternative medicine,” we may conclude that the exclusion of these forms of medicine from Medicare coverage is “discriminatory”.\textsuperscript{145} He observes that those who use indigenous medicine do so mainly because of their cultural beliefs; hence, there is a need for constitutional acceptance of different approaches to health and healing. However, Haigh concedes that this argument is fraught with difficulties.

Haigh claims that a significant barrier to such a claim rests on the difficulty of proving that free access to indigenous medical care is of fundamental importance to users and that lack of access to subsidized indigenous medical care affects their dignity.\textsuperscript{146} Indeed, the Canadian courts have often held that the facts and issues surrounding consumers’ use of alternative

\textsuperscript{142} Shaw, supra note 128 at 60.
\textsuperscript{143} Ibid at 60.
\textsuperscript{144} Ibid.
\textsuperscript{145} Haigh, supra note 128 at 171.
\textsuperscript{146} Ibid.
medicine and the non-inclusion of these forms of medicine within the ambit of covered medical expenses in the Canadian *Income Tax Act* are not within the purview of the equality provision of the Canadian *Charter*. However, while the second strand of Haigh’s argument indeed constitutes a difficult legal hurdle for patrons of indigenous medical care, the former argument might be contestable.

Generally, patrons of alternative medicine have been unable to establish that section 118 of the *Canadian Income Tax Act* inherently draws a formal distinction between them and others on the basis of a personal characteristic. Perhaps, this difficulty arises because alternative medicine is now utilized by an expanding category of ethnic groups, including both Caucasian groups and those from societies where a number of indigenous and alternative therapies originated. However, if it were possible for a given ethnic group to show that there exists among members of that ethnicity a high level of dependency on specific indigenous therapies not covered by the law, the court may consider such a claim as a significant ground for challenging the constitutionality of the impugned law.

Another statutory provision that has been critiqued in Canada is section 43 of the Quebec *Medical Act*, which renders the practice of medicine by non-physicians illegal. Marie Blanc bases the constitutional argument against the provision on the ground that it blocks consumers’ access to traditional Chinese medicine. Blanc suggests that matters of health may be brought under the scope of section 2(a) of the *Charter*, which protects the freedom of conscience and religion of Canadians. Furthermore, the author contends that in the case of a ‘traditional’ form of medicine, such as Chinese herbalism, it may be appropriate and useful to invoke the multiculturalism clause of section 27 of the Canadian *Charter* as an add-on to freedom of conscience arguments. Section 27 of the Canadian *Charter* provides that the *Charter* will be interpreted in a manner consistent with the preservation and enhancement of the multicultural heritage of Canadians.

Blanc contends that traditional Chinese medicine is a “minoritarian cultural norm” which needs to be “rescued” from the “illegality to which a majoritarian system has condemned it” and that “marginal or minoritarian forms of treatment rooted in other cultures have their place

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147 Medical Act, R.S.Q. c. M-9.
in a multicultural society” like Canada. Essentially, Blanc supports an interpretation of multiculturalism that embraces both minoritarian and majoritarian values. Hence, the author suggests that while the definition of multiculturalism remains uncertain, “it can surely include both symbolic and structural ethnicity as mediating principles in the interpretation and application of section 27”. Blanc’s arguments may be read alongside Shaw and Haigh’s to infer that the constitutionally guaranteed right to freedom of conscience (and religion) protects a patient’s belief in a medical therapy or medical subculture. This protection ought to be invoked because of the health benefits derivable from indigenous therapies. Furthermore, the argument for legal recognition of both the therapies and the practitioners as well as for a reorganization of Medicare is based on the conviction that the integration of biomedicine and indigenous medical systems in “a truly comprehensive government healthcare scheme” might result in a more equitable healthcare system, improvements in population health, and “a more efficient use of resources”.

6.3.3.2. The Case against a Constitutional Right to Medical Integration

Ajai opposes medical integration in the Nigerian context on the same grounds on which Blanc bases her argument for integration. From the outset, it is important to note that Ajai’s paper was published in 1990 before the progressive evolution of world medical systems in the last two decades. Ajai bases his argument on the freedom of conscience and secularity provisions of the Nigerian Constitution, which precludes the adoption of a state religion in Nigeria. Describing indigenous medicine as religious and ritualistic, Ajai contends that the Traditional Medicine Board Law of 1980 established by the Lagos State government of Nigeria to integrate allopathic and indigenous medicine is unconstitutional.

The ‘freedom of conscience and secularity’ provisions, which Ajai employs in his arguments, are subject to dual interpretations. Although no Nigerian court has clearly articulated the meaning and application of ‘secularity’ in the present context, there are constitutional facts and political developments in Nigerian states that compel an interpretation of ‘secularity’ in inclusive, rather than exclusive terms. As a starting point, sections 260 and

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150 Ibid.
151 Ibid.
275 of the Nigerian constitution establish federal and state Sharia Courts of Appeal respectively, while sections 265 and 280 create Customary Courts of Appeal for both the federation and the states. These are religious and cultural/traditional law courts. Based on these legal provisions, Zamfara State of northern Nigeria has officially adopted Sharia Law as the Grund norm of the state and specifically acknowledges Islam to be its official state religion. Additionally, Nigeria boasts of a National Cathedral and a National Mosque. These constitutional and political facts compel an interpretation of ‘secularity’ in inclusive terms.

In other words, the secularity provisions can be said to have been designed to protect and nurture Nigeria’s multicultural heritage rather than to project one worldview over another. Biomedicine constitutes a medical subculture. Nigeria has embraced this system alongside other Western worldviews and systems. Indigenous medicine is just another medical subculture, and there is nothing in the laws to prevent an acceptance of a different worldview. Thus, secularism and multiculturalism can be interpreted to ensure that the medical laws of a country embrace rather than reject different creeds. Indeed, as Blanc suggests, there can be a secular interpretation of the freedom of conscience provision because “section 27 itself transcends the sphere of traditional theistic beliefs”.

Additionally, Ajai’s analysis of the legal implications of indigenous medical practice does not reflect recent legal developments in the area of indigenous medicine, and the evolving attitude of Nigerian courts on the subject. For example, the Nigerian Traditional Medicine Bill identifies ‘traditional’ medicine practice in Nigeria as a legitimate medical system largely involving the use of medicinal herbs in the treatment of medical conditions. This conception of ‘traditional’ medicine differs significantly from early conceptions of indigenous medicine as ritualistic, which were fostered after the advent of the colonial church in Africa.

Furthermore, Nigerian courts are beginning to recognize indigenous medical practitioners as experts in their various fields of medical practice. In State v. Abhulimen, the High Court recognized that a registered herbalist specializing in mental health was qualified to give evidence on the state of health of his accused patient. The case involved a murder charge against a patient under treatment for mental illness. The accused patient had broken loose from

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the home of the registered herbalist where he was undergoing treatment and murdered two people. The question before the court was whether the evidence of a registered herbalist who treated an accused could be regarded as that of an expert sufficiently skilled to provide evidence of the mental state of the accused, and whether it could rely on such evidence as proof of insanity. In finding the accused not guilty by reason of insanity, Edokpayi, J. stated:

I am of the view that the 1st to the 6th P.Ws. [Prosecution Witnesses] having testified to the fact that the accused person … was under treatment for mental illness in the house of the 5th P.W. who is a registered herbalist, the defence has discharged the onus placed on the accused person by Section 140 of the Evidence Act and I am of the view that having regard to the meanings of expert in the cases of REX V. UDO UNWA EKPO & ORS. 12 W.A.C.A 153 and EMMANUEL YAO BOATENG V. THE KING 12 W.A.C.A at page 242, the 5th P.W. is sufficiently skilled to be an expert on whose evidence I rely in holding that the accused person was not only insane as at the time of the commission of the offence but was also unable to control his actions.155

This legal development derives from the permissive legal framework that governs medical pluralism in Nigeria.156 While the above case is evidently unrelated to the issue of constitutional legitimacy of indigenous medicine, it confirms the legitimacy of the practice, and by extension the agenda of medical integration, which Ajai argues is unconstitutional. The evolving judicial attitude also captures the increasing importance of a pluralistic system of healthcare delivery to the populace. Perhaps, the courts will continue this progressive approach and interpret cases along the precedent established in Abhulimen in the light of the limitations in extant models of healthcare delivery. Indeed, the important question in view of the difficulty in accessing healthcare is, to cite Bodeker and Kronenberg, “how can attention to cultural aspects of health and health care be a bridge rather than a barrier to increased health service utilization and improved levels of health in developing societies?”157

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155 Ibid, per Edokpayi, J. at pg. 74AC. Emphasis added.
156 See section 17(6) of the Medical and Dental Practitioners Act, supra note 72. Section 17(6) exempts IMPs (recognized in their communities as qualified to practice the systems of medicine traceable to those communities) from the prohibitive provisions of section 17(1), which makes it an offence for persons who are not registered medical practitioners to practice medicine. Note, however, that sub-section 17(7) limits the IMP’s right to practice medicine (see sub-section 6.2.2, supra). Note also that this permissive attitude is at best a parallel approach to governance that is beset with a host of legal and ethical problems: see chapter five, supra, for a discussion of these problems.
157 Bodeker and Kronenberg, supra note 10 at 1584.
6.3.4. The Fundamental Justice Clause: A Constitutional Leeway for Contestation?\textsuperscript{158}

As noted in previous chapters, the courts are generally reluctant to find that impugned legislation in the area of reimbursement for indigenous medical treatment violates constitutionally protected rights. As suggested in chapter three, to achieve the necessary reform, there would need to be more than the one voice of Miller, J. of the Canadian Tax Court who has consistently called for a review of section 118.2 of Canada’s \textit{Income Tax Act}. A different judicial approach, which categorically declares the provisions as fundamentally unjust while identifying the urgent need for legislative reform, is necessary.

In furtherance of their claims, patients may be able to invoke section 7 of the \textit{Charter}, the fundamental justice clause, which has less technical requirements than section 15. Section 7 provides that “[e]veryone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice”.\textsuperscript{159} The three rights enlisted in the provision – the rights to life, liberty and security of the person – may be breached only if the breach does not interfere with the individual’s right to ‘fundamental justice’. The term ‘fundamental justice’ implicates an ideal of fairness in the administration of justice. However, its application extends beyond procedural justice and includes substantive rights. It has been invoked in issues related to public healthcare\textsuperscript{160} and entitlement to social security benefits.\textsuperscript{161} For example, in \textit{Chaoulli v. Quebec}, the Supreme Court of Canada upheld a claim that the \textit{Quebec Insurance Act} and the \textit{Hospital Insurance Act}, which prohibited private medical insurance was a breach of the security of the person provision under the \textit{Quebec Charter of Human Rights and Freedoms} considering the medical consequences of long wait-times in the public healthcare system.\textsuperscript{162}

\textsuperscript{158} As defined in chapter five, ‘\textit{contestation}’ involves a challenge of laws and policies that are considered unfair or prejudicial. In the present context, this challenge may be instituted by patrons and practitioners of indigenous and alternative medicine who consider the extant legal order to be unfair or prejudicial to their interests as healthcare consumers. See chapter five, \textit{supra}.

\textsuperscript{159} S.7, \textit{Canadian Charter of Rights and Freedoms}, \textit{supra} note 133.


\textsuperscript{162} Note, however, that only three of the seven judges found the law to be a violation of section 7 of the Canadian \textit{Charter}.
The fundamental justice clause has also been held to protect the autonomy and personal rights of individuals from state infringement. In *R. v. Morgentaler*, the Supreme Court of Canada held that the Criminal Code’s restrictive requirement that abortion be approved by a therapeutic abortion committee set up by an approved hospital was a violation of a woman’s constitutional rights. The five majority judges concluded that the law engendered risk to health, which constituted a denial of the right to security of the person; four of the majority judges agreed that fundamental justice was breached through the “unnecessarily restrictive procedural requirements for a therapeutic abortion” and for Justice Wilson, in the denial of the woman’s freedom of conscience. Three of the five judges were also willing to conclude that a deprivation of security of the person extends beyond physical health and safety to include some requirement of a deprivation of personal autonomy – at least in the case of medical treatment.

In the context of this study, the question is whether the fundamental justice provision may be invoked to contest a provision such as section 118.2 of the *Canadian Income Tax Act* or other statutes which provide restrictive definitions of medical practice. The facts in *Chaoulli* may be said to reflect the type of difficulties that confront patients who routinely seek alternative therapies. The case law on medical expense tax relief claims in Canada (discussed in chapter three) reveals that while many Canadian patients are turning to alternative medicine for their daily healthcare needs, some other patients seek alternative care as a last option after biomedicine fails to provide relief. In the Canadian case of *Herzig*, the appellant’s wife could either accept a verdict of a life span of six months because her physicians had run out of biomedical alternatives to treat her condition, or a chance of four years life extension through alternative therapies. For many patients in the position of the appellant’s wife, including those who rely on alternative healthcare for their daily medical needs, the absence of insurance coverage and the denial of relief under the *Income Tax Act* undeniably constitute a deprivation of the right to life and security of the person because the law leaves these patients without medical care, especially considering that the prescribed therapies (as in the *Herzig* case) are supported by empirical evidence of safety and efficacy. As in the case of *Chaoulli*, where the court accepted that the healthcare offered in the private sector would have reduced the risk of

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163 *R. v. Morgentaler* (No. 2) [1988] 1 S.C.R. 30 [‘Morgentaler’].
165 *Ibid*.
166 See chapter two, *supra*, where the *Herzig* case is discussed.
death or disability for the plaintiff, the courts (as evident in Herzig’s case) have often accepted the prescribing physicians’ opinion that the alternative therapies are safe and effective.

Blanc adds that a patient may actually support an invocation of section 7 with the argument that few physicians have the requisite expertise to practice traditional Chinese medicine in Quebec and that the absence of qualified practitioners puts patients’ health at risk. 167 As was shown in the research conducted in Nigeria (discussed in chapter four), 61% of healthcare consumers who had used natural health products either prescribed it for themselves or had it prescribed by a family member or relative. In the context of the decision in Morgentaler, it can be argued that the narrow definition of medicine and medical practice in the law and the non-regulation of alternative health practitioners engender risks to health, which are evident in the present culture of self-prescription and the unsupervised use of natural health products. This constitutes a denial of the patient’s right to security of the person because patients are generally unequipped to determine the safety of drugs and other medical products available in the healthcare market. Where patients are compelled by the need for an effective remedy for their medical conditions to utilize medical products that are advertised as capable of curing specific conditions, the state must accept responsibility for its failure to either regulate those products or warn consumers against the use of the products if the evidence supports such a conclusion.

Furthermore, evidence from Nigeria (discussed in chapter three) reveals the long wait-times in biomedical clinics, which often leads patients to seek care in indigenous healthcare centres. A similar argument regarding long wait-times may be made in the Canadian context. The debate about long wait-times is not uncommon in Canada where commentators have questioned the sustainability of the Canadian public health system. A Canadian patient who is compelled to seek medical help from a licensed alternative healthcare clinic based on the health risks arising from long wait-times in the conventional healthcare delivery system should be entitled to certain rights, which include the right to be covered under the public health insurance programme for medical expenditure at the alternative healthcare centre.

Finally, it could be argued that the law disregards the right of patients to personal autonomy and freedom of conscience. As shown in Morgentaler, the court may be willing to

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167 Blanc, supra note 128.
find that an unnecessarily restrictive procedural requirement breaches the fundamental justice clause and violates a person’s right to freedom of conscience. There are a number of ways in which section 118.2 of the Canadian Income Tax Act could be said to embody unnecessarily restrictive procedural requirements. For example, patients are denied the medical expense tax credit even where a physician who is convinced that the therapy is safe and efficacious prescribes the therapy. It will be recalled that section 118.2(2)(a) defines a medical expense as “an amount paid to a medical practitioner, dentist or nurse or a public or licensed private hospital in respect of medical or dental services provided to a person”. Section 118.4(2), which requires the therapy to be administered by a limited class of healthcare professionals, defines a medical practitioner as including “an audiologist, dentist, medical doctor, medical practitioner, nurse, occupational therapist, optometrist, pharmacist, psychologist or speech-language pathologist…” or practitioners who are legally authorized to practice in the provinces where the service was provided. Where the therapy is a product rather than a procedure, section 118.2(2)(n) requires that the product must be prescribed by a physician and recorded by a pharmacist.

Notably, most natural health products are not sold in conventional pharmacies. As such, most patients who meet the first restrictive requirement are unable to meet the second requirement. These procedural restrictions could be construed as a violation of a patient’s right to freedom of conscience and personal autonomy in the choice of medical treatment, and these are arguably part of the values that are protected under section 7 of the Canadian Charter. As discussed above, the Supreme Court in Morgentaler made similar pronouncements as those argued here. In that case, the court held that the Criminal Code’s restrictive requirement on abortion violated a woman’s constitutional rights, engendered risk to health which constituted a denial of the right to security of the person, and according to Justice Wilson, denied the woman’s freedom of conscience. It will be recalled that three of the five judges were willing to conclude that the deprivation of security of the person affects physical health and safety as well as personal autonomy – at least in the case of medical treatment.

However, as Haigh has argued, even though section 7 may be used to contest cases where some medical treatments are either not enlisted or delisted from provincial listings on the basis

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168 See Morgentaler, supra note 163; see also R. v. Oakes, [1986] 1 S.C.R. 103 [‘Oakes’].
169 Morgentaler, ibid.
that the decision-making process should be open and based on public discussion, section 1 – the reasonableness provisions of the Canadian Charter – could be used to defeat a section 7 claim. Section 1 of the Charter provides that the “Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society”. It is evident in this provision that the rights and freedom guaranteed by the Charter are not absolutes. Section 1 envisages that judicial review of an impugned legislation under the Charter should involve two stages:

In the first stage, the court must decide whether the challenged law has the effect of limiting one of the guaranteed rights. If the challenged law does have this effect, the second stage is reached: the court must then decide whether the limit is a reasonable one that can be demonstrably justifiable in a free and democratic society. The first stage involves the interpretation and application of the provisions of the Charter that define the guaranteed rights. The second stage involves the interpretation and application of s. 1 of the Charter.\textsuperscript{170}

It should be noted that the guaranteed rights are themselves derived from the values of a free and democratic society;\textsuperscript{171} thus, “the underlying values of a free and democratic society both guarantee the rights in the Charter and, in appropriate circumstances, justify limitations upon those rights”.\textsuperscript{172} This point was made clear in \textit{R. v. Oakes}. According to the court:

The underlying values and principles of a free and democratic society are the genesis of the rights and freedoms guaranteed by the Charter and the ultimate standard against which a limit on a right or freedom must be shown, despite its effect, to be reasonable and demonstrably justified.\textsuperscript{173}

Thus, there is a single “frame of reference” for the guaranteed rights and the limits on those rights.\textsuperscript{174} In \textit{Oakes}, the Supreme Court of Canada defined the values of a free and democratic society to include “respect for the inherent dignity of the human person, commitment to social justice and equality, accommodation of a wide variety of beliefs, respect for cultural and group identity, and faith in social and political institutions which enhance the participation of

\textsuperscript{170} Hogg, \textit{supra} note 164 at 38.
\textsuperscript{171} See \textit{Oakes, supra} note 168; see also Hogg, \textit{ibid} and Lorraine Weinrib, “The Supreme Court of Canada and Section 1 of the Charter” (1988) 10 \textit{Supreme Court L.R.} 469 at 494 ['Weinrib'].
\textsuperscript{172} Sleight Communications v. Davidson [1989] 1 S.C.R. 1038 at 1056.
\textsuperscript{173} \textit{Oakes, supra} note 168.
\textsuperscript{174} Weinrib, \textit{supra} note 171 at 495.
individuals and groups in society.\textsuperscript{175} These values apparently constitute a stronger basis for the protection of the guaranteed rights than for the denial of the rights. This is because the values of a ‘free and democratic society’ – “by which limits on rights may be justified” – “reflect the very purpose for which rights were entrenched”.\textsuperscript{176} As the constitutional law scholar, Lorraine Weinrib, has argued:

The courts are to forward an ideal of political ordering, one that reflects the very purpose for which rights were entrenched, even as they entertain arguments to justify limits upon those rights. The judicial task is to monitor adherence by Canadian governments to their constitutional commitment to freedom and democracy in the second stage of Charter argument, just as in the first, because the exclusive standard set for limits on enumerated rights and freedoms forwards the same values as does their entrenchment.\textsuperscript{177}

Thus, while it is unlikely that a state can base its impugned policy on alternative medicine on any of the above values, there has been the tendency for the state to invoke other values such as cost and efficiency, which as Weinrib argues, do not constitute justifiable grounds for limiting rights in the eyes of the court.

Weinrib argues that the shared “identity” of values underlying rights and the limits imposed upon those rights accounts for the “consistent rejection of considerations foreign to the enterprise of guaranteeing rights – such as cost, efficiency, custom and convenience – as inappropriate to the second stage of Charter argument”:

Considerations such as these, because they are as inimical to the guarantee of the rights as to the justification of limits upon them, cannot be entertained by a judiciary whose two adjudicative functions in regard to rights share the purpose of realizing the promise of entrenchment.\textsuperscript{178}

However, it important to acknowledge that the legislature is empowered under section 33 of the Charter to deny rights where such denial strengthens the “democratic function”.\textsuperscript{179} According to Weinrib, the right to be denied must be indicated in a manner such that “the issue is debated not only as policy, but as policy that (potentially) infringes constitutional values; the override is

\begin{itemize}
  \item \textit{Oakes, supra} note 168 at 136.
  \item \textit{Weinrib, supra} note 171 at 494.
  \item \textit{Ibid.}
  \item \textit{Ibid} at 494-495.
  \item \textit{Ibid}. See section 33, Canadian Charter, supra note 133. This section empowers the legislature to temporarily deny a right granted by the Charter.
\end{itemize}
temporary and may be renewed only at intervals that correspond with renewed election mandates”. 180 Thus, the state may justify its breach of section 7 of the Charter on the ground that the impugned policy on alternative medicine reflects the state’s interest in protecting the health of citizens against unproven therapies. Alternatively, the state may argue that fiscal constraints constitute a barrier to the regulation and enlisting (within provincial insurance schemes) of alternative medical systems. In fact, one commentator has suggested that section 7 may not be effective in mandating the state to extend Medicare plans to cover alternative medical systems. 181 Nevertheless, these policy arguments must be justified by the state. The court requires that the advocate of an “offending measure” must establish its validity or “justification by a preponderance of probability, applied rigorously”. 182

The major problem with the first argument regarding the protection of the health of citizens is evident in the lack of regulation for alternative healthcare professions. The argument that the modalities are unproven is problematic when we consider that the state has not taken any comprehensive initiative regarding the validation of many of the systems. Such initiative would involve supporting medical research on alternative medicine through public funding. It is common knowledge that alternative health professions are not equipped to generate the needed resources to embark on a comprehensive research project. Since healthcare regulation is the responsibility of the state, and considering that the state consistently supports research into the quality of new biomedical therapies and drugs through its health ministry, the state cannot exempt itself from the responsibility to support research into alternative therapies – especially as they now form a major part of the therapeutic regimen employed by its citizens.

As argued in chapter three, health policies must be based on comprehensive evidence of the safety and efficacy of alternative medicines. In the absence of such evidence, the state cannot simply assume that a given therapy or practice is ineffective or undeserving of regulation because it is classified as ‘alternative’ especially considering the clinical evidence generated by patients who have used these therapies for many years. In order to broaden the category of health professionals under the law, provinces and states would have to regulate proven alternative health professions. In neglecting to regulate the professions, a section 1

180 Ibid.
181 Haigh, supra note 128.
182 Weinrib, supra note 171 at 497.
justification on the ground of policy concerns about patient safety should not be available to the state. A section 1 justification based on patient safety concerns needs to be supported by research evidence showing the lack of safety and efficacy of the alternative modalities employed by a given litigant. Such evidence would constitute an acceptable ground for the denial of legal recognition to the practitioners of the modality. Indeed, the court generally requires “cogent and persuasive evidence” to justify an infringement on a Charter right, and the unsubstantiated assumptions that often underlie the exclusion of alternative therapies from the ambit of the law are neither ‘cogent’ nor ‘persuasive.’

In the specific case of natural health products, there is a further problem with a section 1 justification on patient safety grounds. It will be recalled that Health Canada guarantees through its Natural Health Products Directorate that “all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity”. Through this guarantee, the state implicitly professes to fulfil the patient’s right to autonomy and freedom of conscience in the choice of medical treatment. Nevertheless, provisions such as section 118.2 of the Income Tax Act prevent many patients (especially those who are unable to afford the cost of the alternative medical service or product) from obtaining the full benefits of this guarantee. Furthermore, Health Canada has issued guidelines for the regulation of natural health products with attendant penalties for the violation of the requirements. If citizens accept these assurances, as they should, then the state cannot invoke the ‘lack of efficacy and safety’ rhetoric to challenge a fundamental justice claim. In effect, these guarantees, coupled with the state’s inertia as regards regulating alternative medical services, invalidate a possible justification for the deprivation inherent in section 118.2 of the Income Tax Act and similar statutes under the rubric of patient safety concerns.

However, a different set of issues arises if the state bases its ‘justifiable breach’ argument on fiscal constraints. It would not be an unusual argument were the state to assert that regulation or medical integration would increase healthcare costs or budget deficits. While this

183 Ibid.
185 See Natural Health Products Regulations (effective January 1, 2004), established under the Food and Drugs Act, R.S., 1985, c. F-27.
is a strong argument, it is important to reiterate the lack of comprehensive studies to establish such an outcome. In fact, the few studies conducted to determine the cost-effectiveness of indigenous and ‘alternative’ therapies actually contradict the claim regarding the propensity for regulation and integration to increase healthcare costs. Much like cost-identification, cost-utility and cost-minimization studies, studies on the cost-effectiveness of indigenous therapies reveal savings in healthcare costs for the state.\(^{186}\) As suggested in chapter three, in the absence of evidence to confirm the supposition that regulation and medical integration would increase healthcare costs, the ‘fiscal constraint’ argument should not be a valid ground for justifying a section 7 breach. Moreover, even if it is established that there are genuine fiscal issues to be considered, it remains a controversial issue whether this is a sufficient ground for the denial of the important rights protected by section 7. In \textit{Re B.C. Motor Vehicle Act}, Wilson J. was of the view that a legislation, which indeed breached the standards of the fundamental justice clause, could never be “reasonable” nor “demonstrably justified in a free and democratic society”.\(^{187}\) In the same case, Lamer J. had a differing view. According to Lamer J., a law that violated section 7 could still be justified under section 1 “but only in cases arising out of exceptional conditions, such as natural disasters, the outbreak of war, epidemics and the like”.\(^{188}\) Furthermore, “given the Court’s categorical rejection of argument based on cost, convenience and custom”, empirical evidence of the cost implications of a policy may not be persuasive evidence in the opinion of the court as is generally assumed.\(^{189}\) This is because the demand made by law is for “justification rather than excuse or explanation”.\(^{190}\) Accordingly:

Simplistic resort to statistics or history to show that the impugned policy is a “good thing” or comparison to other jurisdictions to show that it occurs elsewhere, without principled argument as to the values being forwarded, might not meet the requisite standards. The Court has understood that an empirical approach, unrooted in principle, while appropriate for legislative policy-making, is unsuited to justification.\(^{191}\)

\(^{186}\) See chapter three, \textit{supra}, where some of these studies are discussed.
\(^{188}\) \textit{Ibid} at 518.
\(^{189}\) Weinrib, \textit{supra} note 171 at 498.
\(^{190}\) \textit{Ibid}.
\(^{191}\) \textit{Ibid}.
Thus, considering that consumers’ use of alternative therapies often reflect the values protected in a ‘free and democratic society’ (including respect for inherent human dignity, commitment to social justice and equality, accommodation of a wide variety of beliefs, and respect for cultural and group identity), in the absence of ‘cogent and persuasive’ evidence (i.e. other evidence beyond a “simplistic resort to statistics”) for the legislature’s refusal to incorporate alternative therapies into the impugned policy, the policy or legislation can be construed as a denial of the constitutionally guaranteed rights under section 7. And, as noted above, the legislature may not be successful in invoking the values underlying the constitutional rights as a basis for the impugned policy in this context because the values constitute a stronger basis for the protection of the guaranteed rights than for the denial of the rights.

The difficulty with justifying a law that breaches section 7 may be said to inhere in the law’s predilection towards ensuring fairness. The fundamental justice principle itself embodies a substantive principle of fairness. In Rodriguez v. British Columbia, McLachlin J. opined that an “arbitrary” or “unfair” law would violate the principles of fundamental justice. According to the learned justice, “[t]he principles of fundamental justice require that each person, considered individually, be treated fairly by the law”. It can be expected that in ensuring fairness, there would occasionally be fiscal costs for upholding the right in a specific instance (for example, in the case of entitlement to medical expense tax relief) through a given legislation. Should a cost-benefit argument (with specific reference to pecuniary benefit) justify the actions of the state if it declines to cover indigenous medicine in order to reduce public expenditure? This question is best answered by a consideration of the nature of the rights breached and by the experiences of patients who come before the courts in search for justice.

Beyond simply depicting what is clearly a difficult experience for patients, each narrative is evidence of a new trend in healthcare delivery which demands legislative attention. Should a cost-benefit analysis that reveals increased healthcare costs in the regulation of a given therapy be sufficient to override the rights of a patient to life and security of the person? As Peter Hogg has observed, “[s]ection 1 of the Charter would undermine everything that follows it if it were interpreted as permitting the Court to uphold a limit on a guaranteed right whenever the benefits

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of the law imposing the limit outweighed the costs”. In the context of the present discourse, if the benefits of section 118.2 of the Income Tax Act and similar acts are measured in terms of savings in healthcare costs, should this be a justifiable limitation on the right of an indigent Mrs. Herzig to have a four-year extension on her life span? Ethical questions of this nature are always at the centre of debates regarding the rationing of healthcare services.

Nevertheless, beyond the assertion that the nature of the rights breached and the need for legislative response are strong grounds for overriding a cost-benefit analysis that is in favour of limiting patients’ section 7 rights, perhaps the more crucial question is whether a cost-benefit analysis of itself suffices as a ground for depriving patients of their section 7 rights in the present context. A provision such as section 118.2 is arbitrary simply because it is not based on the comprehensive research necessary to justify a decision to deprive patients of their rights under the section. In other words, even where the law is shown to be based on a cost-benefit analysis, the provision remains arbitrary if a right as important as the section 7 right is allowed to be limited by evidence arising from the narrow index of the cost-benefit analysis. Thus, while the state needs to carry out the necessary “political calculus of costs and benefits”, it is no consolation to the 71% of Canadians and more than 80% of Nigerians who use natural health products that the government considers a right as crucial as their section 7 right to be negligible based on a cost-benefit analysis – particularly one that fails to consider the broad range of factors necessary for a decision of this nature.

### 6.3.5. Other Reform Options

Beyond adopting the strategy of contestation, healthcare consumers may seek reform in other ways. Scholars have recommended different initiatives for achieving state regulation and integration. These suggestions range from legislative amendments to judicial intervention and to extra-legal means. Alongside her suggestion of constitutional litigation, Blanc recommends legislative reform although convinced that reform will most likely come through a combination of both, as well as through public pressure. Public pressure could involve greater utilization of

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193 Hogg, supra note 164 at 38.
194 Ibid.
195 See chapter three, supra, where these factors are discussed.
indigenous therapies or “active lobbying”.\textsuperscript{196} Similarly, Haigh advocates for “extra-legal measures of achieving social change” such as through consumer advocacy. In the author’s view, this system is “less controversial or politically uncertain than complex constitutional argument” before the court.\textsuperscript{197}

The works of these authors reveal a major lacuna in the medical laws of many countries, and this is the lack of legislative provision for comprehensive health insurance coverage for both allopathic and indigenous medicine. While the unavailability of the right to healthcare has been a contested issue, the debate regarding whether indigenous therapies should be included in the list of covered services touches on the importance of having laws that clearly articulate the right to comprehensive healthcare with coverage of indigenous medicine. The authors’ suggestion regarding public pressure or consumer advocacy is significant given the complexities associated with asserting a right to indigenous healthcare under the constitution. While these suggestions provide feasible options for achieving reform, it is important to delineate what organized advocacy and other forms of legal challenge outside constitutional claims would involve. I address these issues under the other levels of the healthcare system.

\textbf{6.4. The Healthcare Practitioner Level}

Practitioners, like consumers, are also primary actors in any grassroots struggle for reform. Practitioners need to pursue reform through dialogue and negotiation with the state. However, this process must begin with a dialogue between practitioners of indigenous healthcare. Indigenous healthcare practitioners would need to collaborate and work in cohesion in their pursuit of legitimacy and integration. Elsewhere, I have noted that practitioners need to focus on their “shared agenda” to achieve these goals.\textsuperscript{198} A ‘shared agenda’ implies “a unity of interest among indigenous healthcare practitioners in obtaining state legitimation”.\textsuperscript{199} It also denotes the need for collaborative efforts from indigenous medical practitioners toward addressing the issues of medical efficacy and safety, as well as the organization and management of their professional associations, which are important matters to be addressed in

\textsuperscript{196} Blanc, \textit{supra} note 128.
\textsuperscript{197} Haigh, \textit{supra} note 128 at 190.
\textsuperscript{198} Iyioha, “In Search of Law’s Residence”, \textit{supra} note 26 at 255-257, 266-269.
\textsuperscript{199} \textit{Ibid} at 255.
the pursuit of legitimacy.\textsuperscript{200} As noted in chapter two, while different indigenous medical systems may share some philosophies and “a holistic and pragmatic approach to illness and treatment”, they remain largely heterogeneous in their approaches to treatment.\textsuperscript{201}

Thus, it is not uncommon to find practitioners within the same society holding back information on their modes of practice for fear of losing their clientele to their colleagues. This attitude exists among practitioners in Canada as well as in South Africa and Nigeria.\textsuperscript{202} In a research conducted by Merrijoy Kelner \textit{et al.}, it was observed that there exists a lack of cooperation between practitioners of ‘complementary and alternative’ medicine, which has hindered their pursuit of legitimacy and integration.\textsuperscript{203} Other scholars have noted that the primary problem facing indigenous healthcare providers is finding a common ground on which to initiate their agenda for regulation and integration. According to Philip Singer, who writes about Indigenous Nigerian healthcare providers:

…The major problem facing the traditional healers is not the opposition to them by modern medical practitioners, whom they overwhelmingly outnumber, but their own internal factional splits over questions of secrecy, experimentation, organization, leadership…Therefore, the problem is not cooperation with the modern physicians, but of competition among themselves…it is simply a struggle for power.\textsuperscript{204}

The problem of biopiracy at the international level has further complicated this issue. The problem has provided further reasons for secretive and exclusive practice. The struggle for power between the practitioners, whether in Canada, Uganda, or Nigeria, has had the deleterious impact of stalling legitimization.\textsuperscript{205} To counter this situation, practitioners would need to harness what I have termed \textit{associative power} towards realizing their goals.\textsuperscript{206} Associative power, as I have noted elsewhere, “may be found in any convergence of goals,

\begin{flushleft}
\textsuperscript{200} \textit{Ibid.}
\textsuperscript{201} \textit{Ibid} at 255-256; Baronov, \textit{supra} note 2 at 20.
\textsuperscript{202} See chapter 4, \textit{supra}, for a discussion of this issue.
\textsuperscript{205} See Iyioha, “In Search of Law’s Residence”, \textit{supra} note 26 at 256.
\textsuperscript{206} \textit{Ibid} at 256-257, 266-269. ‘Associative Power’ was first introduced and discussed in Iyioha, “In Search of Law’s Residence”, \textit{supra} note 26.
\end{flushleft}
Indigenous healthcare providers need to put aside rivalry and focus on their shared goals in order to address some of the primary issues associated with the legitimization process. Some of these issues, as noted above, include tackling concerns surrounding efficacy, safety and practice standards, and ensuring cohesion in the establishment and leadership of their professional associations. These issues form the core of a shared agenda.

Beyond these, integrated medicine at the level of the healthcare practitioner will benefit from a reform of both the tort of medical negligence and medical practice laws. These laws could be reframed or (re)interpreted to embrace the new paradigm of integrated healthcare. Indigenous healthcare providers and biomedical practitioners of indigenous medicine can contest extant laws on biomedical practice whether as defendants in negligence suits or as applicants in claims over reimbursement for medical services rendered. These propositions are discussed in the next subsections.

6.4.1. Medical Negligence Law

The law of medical negligence aims to protect injured patients and sanction healthcare professionals who have not exercised due care and skill in their practice. The legal process has often construed as illegitimate any medical practice that falls outside the recognized biomedical paradigm. Although clinical practice is evolving to integrate indigenous therapies into routine biomedical practice, legal authority is yet to grasp fully the “paradigmatic shifts” toward “expanded patient choice”. In Davar v. The Queen, Justice Miller bemoaned the slow pace of legal development in this area when he remarked that the law needs to “catch up” with societal behaviour. The analysis in this subsection focuses on how legal rules should evolve to embrace integrated healthcare. Apart from protecting patients who use a combination of

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207 Ibid at 268.
208 Ibid.
209 Ibid.
210 See sub-section 6.2.3 supra, for a full discussion of the nature and possible outcomes of such litigation where the litigation is instituted by a healthcare consumer.
211 See generally ‘Cohen, Beyond Complementary Medicine’, supra note 78 at 23.
212 Ibid.
indigenous and biomedical therapies, well-established legal principles can also protect practitioners from legal liability.

The development or evolution of legal rules on integrated medicine is complicated by the content of existing laws. Plainly stated, medical integration does not fit within existing medical negligence law.214 This is because medical malpractice and regulatory laws derive from the Western allopathic system of diagnosis and treatment.215 As such, the law of medical negligence effectively places non-biomedical practices within the definition of malpractice. As one scholar has noted, “alternative medicine and malpractice law are an awkward fit”; there are unresolved questions regarding “the appropriate standard of care in alternative contexts” and how the standard may be determined.216 There are also questions about the defences available to biomedical healthcare providers who practice indigenous or alternative medicine. These questions need to be addressed in the interest of integration.

6.4.1.1. Defining Medical Negligence

Medical negligence occurs when a physician deviates from the biomedical standard of care and that deviation causes the patient injury. Generally, the plaintiff in an action for negligence must prove (1) the existence of a duty of care, (2) a breach of that duty, and (3) a causal connection between the defendant’s negligent act and the plaintiff’s injury.217 The physician’s duty of care covers the areas of diagnosis, medical advice and treatment.218 Standard forms of negligence encompass errors in diagnosis or treatment, failure to attend, treat or refer the patient, and failure of advice or communication.219 In order to determine the existence of a breach of the standard of care, the court assesses the standard expected of the practitioner, and then considers whether the practitioner’s conduct fell below the applicable standard.220

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214 See generally ‘Cohen, Beyond Complementary Medicine’, supra note 79.
215 Ibid.
216 Feasby, supra note 1.
219 Jones, ibid at 113. See also Iyioha, Deregulation, ibid.
220 Jones, ibid at 21. See also Iyioha, Deregulation, ibid.
Presently, indigenous and alternative medicines are commonly defined as unconventional therapies that fall outside the conventional allopathic healthcare system. Indigenous medical providers largely operate within standards different from those operative in biomedical practice. Thus, the question is whether physicians commit malpractice by incorporating non-allopathic therapies into their treatment regime.\textsuperscript{221} The relevance of this question is evident in the fact that legislatures and the courts often rely on the absence of “general medical acceptance of specific procedures or lack of FDA approval as indicative of failure to follow the standard of care”.\textsuperscript{222}

Michael Cohen, a commentator on complementary and alternative medicine and the law, has suggested that by definition, complementary and alternative medicine (CAM) falls outside biomedical standards of what is medically accepted. Thus, by the very definition of CAM or indigenous medicine as “non-conventional therapies which fall outside biomedical standards”, CAM/indigenous medicine may be interpreted as malpractice. This state of the law, while aiming to protect patients from harm as well as from “overreaching practitioners”, imposes limitations on the practice of indigenous medicine, and this drives the need to reconceptualize medical malpractice law.\textsuperscript{223} It is important for medical negligence law to evolve based on the relativity of medical philosophies and cultures and even medical standards. Indeed, while acknowledging that “behind the complexity and relativity of legal phenomena lies a degree of universality,” it is necessary to recognize that “standards have no universal validity” because they are constructed to “meet specific human conduct and human expectations under given conditions”.\textsuperscript{224} Thus, while the medico-legal duty of care may have a certain level of universal validity, the same cannot be said of the applicable standards.\textsuperscript{225} In other words, while the duty of care standard in medical negligence law has universal application – that is, professionals are to be held to the standard of care they profess to possess – the content of those standards differ from one profession to another.

However, the underlying question is how medical negligence law should be reconceptualized to achieve equality between medical systems. One way in which the state has

\textsuperscript{221} See generally, Beyond Complementary and Alternative Medicine, supra note 79.
\textsuperscript{222} Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 56.
\textsuperscript{223} Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 23.
\textsuperscript{225} Ibid.
attempted to allow the practice of IMS by physicians is through the redefinition of malpractice in dual or integrated medical practice. United States statutes and case law, and some Canadian provincial Medical Practice Acts evince a trend towards a modified definition of malpractice in the context of the professional standard of care which a regulatory College expects of its physicians. For example, according to the Medicine Act of Ontario, 1991 physicians may deviate from accepted medical standards in accordance with patients’ choices, as long as such deviation does not occasion harm.226 The Alberta Medical Profession Amendment Act, 1996,227 as well as a number of United States medical disciplinary statutes (known as Medical Freedom Acts), such as those of Oregon, Washington and Alaska, have also been amended to reflect this new emphasis on the occurrence of harm as the single standard for a finding of malpractice or professional misconduct in integrated medical practice rather than on the traditional standards which emphasized deviation from accepted standards as well as occurrence of harm. It is noteworthy that the provisions of these statutes invoke the conventional definition of malpractice under medical negligence law. As set out above, medical negligence occurs when a physician deviates from accepted standards and the deviation results in harm. Thus, the harm proviso as outlined in the above laws is discussed here in both the context of its application to professional disciplinary actions and its possible relevance under conventional negligence law. Given its incorporation into statutes and case law, I will term this provision the ‘harm principle’.

I. The Harm Principle

Generally, malpractice liability in the case of dual medical practice may be determined by recourse to three different standards: the conventional medical standard, which as noted above could be interpreted to render the practice of indigenous medicine malpractice per se, the standards of the indigenous medical practice itself (otherwise known as the ‘same school rule’), and the mixed practice standard.228 The mixed practice standard involves a combination of the standards operable within the biomedical and indigenous medical system. The court determines the professional standard of care by seeking the expert opinions of other dual practitioners who

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227 Alberta Medical Profession Amendment Act, S.A.1996, c. 27.

practice integrated medicine.\textsuperscript{229} It is noteworthy that the mixed practice standard may be difficult to implement because of the limited number of physicians who integrate indigenous medicine into practice. It will also be difficult to identify “a coherent and distinct standard of care – one that is somehow distinct from either conventional or alternative medicine – against which to judge the defendant’s conduct”.\textsuperscript{230}

On the other hand, when the conventional medical standard is employed, the courts hinge the standard of care on the dual practitioner’s biomedical expertise rather than the standards operable within the alternative paradigm to determine negligent conduct.\textsuperscript{231} In this case, the dual practitioner who is held to the standards acceptable to the medical community may become liable for malpractice per se based on the law’s biomedical definition of medical negligence.\textsuperscript{232} In rejecting the existing biomedical scope of practice laws on the grounds that they are “reductionistic” and “problematic”, Michael Cohen suggests that medical negligence law could be reconceived in the interest of integrated medicine by amending the applicable standards in negligence law to deemphasize a physician’s deviation from standard practice, while emphasizing the harmful result of that deviation.\textsuperscript{233} This suggestion is a statutory provision in some Canadian provincial statutes and US statutes and case law.

According to the \textit{Medicine Act of Ontario, 1991}\textsuperscript{234} a physician is not guilty of professional misconduct merely because he or she ‘deviates’ from traditional standards of care. Liability is imputed to the physician only where it is shown that the chosen therapy poses a greater risk of harm than the traditional therapy. Section 5.1 of the Act reads as follows:

\begin{quote}
A member shall not be found guilty of professional misconduct or of incompetence under section 51 or 52 of the Health Professions Procedural Code solely on the basis that the member practices a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient’s health than the traditional or prevailing practice.\textsuperscript{235}
\end{quote}

\textsuperscript{229} \textit{Ibid}; Iyioha, Deregulation, supra note 218.
\textsuperscript{231} Studdert \textit{et al.}, “Medical Malpractice Implications of Alternative Medicine”, supra note 228; see also Iyioha, Deregulation, supra note 218.
\textsuperscript{232} It is noteworthy that the application of a medical standard of care may simply reflect the “dual practitioner’s duty in clinical situations that implicate knowledge of both alternative and conventional medicine”: Studdert \textit{et al.} “Medical Malpractice Implications of Alternative Medicine”, supra note 228.
\textsuperscript{233} See Cohen, Beyond Complementary Medicine, supra note 79 at 23-34.
\textsuperscript{235} \textit{Ibid}. Emphasis mine.
Similarly, Alberta – the first province in Canada to recognize alternative medicine – amended its *Medical Profession Act* to incorporate the harm principle; section 34(3) of the province’s *Medical Profession Amendment Act, 1996* provides that:

A registered practitioner shall not be found guilty of unbecoming conduct or be found to be incapable or unfit to practice medicine or osteopathy solely on the basis that the registered practitioner employs a therapy that is non-traditional or departs from the prevailing medical practice, unless it can be demonstrated by the College that the therapy has a safety risk for that patient unreasonably greater than the prevailing treatment.\(^{237}\)

In Washington, the Medical Freedom Act provides that the administration of a “non-traditional treatment” is not by itself evidence of malpractice, provided the treatment does not occasion harm or create unreasonable risk to a patient.\(^{238}\) These are some of the statutes that incorporate the harm principle.\(^{239}\) This principle requires careful examination.

The proposal to emphasize the harm criterion whether in the area of negligence law or in the context of the standard of malpractice or professional misconduct under state medical practice Acts is problematic. This proposal, simply stated, suggests that a physician’s ‘deviation’ from traditional standards will be accepted except where it results in harm. Before addressing the problem with the principle, it is important to differentiate the requirement that the chosen therapy must not pose a greater risk to the patient than the conventional (biomedical) therapy from that which imputes liability to the practitioner based on the mere occurrence of harm. While the first requirement may be regarded as only an *improved version* of the harm principle, the provision – at least with a few amendments discussed below – constitutes a reasonable reformulation of the medical standard of negligence in the context of integrated medicine as suggested by Cohen or of the standard of professional misconduct or malpractice under state medical practice laws.

The present analysis focuses on the second formulation which requires a finding of harm to establish liability. In implicitly accepting that indigenous medical practice be cast as ‘deviation from the standard’ – as it would be if the above recommendation is adopted – it is


\(^{237}\) *Ibid.*


\(^{239}\) Other statutes that incorporate the harm principle are summarily discussed in sub-section 6.4.1.4, *infra.*
obvious that this amended definition of malpractice in integrated medical practice does little to enhance the status of indigenous medical systems. The process of establishing medical negligence in the biomedical context is itself a multiple-staged process requiring proof of a duty of care, breach of the duty and a causal relationship between the practitioner’s negligent act and the patient’s injury. A healthcare professional practising biomedicine does not become liable for medical malpractice simply because his or her medical treatment causes injury to a patient. A cause of action usually involves a determination that the medical professional breached the required standard of care.

By the same analogy, there ought to be a determination as to whether a particular IMP or integrated health physician has breached the relevant standard of care applicable to his or her area of practice. Thus, the new fiat-like standard – that malpractice liability in the context of integrated or dual medical practice is to be determined by the existence or absence of harm – creates a double standard as between the law’s treatment of biomedicine and indigenous medicine. The proposal endorses an insidious hierarchy between biomedicine and other medical systems. It implicitly endorses the uncomplimentary definition of indigenous medicine as conduct ‘deviating’ from or operating ‘below’ the standard of biomedicine – that is, as ‘substandard’ medicine.

Furthermore, it appears that the harm principle was designed to create some space for indigenous medicine within the biomedical system. In other words, there does not seem to be a legislative intent to establish equality between the medical systems. The principle seeks to accommodate the delivery of indigenous and alternative medicine by medical professionals in circumstances where they have acquired the necessary skills for the administration of a given therapy. The amended Acts have no contemporaneous provisions on how IMS and IMPs may be fully integrated into the state healthcare delivery system. The policy – that is, to support through legislative provisos the delivery of indigenous medicine by physicians – is hardly different from the state’s predilection towards the model of co-option in which biomedical professionals exclusively provide alternative medical services. It is important to note that while the delivery of alternative healthcare by physicians is not unethical of itself, the ethical problem identified with such a model stems from the concomitant denial of legitimacy to

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240 See chapter five, supra, for a discussion of the problems associated with the co-optative model of integration.
alternative healthcare professionals, and the resultant domination of the alternative healthcare paradigm by biomedical actors.

Beyond the co-optative model of integration which the harm principle reinforces, there is a further problem with the erroneous factual and legal assumptions made by the principle. Although the legislative intent might be to protect patients, the principle may be interpreted as an overextension of the law’s interest in patient safety because it assumes that indigenous systems of medicine can be practiced without the occasional deleterious outcome that is customary in medical practice. Usually, in the context of negligence law, such adverse effect to result in liability must be attributable to negligent conduct. Since conventional negligence law singles out fault or blameworthy conduct on the part of the healthcare professional to establish guilt, it is problematic that the amended laws should overlook this traditional standard in the case of integrated or dual medical practice. Even in the context of a disciplinary action under state medical practice laws, liability does not automatically attach to a physician’s conduct based on an adverse result from the medical intervention. Liability results where the physician’s conduct is shown to have fallen below the standards of the profession.

Integrated medicine will greatly benefit from the institutionalization of legal principles that recognize the difference between medical systems and accept indigenous medicine as a body of knowledge equivalent to, though different from, biomedicine. Equally important is the need for law to recognize indigenous healthcare professionals as a distinct professional group. Effectively, policymakers need to recognize that it is not necessary to analyze the tort of negligence through biomedical lenses. In legal interpretation, courts must acknowledge the restrictedness of the definition of negligence in an unequivocal acceptance of the diversity or plurality of medical systems, rather than regard the practice of other well-developed systems as ‘deviations’ from the rule – deviations that are condonable only if a certain condition does not occur.
II. Reframing Negligence Law in the Integrated Healthcare Context: An Alternative Approach

Reform of the tort of medical negligence in the context of integrated medicine is aimed at enabling biomedical practitioners to integrate their knowledge of multiple therapeutic regimens into clinical practice without fear of contravening medical malpractice law. It also aims to ensure that licensed indigenous healthcare providers who practice independently or collaborate with physicians in clinical settings are not judged through biomedical standards of care. As noted above, there is nothing inherently unethical or reprehensible about integrated medical practice by physicians so long as the state concurrently strives to license alternative healthcare practitioners to provide the services to healthcare consumers. Any principle for determining malpractice liability in the context of integrated or alternative healthcare must be based on an egalitarian framework that embraces the ongoing evolution in healthcare delivery.

In pursuance of this objective, medical negligence may be conceived as conduct falling below the standard of care required in the specific system of medicine practiced by the healthcare professional and which causes injury to the patient. This established conception eliminates the need to emphasize the harm angle of the definition of medical negligence. The approach ensures that dual or integrated medical practitioners are held to the standards applicable to the practitioners of the intervention which they have administered, and that these standards are applied in determining whether the biomedical practitioner “has acted with the appropriate degree of care and skill required for that practice”.241 This approach, commonly denoted as the ‘same school rule’, provides that:

...Health care professionals are entitled to have their treatment of patients tested by rules and principles that conform to their training and to standards set by their immediate professional peers, not by those of some other school. This rule is not confined to generalist, specialist, and subspecialist disciplines within conventional medical practice; courts have also applied it when evaluating the conduct of a wide range of schools of alternative medicine... 242

242 Studdert et al., “Medical Malpractice Implications of Alternative Medicine”, supra note 228.
As far back as 1956, the Canadian Supreme Court upheld the importance of judging a medical practitioner according to the standards of his or her school of practice. In *Wilson v. Swanson*, the Supreme Court stated that:

The medical man must possess and use, that reasonable degree of learning and skill ordinarily possessed by practitioners in similar communities in similar cases, and it was the duty of a specialist such as the appellant, who held himself out as possessing special skill and knowledge, to have and exercise the degree of skill of an average specialist in his field. What the surgeon by his ordinary engagement undertakes with the patient is that he possesses the skill, knowledge and judgment of the generality or average of the special group or class of technicians to which he belongs and will faithfully exercise them. In a given situation some may differ from others in that exercise, depending on the significance they attribute to the different factors in the light of their own experience. There is the question of judgment. The test can be no more than this: was the decision the result of the exercise of the surgical intelligence professed? Or was what was done such that, disregarding it may be the exceptional case or individual, in all the circumstances, at least the preponderant opinion of the group would have been against it? If a substantial opinion confirms it, there is no breach or failure.243

However, in applying the standard of the indigenous medical paradigm, it is important to note that a biomedical practitioner may be held liable for breaching his or her duty to refer.244 A medical professional has a legal duty of referral in circumstances where a patient’s condition exceeds his or her expertise.245 As Studdert *et al.* have noted:

A relatively common allegation in claims against alternative medicine practitioners is failure to refer patients in need of medical treatment to an appropriate form of conventional medical treatment; other suits allege the use of alternative therapies that eliminate or reduce a patient’s chance at better recovery by conventional treatments. When these types of claims are brought against dual practitioners, application of alternative medicine standards is problematic.246

Dual or integrated medical practitioners should not be able to shield themselves from liability under the ‘same school’ rule in circumstances where there exists a legal duty to refer the patient to an alternative practitioner skilled in the relevant area of medical practice. Additionally, practitioners may be liable for misrepresentation if they undertake medical procedures or administer treatments in cases where they have not disclosed the limits of their expertise.247

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244 Studdert *et al*., “Medical Malpractice Implications of Alternative Medicine”, *supra* note 228 at 175.
245 Iyioha, *Deregulation*, *supra* note 218.
246 Studdert *et al*., “Medical Malpractice Implications of Alternative Medicine”, *supra* note 228 at 175.
247 Iyioha, *Deregulation*, *supra* note 218.
Beyond these important caveats, the application of the standards operable within the indigenous medical profession remains the more favourable approach. In defining the standard of care according to the specific method of treatment that has been administered, the legal question should be whether the physician has complied with the professional guidelines for the administration of the given therapy. The court must inquire whether the physician obeyed appropriate medical ethics as defined by the paradigm within which he or she practices.

Furthermore, the court may question whether the indigenous therapy was the ideal option among a range of biomedical and indigenous options. On this issue, Michael Cohen has suggested that in order to establish malpractice liability in the alternative medical context, the courts should assess the following three factors:

“(1) the risk of danger or injury created by the specific therapy, (2) the extent to which the patient’s condition was likely to result in death or disability irrespective of complementary or alternative care, and (3) the extent to which the complementary and alternative therapy displaced conventional care and the extent to which the neglect of conventional care was the actual and proximate cause of the injury”.

Cohen’s first point is important. As suggested above, the chosen therapy must be the best among different options available to the healthcare provider. Such a therapy must not pose a greater risk of harm to the patient than would other alternatives whether biomedical or indigenous. However, the third point above raises some concerns. The proposition presents biomedical care as the standard to which the healthcare provider must have first recourse. In the interest of integrated medicine, the more progressive proposition should be that the courts need to assess the extent to which the prescribed therapy displaced a more effective or less risky option – whether biomedical or indigenous. Thus, Cohen’s proposition arguably reinforces the hierarchical nature of the harm principle.

This study proposes an alternative to Cohen’s suggestion, which would effectively entrench a non-hierarchical integrated healthcare system. The alternative approach is that the law should require the reasonable physician to weigh his or her knowledge of different medical systems and consider which system best suits the condition of the patient. While the evolution of law, ethics and medical practice may in the future require biomedical practitioners to be knowledgeable about well-established alternative medical systems, the proposal requiring

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248 Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 34.
biomedical practitioners to compare their knowledge of different therapeutic paradigms in the search for the best option should not necessarily mandate healthcare providers to be knowledgeable about all alternative systems of medicine.

Where injury results from the practitioner’s chosen therapy, the court should assess whether the physician adhered to the practice guidelines set out by the indigenous or alternative healthcare profession, and where necessary the biomedical profession, since the physician is involved in dual medical practice. Some important guidelines applicable to the physician who decides to utilize a new or non-biomedical therapy are outlined in the case of Ravikovich v. College of Physicians and Surgeons of Ontario.249 According to the guidelines:

The drug must be proven safe. The physician must record in considerable detail the clinical state of the patient and the changes in this state, both good and bad, that are produced by the medication. The physician should be aware of all of the pertinent publications that bear on the clinical problem as well as on the proposed treatment.250

The Ravikovich case involved a physician who was charged with professional misconduct for failing to maintain the standard of practice of the medical profession based on his utilization of diagnostic and therapeutic methods that allegedly had no proven scientific validity. The disciplinary committee of the College found him guilty of professional misconduct. The Committee reiterated the harm principle, noting however, that the use or recommendation of a non-traditional treatment is not in itself proof of deficient clinical ability.251

By implication, the decision of a disciplinary committee adjudicating in circumstances comparable to the Ravikovich case would be upheld if the defendant’s departure from biomedical methods posed greater risks to the patient outside those ordinarily associated with the biomedical method.252 The requirement that the blameworthy conduct must be such that poses serious risks outside those usually associated with the biomedical method implicitly

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251 This principle is recognized under Ontario Law: O. Reg 52/95, made under the Medicine Act, 1991, supra note 14.

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suggests that to result in liability, the risks associated with the chosen treatment must exceed that of the traditional or biomedical option. As a further alternative formulation of the negligence rule, we may include an additional proposition that to result in negligence the risks of the chosen therapy must exceed that of the best option – regardless of whether it is biomedical or indigenous – for the patient’s medical condition.

This formulation categorically requires that the physician must not be negligent in the choice of therapy; simply, the chosen therapy must be the most appropriate in terms of effectiveness and safety in comparison to other options. The stipulation of ‘biomedicine’ expressly or implicitly as the approach against which the risks of the indigenous therapy must be measured overlooks the simple fact that some indigenous therapies are more effective for certain conditions and for different stages of a medical condition. Thus, among the circumstances that may give rise to liability, we should include the situation where the chosen therapy – whether indigenous or even biomedical – creates greater risks than those posed by another indigenous therapy for the same medical condition.

Nevertheless, in pursuing the proposition that the courts should inquire whether the standards of the indigenous medical profession have been met, the problem that arises is what constitutes a medical profession or recognized system of medicine. The resolution of this question can assist the courts in determining the contexts in which they could apply the ‘same school’, mixed practice, or conventional medical standard. Notably, these same standards are applicable to the indigenous medical provider. The next subsection examines the legal standards of care applicable to the practice of indigenous medicine as part of the broader analysis of what constitutes a recognized system of medicine.

6.4.1.2. Malpractice in the Indigenous Medical Context: What is a System of Medicine?

When considering malpractice in the indigenous medical context, a fundamental question that must be addressed is, “what is a profession”?253 This question is pertinent because in the determination of liability, the court is expected to apply the standards of the particular healthcare profession to which the defendant belongs. The court’s dicta in Ter Neuzen v.

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253 See Feasby, supra note 1.
Korn suggests that once a practice is established as generally accepted within a profession, then the courts will defer to the expertise of the profession as a whole. The inference from this case is that the court’s deference to the profession is a “recognition by the court that a “profession” has constructed a body of practices over time and through experimentation that has proven to be safe and effective and that the court cannot presume to know better than the accumulated knowledge of the profession”. On these grounds, Colin Feasby identifies three indices of a health profession. According to Feasby:

There are three indicia of a health profession: (1) statutory recognition; (2) specialized education; and (3) substantially different treatment. Statutory recognition is in some respects an anomalous indicator as it can be considered to be a legislative recognition that (2) and (3) have been satisfied. If the first marker (statutory recognition) is present, in most cases a court would hold that a school of medicine was, indeed, a profession without further inquiry. If there was no statutory recognition, however, I suggest that it would still be open for a court to find that an alternative school of medicine was in fact a profession, based on the fact that it was characterized by both specialized education and substantially different treatment.

Where these three indices are found to exist, the standard of care for determining malpractice will be that of the ‘profession’. Although there is a dearth of Canadian case law on the subject, the general rule is that the standard of care applicable to biomedical practice also applies to alternative medical providers who are found to belong to an established profession. For example, a chiropractor is expected to exercise the “degree of care, diligence, judgment and skill which is exercised by a reasonable chiropractor under like or similar circumstances”. This standard derives from the finding that chiropractic is a ‘profession’. In Nevada, malpractice in the context of homeopathic practice is defined as “failure on the part of a homeopathic physician to exercise the degree of care, diligence and skill ordinarily exercised by homeopathic physicians in good standing in the community in which he practices”.

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255 Ibid.
256 Feasby, supra note 1.
257 Ibid.
258 See ibid; Barber v. Wilson, [1996] O.J. No. 1275 (QL) at para. 5 ['Barber v. Wilson'].
259 Nev. Rev. Stat. § 630A.060, ‘Community’ as used in the section “embraces the entire area customarily served by homeopathic physicians among whom a patient may reasonably choose, not merely the particular area inhabited by the patients of that individual physician or the particular city or place where he has his office”: added to the N.R.S. by 1983, 1479, ibid.
The relevant standard of care is to be determined through the testimony of experts from within the school of the provider under trial for malpractice. This, as noted above, is the ‘same school rule’, which is founded on the logic that it would be unfair for a practitioner of one school who practices a different method of treatment to assess the skill of another practitioner who uses a different method. In addition, “the rule respects the intention of the legislature as expressed in the regulation of different professions under different rules”. In Gibbons v. Harris, the Alberta appellate court affirmed that opinions about the applicable standard of care in a case on chiropractic malpractice should be made by a practitioner trained in the same professional school as the defendant. In that case, a chiropractor misdiagnosed and erroneously performed spinal manipulation on a child with degenerative vertebrae. This rule was reaffirmed in Penner v. Theobald, where the court held that a chiropractor who faces allegations of negligence is to be judged not by the standards of “the merely reasonable man but the standard of what may reasonably be expected of the ordinary, careful, competent chiropractor”. Thus, the professional views of biomedical practitioners who are not trained in the theory or practice of the alternative therapy under judicial scrutiny are not the operative standard.

On the other hand, where the medical ‘system’, which the indigenous provider practices, is not a recognized profession, and no professional standard of care is identified, a different consideration applies. The courts will be obliged to apply the basic rules of negligence law, in which case the applicable standard will be “that of the reasonable person or that of a medical doctor”. Feasby suggests that the appropriate standard should be that of a medical doctor. In this case, no “special deference” is accorded to practitioners’ “professional explanations of their conduct as situated within, and informed by, their school of thought regarding diagnosing and treating ill health”. Evidently, where there is no identifiable medical system or

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260 See Feasby, supra note 1.
261 Ibid.
262 Ibid.
264 See Iyioha, Deregulation, supra note 218.
265 Penner v. Theobald (1962), 35 DLR (2d) 700 (CA) at 704 [‘Penner v. Theobald’].
266 Ibid.
267 Ibid.
268 Feasby, supra note 1.
269 Ibid.
270 Crouch et al., supra note 241 at 100.
profession, the legal impasse is usually resolved through recourse to rules applicable to biomedical practice. The question, then, is what are the factors that should influence the court in deciding whether a given set of practices or methods of treatment constitute a ‘profession’ or ‘system of medicine’?

I. Systems and Non-Systems
In the determination of whether a given set of medical practices constitute a medical system or healthcare profession, the adjudicator may have recourse to one set of criteria, which suggests that a health profession should have statutory recognition, specialized education, and a substantially different treatment. Feasby notes that the first criterion is usually an indication that the ‘profession’ does have the latter requirements. In reality, the latter requirements do not always guarantee that a group of practitioners will obtain statutory recognition. Many indigenous and alternative health professions that have the latter requirements have not obtained state recognition. Lobbying and political negotiations, accompanied by other social and economic factors, such as consumer interests and fiscal considerations (discussed in previous sections), will usually influence policy decisions in this area.

For Murray Last, to assess the extent to which a health profession is systematized, there would need to be a system in which:

1. There exists a group of practitioners, all of whom clearly adhere to a common, consistent body of theory and base their practice on a logic deriving from that theory.
2. Patients recognize the existence of such a group of practitioners and such a consistent body of theory and, while they may not be able to give an account of the theory, they accept its logic as valid.
3. The theory is held to explain and treat most illnesses that people experience.

Last applies the above criteria to indigenous medical practice in a Northern Nigerian village and concludes that without an “association”, “examinations” or a “standard treatment”, indigenous “healers” in the Malumfashi area were a “category” rather than “a corporate group”.

271 Feasby, supra note 1.
272 Ibid.
273 Murray Last, “The Importance of Knowing About Not Knowing” in Roland Littlewood, ed., On Knowing and Not Knowing in the Anthropology of Medicine (Walnut Creek, CA: Left Coast, 2007) at 5.
274 Ibid.
However, he concedes that the “technicians of traditional medicine” such as the barber surgeon, the bonesetter, and the midwife constitute “a separate group”; these practitioners are accorded the status of professionals.275 Last then argues that only this “small part” of indigenous medical practice – “the technical specialists” – may be considered as comprising a system; and it is these groups of professionals that “are being drawn gradually into the government’s orbit”.276 For other practitioners outside this group, Last contends that:

> [t]he range of traditional healers that serves the Malumfashi area cannot be said to adhere to a single consistent theory of logic, except in so far as they are defined negatively, as not offering hospital or Islamic medicine. Nor, since traditional medicine is too diffuse to be monopolized, do healers form an exclusive group.277

Last’s grand conclusion from the above “brief account” (to employ the author’s own words) of the specific area of Malumfashi is that “traditional medicine, if not perhaps a “nonsystem”, is now extremely unsystematized in practice”.278

Before attempting to debunk Last’s thesis, it is important to draw attention to the fact that the author’s research was largely carried out in the sixties and seventies and at a time when there were few existing professional associations of indigenous healthcare providers, most of which were located outside the area of research. In spite of the very limited geographical scope of the research, it is surprising that Last draws an inductive conclusion that “traditional medicine” is “now extremely unsystematized”. Although the author’s postscripts were written after recent visits to the area of research in 1991 and 2005, Last’s analysis and views still do not depict indigenous medical practice as it is in most parts of the country. In order to debunk Last’s analysis, let us examine his three-step criteria of a “system”, the absence of which could render a method of practice a “nonsystem” to adopt the author’s term. Last’s second and last criteria may be considered as logically connected. Thus, the two criteria that need to be addressed are adherence to a common, consistent body of theory, and consumer/patient recognition of the logic and effectiveness of the theory.

275 Ibid.
276 Ibid at 8.
277 Ibid at 6.
278 Ibid at 8.
A. A Shared Body of Theory

To address the first criterion, it is necessary to examine the defining features of indigenous medical systems. As noted in chapter 2, indigenous medical systems in totality have four fundamental distinguishing features which, taken together, form a system operating on a unified set of theories. These features include the belief in the existence of natural, psychosomatic, psychosocial and transcendental causes of illness. Again, as noted in chapter two, biomedicine was introduced into a setting in which there was already a belief in the natural, scientific etiology of illness. Hence, biomedicine’s monolithic explanation of disease as based on phenomena from the natural world simply constituted one aspect of an already existing system. In fact, due to the interrelatedness of the four defining features of indigenous medicine, it can safely be argued that indigenous and alternative medicines across the globe – irrespective of the individual variations in the practices – have a single theory. This is that true healing comes not simply from the treatment of the physical symptoms of the illness, but also from a holistic treatment of the body and the mind. This is because disease is not purely the outcome of a biological, body-based process; disease and ill health are also traceable to an imbalance in the mind and in social and spiritual relationships.

When we move away from this general theory, it is arguable that what we find within specific medical cultures is a diverse range of medical subcultures. These subcultures, it might be contended, operate on largely different principles, which might be said to preclude a unified theory of indigenous medicine. However, a look at some basic facts certainly contradicts this generalized picture generated by Last, and which is common in medical anthropologies. Much like biomedicine, indigenous/alternative medicine is constituted by various schools of specialization. From the more well-known systems of chiropractic, acupuncture, osteopathy and psychotherapy,\textsuperscript{279} to the well-developed systems of midwifery, herbalism, bone-setting, naturopathy, and massage therapy, to name a few, there exists a coherent body of theory regarding how each of these systems are to be practiced. Although not all of these schools of practice have “formalized agreements around standards of care”, most of the more developed,

\textsuperscript{279} Osteopathy and psychotherapy are included here because these therapies were once described as ‘alternative’ or ‘unconventional’. Regulation and integration have drastically changed the labeling of these systems from the so-called ‘fringe medicine’ to ‘mainstream medicine’: see chapter three, \textit{supra}, for a discussion of the progression of osteopathy from alternative to conventional medicine.
and some of the less-developed, schools have established practice guidelines, which as Cohen has observed, “could serve as the basis for standards of care in malpractice actions”.\textsuperscript{280}

For example, the American Association of Naturopathic Physicians has established guidelines for general naturopathic practice.\textsuperscript{281} The guidelines address such issues as the naturopath’s obligation to “keep up with changes in professional practice, to make appropriate referrals, to conform with the professional code of ethics, to take thorough histories, to maintain clear records, and to perform appropriate physical and mental examinations”.\textsuperscript{282} The association’s professional guidelines also outline criteria “for making diagnoses using conventional and other diagnostic methods (such as those of Ayurvedic and Oriental medicine)”.\textsuperscript{283}

Granted the existence of these standard guidelines, individual practitioners of indigenous medicine may generally vary methods or procedures in the administration of their medicines or services to suit the specific conditions of individual patients. Should the individualized nature of the procedures prevent the denotation of a particular indigenous medical practice as a profession? As long as there is a common broad theory of practice and there are general standards of practice, the answer must be given in the negative. The specific theoretical differences between schools or branches of indigenous medicine or the internal differences in the administration of the therapies in each school should not preclude the definition of indigenous medical practices as professions or systems. The variability in administrative procedures is itself the very nature of the paradigm of the indigenous medical system, which through the ages has pulled millions of patients to this system of medicine.

\textit{i. Professional Associations of Indigenous Medical Providers}

There are professional associations of indigenous healthcare practitioners, as well as association rules which define the practitioners as a coherent group of professionals. For example, Nigeria boasts of the Nigerian Traditional Medical Association, a National College of Alternative Medicine, the Nigerian Academy of Natural Medicine, a Council of Physicians of Natural Medicine, as well as a Traditional Medicine Board in many states of the federation. There are

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\textsuperscript{280} Cohen, \textit{Legal Boundaries and Regulatory Perspectives}, \textit{supra} note 16 at 65. \\
\textsuperscript{281} \textit{Ibid.} \\
\textsuperscript{282} \textit{Ibid.} \\
\textsuperscript{283} \textit{Ibid.}
\end{flushleft}
also the Nigerian Homeopathic Medical Association, the Nigerian Naturopathic Medical Association, the Nigerian Society of Medical Acupuncturist, the National Centre for Genetic Research and Biotechnology, as well as an association of professionals who conduct scientific identification, conservation, and utilization of medicinal plants in Nigeria. While the members of the professional associations may have personalized modes of practice, yet they share similar standards of what the professions expect of their practitioners. Contrary to Last’s contentions, the existence of these associations suggests a level of synchronization in the therapeutic approaches to medical treatment, as well as in the medical and professional goals, of each organization.

Critics have often argued that indigenous medicine is more or less experimental in nature. This critique implies that indigenous medicine has no well-developed or well-formed body of knowledge practiced by members of the indigenous healthcare professions. A US court dicta in the case of Andrews v. Ballard, addresses this supposition. In Andrews, the court examined the rules established by the Texas Board of Medical Examiners, which restricted the practice of acupuncture to biomedical practitioners. The rules assume acupuncture to be an “experimental procedure, the safety [and effectiveness] of which have not been established”. According to the court, “acupuncture has been practiced for 2000 to 5000 years. It is no more experimental as a mode of medical treatment than is the Chinese language as a mode of communication. What is experimental is not acupuncture, but Westerners’ understanding of it and their ability to utilize it properly”.

ii. Professionalism and Education within Indigenous Medical Systems

Indigenous medical practitioners constitute a well-defined group of professionally trained persons whose years of training equips them to practice this specialized form of medicine. Among the various professional groups of practitioners identifiable in different societies are well-trained experts in the different areas of medical practice. Much like the case of biomedicine, non-experts and quacks can also be identified among these groups. Although there are now formal institutions of training in many parts of the world, early forms of training

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285 Texas State Board of Medical Examiners Rule 386.01.12-001(c).
286 *Andrews, supra* note 284 at 1053.
involved long years of apprenticeship with an established practitioner. The period of training spanned from between seven to fourteen years.\textsuperscript{287} As Chavunduka reports, “medical certificates and badges” are now used to identify the specific expertise and training of a practitioner.\textsuperscript{288}

With specific reference to African pluralistic medicine, Baronov affirms that:

\begin{quote}
Whatever its levels of proven efficacy, it is evident that to practice African pluralistic medicine, a prospective PMP [pluralistic medical practitioner] must undergo a process of specialized study and training that introduces him or her to an established body of knowledge and techniques…This widespread reliance on training and apprenticeship to prepare PMPS underscores the significant empirical-rational content of African pluralistic medicine. In a similar fashion, the lay public’s distinctions between PMPS follow from explicit empirical-rational premises.\textsuperscript{289}
\end{quote}

Practitioners differ in terms of skill and ability, and patients take a keen interest in a practitioner’s level of skill before consultation.\textsuperscript{290} In fact, “individuals must experience, and the general public must see evidence of, a [pluralistic medical practitioner’s] efficacy”.\textsuperscript{291} There are informal rating systems, which “discriminate” between the well-qualified and less-qualified practitioners.\textsuperscript{292} As noted above, there is also a tradition of referral and consultation between practitioners based on the symmetry (on a general level) of their knowledge, practices and skills. All of this suggests that there is a logical and systematized body of knowledge governed by uniform and rational “rules of application and practice”.\textsuperscript{293}

Some schools of practice have pedagogic materials on their theory of practice. Aside from the well-known indigenous professions that have well-established educational institutions, there are other colleges and institutions for the training of integrated medical practitioners in different countries. For example, the United States boasts of several such institutes including the Arizona Centre for Integrative Medicine and the Harvard Medical School Osher Research Center for research and education in complementary and integrative medical therapies. In Nigeria, the Federal Ministry of Health has approved the establishment of a college for research and

\textsuperscript{288} G.L. Chavunduka, Traditional Healers and the Shona Patient (Gwelo: Mambo Press, 1978) at 83.
\textsuperscript{289} Baronov, supra note 2 at 151.
\textsuperscript{290} Ibid.
\textsuperscript{291} Ibid at 152.
\textsuperscript{292} Ibid at 149-150.
\textsuperscript{293} Ibid.
education in integrated medicine. Additionally, Osun State University in Nigeria is about to introduce a degree programme in integrated medicine. These educational institutions offer what may be described as an ‘interconnected’ theory of practice within which we can identify common philosophies. In other words, regardless of the conceptual differences that may exist between the individual practices, there can be identified within the practices a unified belief system and interlinking medical philosophies.

It is important to note that the individualized and personalized nature of indigenous medical practice—which constitute reasons for Last’s skepticism—are themselves part of the defining features of integrated medicine. While this personalized care makes the applicable standards of care more fluid, there appears to be no reason why a member of another school within the same profession cannot testify as to whether the defendant’s choice of method, though a variant of the more general methods employed in the profession, falls below the appropriate standards expected of practitioners. In fact, the individualized nature of indigenous medical practice and the consumer faith in its holistic theory of disease by all accounts is the major attraction in this medical system, and this issue forms the second arm of Last’s criteria of a medical system.

B. Patient/Consumer Recognition of the Effectiveness of the Theory

It has been recognized that the primary patrons and advocates of indigenous medicine are patients and consumers who are convinced that the holistic system of care offered by indigenous medicine is effective for their medical conditions and general health. For many patients and consumers, indigenous practitioners work within defined theories, even though these theories are applied in a personalized and individualized manner. The impressive statistical data on consumer patronage of indigenous medicine in both North America and the global South is evidence that indigenous medical systems meet Last’s latter criteria regarding consumer/patient recognition of the logic and effectiveness of the theory. Needless to state, it is basic knowledge that belief in the efficacy and logic of a therapy often translates into patronage.

II. Applying the Above Evidence in the Context of the Same School Rule

Where the court finds—based on the available evidence on a given method of practice—that there is a system rather than a non-system, then it would apply the accepted standards within
that system in the determination of the practitioner’s liability. It would be necessary for the court to look out for general standards of practice whether or not the administration of the therapy is personalized. As noted above, where the court finds incongruent practices without a common interconnecting theory and concludes that there is no ‘profession’ in existence, then it must have recourse to the biomedical standard of care which applies the ‘same school rule’. In this situation, a physician who practices in the same school as the defendant practitioner would testify as to the required standard in biomedical practice. In the case of an IMP, the practitioner would be held to the standards of the biomedical profession. However, the ‘same school rule’ is not absolute.

6.4.1.3. Exceptions to the Same School Rule
There are three exceptions to the same school rule. These exceptions, which are evident from the case law, are as follows:

(1) Where a complementary/alternative practitioner strays outside the scope of permissible practice;

(2) Where there is “overlap” between standards at issue between schools of practice;

(3) Where the alleged malpractice relates to diagnosis as opposed to treatment. 294

I. The Scope of Practice Exception
This exception operates when indigenous or alternative practitioners administer therapies that are not within their scope of competence. 295 Ontario’s Regulated Health Professions Act, 1991 (RHPA), 296 has a harm clause which seeks to prevent both non-health and health professionals from operating outside the boundaries of their respective professions and from treating or rendering healthcare advice when it is foreseeable that serious harm may result. 297 Section 30(1) of the RHPA provides as follows:

294 Crouch et al., supra note 241 at 97.
295 Iyioha, Deregulation, supra note 218.
296 Regulated Health Professions Act of Ontario, supra note 59.
297 Iyioha, Deregulation, supra note 218.
No person, other than a member treating or advising within the scope of practice of his or her profession, shall treat or advise a person with respect to his or her health in circumstances in which it is reasonably foreseeable that serious physical harm may result from the treatment or advice or from an omission from them.298

This clause implicitly sets the rule that persons administering therapies or practicing a system or method of treatment which is “outside their scope of competence or school of practice will be held accountable to the standards of that school”.299 Such professionals are also more likely to be held liable for negligent practice.300

II. The Overlap Exception
This second exception is operative where there is a convergence of standards between different professions, for example, where a chiropractor employs a biomedical procedure in the course of treatment. According to this exception, where a healthcare provider of one professional school practices a system of medicine that is also traceable to other professional groups, “an expert from a different school than that of the practitioner accused of malpractice can testify as to the appropriate standard of care”.301 In this situation, the testimony of the physician on the relevant standard of care will be the acceptable standard.302 This exception is known as the “overlap” exception.

The overlap exception originates from US case law in Rosenberg v. Cahill.303 In this case, a chiropractor was indicted for failing to see the patient’s tumours on an x-ray. He misdiagnosed the patient’s condition and prescribed manipulation therapy. His argument at trial was that a physician could not give testimony on the standard of care required of chiropractors. The court noted the overlap of two systems or schools of medical practice based on the chiropractor’s use of an x-ray in diagnosis, and held that the facts of the case would allow a deviation from the same school rule.

298 Section 30(1), Regulated Health Professions Act, supra note 59.
299 Iyioha, Deregulation, supra note 218.
300 See Crouch et al., supra note 241 at 97. See also Iyioha, Deregulation, ibid.
301 Crouch et al., ibid at 97.
302 Feasby, supra note 1.
III. The Diagnosis Exception

This exception can be identified as “the Canadian exception” to the same school rule. This is because Canadian law draws a distinction between the standard of care in treatment and the standard of care in diagnosis. The exception is as between “preliminary involvement (diagnosis) and treatment”. The principle is that where the negligent act is in the area of diagnosis and not the treatment itself, the court will be inclined to apply the standards of the profession that practices the method of diagnosis employed by the practitioner, and in this regard, the Canadian court usually upholds the biomedical standard of diagnosis as the accepted standard. The Alberta Supreme Court case of Gibbons v. Harris endorses this principle. According to the court:

Upon this question there is obvious distinction between diagnosis and treatment. Diagnosis is the process of discovering what is actually in real truth the exact physical nature of the trouble. Upon this question there cannot be any question of different schools of opinion.

In Gibbons, the defendant chiropractor argued that he did exercise reasonable skill and care in the treatment procedure, and that the treatment accorded with the methods of his school. He also contended that experts from other professional schools could not be admitted as witnesses to testify that this treatment was unacceptable.

The court rejected this argument and held that the general rule (i.e. the same school rule), which prevents medical practitioners from assessing a chiropractor’s standards of care applies only where the practitioner’s diagnosis is correct. According to the court, there could be no question of different schools of opinion on the question whether the diagnosis of a certain practitioner was correct. The court held that where there is an incorrect diagnosis “through culpable lack of skill and care”, it is difficult to see how the defendant can still say that his treatment was reasonably skillful and careful”. The Ontario Court of Justice followed this decision in the 1996 case of Barber v. Wilson. In both the Gibbons and Barber cases, the

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304 Iyioha, Deregulation, supra note 218.
305 Gibbons v. Harris, supra note 263.
306 Iyioha, Deregulation, supra note 218.
307 Gibbons v. Harris, supra note 263.
308 Ibid at 925.
309 Ibid.
310 Ibid at 928.
311 Barber v. Wilson, supra note 258.
courts held that Canadian physicians could provide evidence of the applicable standard where the accuracy of diagnosis is contested.\textsuperscript{312} Thus, it is likely that the courts would question the method and standard of treatment where an incorrect diagnosis is made.\textsuperscript{313}

However, the Manitoba Court of Appeal case of \textit{Penner v. Theobald}\textsuperscript{314} provides a different perspective to this exception. In that case, it was found that the chiropractor did not use reasonable care and skill in diagnosis. On appeal, though the court rejected the contention of the defendant that “no diagnosis was necessary”, it did allow the argument that the form of diagnosis peculiar to the profession was sufficient.\textsuperscript{315} In considering the applicable standard in the case of diagnosis, the court stated that:

\begin{quote}
It should be noted that types of diagnoses may vary with types of health care; the types of diagnoses are naturally founded on the basic principles of each particular system. For that reason diagnosis by a medical doctor or an osteopath or a chiropractor may differ in some respects; but of the necessity for some type of diagnosis, or as the chiropractors prefer to call it, analysis, I do not think there is any doubt. The only question to be considered in the instant case is whether or not the diagnosis or analysis carried out by the defendant in regard to the plaintiff was sufficient by chiropractic standards.\textsuperscript{316}
\end{quote}

Essentially, the court recognized the “existence of different diagnostic systems in different health care paradigms”.\textsuperscript{317} The court’s decision guarantees that the question whether the diagnostic method employed by the practitioner satisfied the diagnostic standard of care required by the practitioner’s school of practice can be considered as a separate enquiry from the standard of care in treatment.

According to the court:

\begin{quote}
What is important is whether or not the diagnostician succeeds in ascertaining the source and nature of the illness or injury from which the patient suffers. In doing so, a practitioner naturally and properly follows the methods characteristic of the school of health care of which he is a member; therefore, it is by the methods and practices which characterize his school that he must be judged in determining whether or not he was negligent in his diagnosis.\textsuperscript{318}
\end{quote}

\textsuperscript{312} \textit{Ibid.}
\textsuperscript{313} See generally, Feasby, \textit{supra} note 1.
\textsuperscript{314} \textit{Penner v. Theobald, supra} note 265.
\textsuperscript{315} \textit{Ibid.}
\textsuperscript{316} \textit{Ibid.}
\textsuperscript{317} Iyioha, \textit{Deregulation, supra} note 218.
\textsuperscript{318} \textit{Penner v. Theobald, supra} note 265.
Elsewhere, I have argued that the decision in *Penner* evinces “a more functional application of the law of negligence” to indigenous medical practice; this legal position, which is reminiscent of the approach adopted by the US court in *Rosenberg v. Cahill*, is more “accommodating of the reality of the growth” and development of indigenous medical therapies.  

Crouch et al. have noted that the decision in *Penner* is also “more respectful of differing schools of thought.” In recognizing that systems of medical practice “do not merely differ at the stage of treatment, but in some cases operate within entirely different paradigms and understandings of illness, with unavoidable implications for diagnosis,” the court effectively “charts a path for further judicial interpretation of tort law to suit the peculiar nature” of indigenous medical practice.

While this argument remains persuasive, the fact that the court’s decision in *Penner* is “incompatible” with the decisions in *Gibbons* and *Barber* might imply that the diagnosis exception to the same school rule is the tenable rule under Canadian law. This implies that the Canadian court is willing to accept “divergent forms of treatment” as long as the patient is aware of his or her condition through a physician’s diagnosis “and, presumably of the possible treatments available from the orthodox medical community.” It can be argued that this judicial attitude places the scientific or medical model of diagnosis “in a paternal fashion, atop the hierarchy of approaches to the analysis of health.” However, Feasby suggests that this legal position protects the interests of patients since “diagnosis determines treatment”. In the author’s view:

> If a diagnosis is affected by the ideological views of the health care provider, the right to informed consent is rendered meaningless. In this respect, the courts’ attempt to standardize diagnosis around the medical model, admittedly in an arbitrary and conservative fashion, can be seen as a way of protecting patients.

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319 Iyioha, *Deregulation*, supra note 218.
320 Crouch et al., *supra* note 241 at 99.
321 Ibid.
322 Iyioha, *Deregulation*, supra note 218.
323 See Feasby, *supra* note 1 where the author raises doubt regarding whether the diagnosis/treatment distinction is viable under Canadian law.
324 Ibid.
325 Ibid.
326 Ibid.
327 Ibid.
Although Feasby’s views are credible, the argument can be turned on its head; in other words, this same argument can produce an equally negative result for patients. For example, if a patient’s medical condition could be more effectively diagnosed through another healthcare paradigm and the diagnosis is affected by the law’s insistence on a particular model of diagnosis, then the informed consent principle is as well rendered meaningless. Perhaps, the more pragmatic approach is not to rule out the propensity of any one diagnostic method to produce adverse results for a patient. Indeed, there are countless cases where a patient’s medical condition is not diagnosable through biomedical methods. As is further elaborated below, Canadian and Nigerian IMPs and integrated health physicians have confirmed this occurrence.

While identifying the implications of an ideologically-influenced diagnosis on informed consent, Feasby observes that “judicial endorsement” of conventional medical standards of care over alternative standards is “unfair in an increasingly pluralistic society permeated by postmodern values”, although it is one that is now firmly entrenched in “legislation governing health professions and in the allocation of state resources to fund conventional medicine and medical research”.328 Indeed, it should also be highlighted that the Canadian exception to the same school rule effectively reveals the hierarchical lenses through which positive law views the relationship between biomedical and indigenous forms of treatment. However, to go beyond the rhetoric of unfairness and disparity in the law’s treatment of indigenous and biomedical diagnostic methods, the more crucial issue is how the law can ensure that both approaches are brought to the knowledge of the patient – not simply to protect the right to informed consent, but also to reduce the incidence of harm. Thus, while a strong case could be made for the diagnosis exception in the interest of patient safety, an even stronger case can be made for reform of the exception in the interest of patient safety, patient autonomy and medical diversity. Therefore, while the diagnosis–treatment distinction may be beneficial to the principle of informed consent, a case can be made for a more nuanced standard of care in the area of diagnosis.

This study recommends that a new standard of care could involve a mandatory duty of disclosure owed by practitioners to patients requiring practitioners to inform patients of the likelihood of divergent diagnoses between the different health approaches. Practitioners would

328 Ibid.
also be required to inform patients of their right to seek a second diagnostic opinion before treatment could commence. Practitioners who lack appropriate tools for diagnosis should also be held to a duty to refer the patient to the appropriate practitioner, expert, or diagnostician. Beyond protecting patients’ right to material information and assisting them in making informed decisions, such a duty would also ensure that the occurrence of wrong diagnosis is reduced.

This proposal is also relevant in the integrated health clinic where different healthcare professionals may collaborate in the care of patients. In the context of the integrated health clinic, this new standard would guarantee that practitioners disclose all necessary information to the patient where there are divergent opinions on the nature of, or treatment for, the patient’s medical condition. An investigation of the practices among some Canadian and Nigerian IMPs and integrated health physicians (IHPs) reveals that the practitioners would be amenable to such a modified standard of care.\(^{329}\) In other words, the current practices of the clinics and centres surveyed showed a flexible, broad-based approach to diagnosis. The law can assist in promoting this approach through the modified standard of diagnosis outlined above.

IV. Diagnosis and Treatment in the Integrated Health Centre (IHC): Perspectives from IMPs and Integrated Health Physicians (IHPs)

Information on the processes of diagnosis and treatment within integrated health centres (IHCs) may provide indices to determine, on the one hand, whether the practice among some IMPs and IHPs accords with the diagnosis exception, and on the other hand, to ascertain the viability of the new standard of care described above in the context of current practices in different IHCs. Interviews were conducted in Nigeria and Canada to determine the practice within different integrated healthcare centres or clinics. The interviews were conducted in eight integrated healthcare clinics, four in Vancouver and Toronto and four in Edo State, Nigeria. As already outlined, the interviews conducted in Nigeria where the author was assisted by researchers were structured while those in Canada were semi-structured. Collectively, three questions were asked – the first two in Nigeria and the third in Canada:

1. How do you diagnose a medical condition? E.g., through laboratory tests, physical examination, consultations with the client, esoteric means, etc? Please identify all that apply.

2. Do you work in collaboration with other conventional or indigenous medical practitioners when you treat your patients? If yes, who diagnoses and who treats?

3. In the areas of diagnosis and treatment, how are responsibilities shared between the practitioners?
   - Who conducts patient examination – physicians or CAM practitioners or a team?
   - Who makes the decision about diagnosis/treatment?
   - Is diagnosis conducted through biomedical/conventional means or through alternative paradigms?330

The answers provided by the practitioners reveal a number of important points. The first is that the practitioners do not seem to face any major difficulty in the choice of a method of diagnosis; the choice of a method is usually based on objective considerations such as the availability of the appropriate diagnostic tools and the nature of the patient’s medical condition. In the latter case, the practitioner inquires whether the patient’s medical condition is one that can be properly diagnosed through the diagnostic methods of the practitioner’s professional school. A second point is that the apportionment of responsibility as regards diagnosis and treatment is not based on an insular view of the superiority of one medical culture over another, but simply on the utility and strengths of one method over another given the nature of the specific medical case. Thus, while diagnosis through biomedical methods was the appropriate approach in a given medical situation, diagnosis through a specific indigenous medical paradigm was the better approach in another situation.

A. Interviews in Canada

Four Canadian Integrated Health Practitioners (IHPs) were interviewed across Toronto and Vancouver. The centres in which the interviews were conducted are: the Integrative Health Institute and Medcan Clinic in Toronto and Inspire Health Integrated Cancer Care Centre and Qi Integrated Health Centre in Vancouver. All the centres are staffed with licensed alternative healthcare practitioners and physicians. The number of practitioners from each professional group varied between the centres. There were more physicians and fewer alternative healthcare providers in two of the centres, and in the other two, the case was the reverse. However, at the

330 Ibid.
time of the interview in November 2009, the *Qi Integrated Health Centre* had only one physician who practices as a naturopath in the clinic. The director noted that a healthcare provider who would practice in the capacity of a physician was to join the clinic in July 2011.\textsuperscript{331}

In Vancouver, a Co-Founder of the *Inspire Health Integrated Cancer Care Centre* and the Clinical Director of the *Qi Integrated Health Centre* were interviewed on a broad range of issues, including the above three questions on modes of diagnosis and treatment in the integrated health centre. In the interviews conducted in Toronto, a similar set of questions was put to a Co-Director of the *Integrative Health Institute* and an Associate Medical Director of the *Medcan Clinic*.

In all the interviews, the practitioners observed that diagnosis often depends on the nature of the medical condition. Thus, there was no unidirectional adherence to the biomedical diagnostic method as the Canadian exception to the same-school rule requires. Rather, there was a convergence of opinion on the incorporation of multiple methods of diagnosis within the diagnostic and therapeutic regimen of the IHP. According to Hal Gunn, MD, the Clinical Director of *Inspire Health Integrated Health Centre*:

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\text{… We honour the value of Western diagnostic methods because they are very good for the illness part of treatment; but we also honour our intuitions and all of the other things that are important in the broader diagnosis of healing and health. So, we are very open to that broader spectrum of possibilities when it comes to diagnosis.}
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Dr. Gunn observes that in the specific case of cancer, patients obtain a biomedical diagnosis of their condition before arrival at the Centre. However, he notes that the Centre is open to a broad definition of diagnosis as would be expected in the expanded healing tradition represented by integrated medicine. According to the practitioner:

\[
\text{…One of our important roles is to help explore and uncover any of the barriers to healing; and if you broaden the definition of diagnosis to include those barriers, I believe an important part of the broader healing traditions is to understand what…factors are involved in a particular individual’s journey and to help to understand how to shift those factors towards you.}
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\textsuperscript{331} *Ibid.*
On whether he would welcome diagnosis [from other practitioners within the Centre] based on taxonomies that are not identifiable within biomedicine, he replied:

Yes, from a mind, body and spirit perspective, absolutely. This kind of diagnosis in its broadest terms happens everyday and all the time in our relationships with patients. I believe that our intuitions as practitioners, and connecting to that, are the most valuable diagnostic tools we have.

Dr. Erin Wiley, ND, of the Integrative Health Institute in Toronto shares a similar perspective on the utility of different diagnostic paradigms in integrated medical practice. First, Wiley identifies the similarities between the diagnostic methods employed within different medical systems. She observes that Naturopaths and general practitioners share similar diagnostic and therapeutic methods. According to Wiley:

The education we received at the Naturopathic Medical College…was basically based on the same curriculum as traditional medical schools here in Ontario. … The same physical exams, the same stethoscope…those same tools are all equal. Same with lab tests… So, Naturopathic medicine is very similar to that of the general practitioner….

However, she notes that the chosen diagnostic method is usually linked to the nature of the patient’s condition:

But we do learn about when to refer a patient for certain types of tests…x-rays, CT Scans… We are trained to identify or…diagnose…concerns through full physical examinations. Other practitioners such as Chiropractors, their focus is more on the musculoskeletal system …

While highlighting differences in the diagnostic techniques employed by various schools of indigenous health practitioners, Wiley identifies the use of the stethoscope as one biomedical device often employed by practitioners who integrate biomedical techniques into the diagnostic process:

Depending on the scope and why the client is accessing them, their methods of diagnosis are different. With massage therapy, it is basically physical diagnosis; their mode of treatment is through manipulation of muscles and tissues. … They…use the stethoscope in school when somebody comes in with chest and lung pain and they think it is a musculoskeletal issue to rule out that nothing is going on with the lungs; they do want to listen to the lungs but just as a precautionary method. …
Next, Wiley notes that where there are signs of a future medical problem based on the lifestyle of the patient, the integrated medical practitioner can make a health promotion diagnosis to prevent the occurrence of the condition:

In addition to our Western diagnosis, we may also make a traditional Chinese medicine diagnosis. … So, we may have multiple views on diagnosis, or we make a Naturopathic medical diagnosis, let’s say a diagnosis of adrenal fatigue…on top of anemia. … The physician won’t make a traditional Chinese medicine diagnosis or a health promotion diagnosis such as adrenal fatigue. The patient may not meet the criteria for a full blown hypothyroidism on their lab result but we feel they are walking a path towards that, so we will want to make an intervention to prevent them from going full blown.

The health promotion diagnosis which may be simply termed ‘preventive diagnosis’ constitutes one of the primary strengths of integrated medicine. Len Saputo describes this integral approach to healthcare as ‘functional medicine’, observing that this approach to healthcare is not routinely practiced within the biomedical healthcare system because “the disease care model has little interest in addressing and dealing with wellness and prevention”.  

It is important to note that this functional approach does not lose the focus on relevant biomedical approaches to investigating a patient’s medical condition.

Wiley confirms that regardless of the systemic label attached to a given diagnosis, there were many cases where the diagnosis obtained through an alternative paradigm was the same as that obtained through the biomedical method. According to the practitioner, “[i]t’s a different name, or a different way of looking at the same thing”. Considering the current tradition in which the choice of diagnostic method is governed by the patient’s medical condition as well as by the importance the IHPs place on holistic diagnosis, it can be rightly concluded that a modified standard of disclosure and diagnosis requiring a practitioner to advise a patient to seek a second opinion (where the IHC lacks the appropriate tools to make a correct diagnosis), while referring the patient to an appropriate centre or specialist, can easily be implemented within the IHC.

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333 Iyioha, International Research, supra note 49.
B. Interviews in Nigeria

The practitioners interviewed in Nigeria expressed similar views to those expressed by their Canadian counterparts. They affirmed that IMPs employ multiple diagnostic methods, and stated that the choice of method was often determined by the needs of a particular patient, as well as the availability of the appropriate tools for diagnosis.\textsuperscript{334} The practitioners generally acknowledged the strengths of the biomedical approach to diagnosis. The Clinical Director of the Pax Herbal Clinic and Laboratories, Fr. Anselm Adodo, emphasized the importance of laboratory tests:

\begin{quote}
We emphasize…laboratory tests. [T]he orthodox clinical diagnostic method is still the most reliable way. … There are cases where from the physical appearance you will know what a patient has (sic)… you can begin with that, pending when you can prescribe more detailed analysis.
\end{quote}

The Director further expressed sentiments on the issue of diagnostic methods similar to that inherent in the Canadian exception to the same school rule. In his opinion:

\begin{quote}
The doctors are specialists in diagnosis; that’s where the difference is. Without diagnosis, you [prescribe] the wrong treatment.
\end{quote}

Other practitioners also hinted at the relevance of laboratory tests while noting that the lack of infrastructure in the rural neighbourhoods impeded access to such tests. According to Ehinoma Aiguobarueghian, “a medical condition is diagnosed through physical examinations and consultations with the clients. Laboratory tests are rare in the villages because of constant lack of electricity”.\textsuperscript{335} However, the practitioner further observed that the emerging relationship between IMPs and physicians had eased the difficulties faced by IMPs in the area of diagnosis. According to the practitioner:

\begin{quote}
… [t]here is a growing relationship between us [IMPs] and the conventional medical practitioners. We consult ourselves when there are specific problems. Most of the time, they carry out the diagnoses and…depending on the type of illness, any one of us treats.
\end{quote}

\textsuperscript{334} Ibid.
\textsuperscript{335} Ibid.
Another practitioner, Musa Ebohon, reiterated the use of “physical examination and consultation with patients” as the primary diagnostic method. He further noted that while medical laboratories are crucial to correct diagnosis, “a medical lab is not [always] available” in the IHC because of the huge medical expenses attendant to this method of diagnosis. However, the practitioner noted that the problem was often resolved through a collaborative relationship with the biomedically-trained practitioners. While observing that there is sometimes a shared task of diagnosis and treatment between both practitioners, which is often dependent on the nature of the patient’s medical condition, the IMP clearly noted that “from time to time”, the physicians gave the IMPs “reports” on the nature of the medical treatment required by the patient.

The collaborative relationship described by these IMPs clearly evinces one of the ideals inherent in an integrated approach to healthcare delivery. This approach to medical practice prioritizes patient safety and eschews parochial concerns about maintaining philosophical boundaries between medical systems. Simply stated, at the centre of this approach to medical practice is the goal of optimal healthcare delivery. While a system of regulation framed around the Canadian exception to the same school rule may introduce unnecessary rigidity into medical practice and limit the ability of IMPs to make ‘preventive diagnosis’ or such other useful diagnoses peculiar to the indigenous medical paradigm, it does seem obvious that these Nigerian IMPs will be amenable to a modified standard of disclosure and diagnosis. This new standard, as noted above, would require the IMPs to treat only on the basis of a diagnosis obtained through the best method appropriate to the patient’s medical condition and to inform the patient, where necessary, of the possibility of divergent views on diagnosis and of the mandate to seek a second opinion before treatment commences.

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336 Ibid, interview conducted with Musa Ebohon, a Nigerian IMP.
337 A dissenting view to this approach may be that it might increase costs for patients, especially considering the argument that integrated healthcare is aimed at lowering costs. The counter argument is that a collaborative approach to diagnosis and treatment can be designed to prevent increased patient fee. See section 6.6 infra on integration at the ‘Healthcare Clinic Level’ for interview results on how such a collaborative system between two major healthcare centres – a teaching hospital and an IHC – operates in Nigeria without necessarily increasing costs for the patient.
6.4.1.4. Provincial/State Medical Practice Laws and Professional Discipline

Another legal issue arising from medical integration is implicit in the restrictive rules of practice set by state medical disciplinary boards. Beyond incurring liability in tort for medical negligence, dual practitioners of indigenous medicine and biomedicine may also face professional disciplinary procedures under state medical practice laws for deviating from the biomedical standard of care. While biomedical physicians seem to have an unlimited scope of practice under state medical practice laws, their departure from biomedical standards to provide alternative care “creates the risk of medical board discipline for ‘unprofessional conduct’”.

For example in North Carolina, before the amendment of the relevant law, the mere “departure from, or failure to conform to, the standards of acceptable and prevailing medical practice…irrespective of whether or not a patient is injured thereby” constituted unprofessional conduct. The phrase “acceptable and prevailing medical practice” implies that physicians who practice integrated medicine are exposing themselves to “legislatively authorized sanction” for adopting a therapy outside conventional biomedicine.

Similarly, in Florida, “any departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice in…[the physician’s] area of expertise as determined by the [state medical board], in which proceeding actual injury to a patient need not be established” constitutes an unprofessional conduct. The cases that have come before US state medical boards arise “not because of demonstrated injury to patients or even complaints by patients”, as Cohen observes, “but because the treatments challenged medical boards’ views of safety or effectiveness within the practice of medicine”. Furthermore, Cohen notes that “to the extent that such treatments divert patients from conventional biomedical practices, including surgery, they pose an economic challenge to biomedicine”.

One such case is Rogers v. State Board of Medical Examiners, where a physician who practiced chelation therapy sought judicial review of the Florida state medical board’s decision placing him on probation for one year. It is noteworthy that the board did not make any finding

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338 Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 87.
340 Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 87.
342 Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 88.
343 Ibid.
344 Rogers v. State Board of Medical Examiners, 371So. 2d at 1037.
of harm to patients. The physician had also clearly informed patients of the medical community’s negative opinion about the therapy and that the said therapy was yet to be proven effective. Furthermore, the physician’s patients were willing to testify about the benefits they had derived from using the physician’s therapy. Based on the absence of harm, coercion or misrepresentation, the court held that the board could not encroach on patients’ right to a given therapy “simply because that mode of treatment has not received the endorsement of a majority of the medical profession.” 345 The court further stated:

We can only wonder what would have been the condition of the world today and the field of medicine in particular had those in the midstream of their profession been permitted to prohibit continued treatment and thereby impede progress in those and other fields of science and the healing arts.…

Orthodoxy in medicine is like orthodoxy in any other professional field. It starts as a theory or tentative belief in some particular course of action…Right or wrong, a dissenting view is regarded as a criminal subversion of the truth and the holder is often exposed to slander and abuse by his orthodox colleagues…It was the dead hand of orthodoxy that delayed the advance of knowledge through the Middle Ages. Even today, these same oppressive forces may shackle the advancement of medicine…It is only on the edges of the stream of medicine in which advancement can take place. 346

On appeal, the appellate court upheld the decision of the lower court on the ground that the Board’s action was both arbitrary and unconstitutional under Florida’s due process clause.

In Gonzalez v. New York State Department of Health, 347 the physician was indicted for negligence and incompetence by the Office of Professional Medical Conduct (OPMC) for treating his patients with advanced and terminal cancer with nutritional therapy. Although his patients had voluntarily chosen this therapy after trying or rejecting conventional medicine, the court held that physicians are expected to abide by the prevailing standards of medical care regardless of the existence of patient consent.

In another case, Re Guess, 348 a biomedical practitioner who practiced homeopathic medicine in circumstances where biomedicine failed to help his patients was indicted for professional misconduct. The North Carolina Board of Medical Examiners alleged that the

345 Ibid at 1041.
346 Ibid at 1041-1042.
348 Re Guess, 393 S.E.2d at 833 [‘Guess’].
The court reversed the board’s decision holding that a proper ground for revoking the physician’s licence would be if the physician’s conduct causes harm to the public. The court held that “conduct that is merely different from that of other practitioners” did not suffice. However, on further appeal, the North Carolina Supreme Court held that the relevant legislation did not require the establishment of harm in order to find a physician liable for misconduct in the circumstances stipulated by the legislation. It is noteworthy that the court also found that the Board did not infringe patients’ right to choose and consent to therapies of their choice.

Today, the North Carolina statute has been reformed. The new medical disciplinary legislation, which is one of several statutes enacted to incorporate the harm principle as a criterion for liability, was introduced as a response to Re Guess. The law now provides that “the Board shall not revoke the license of or deny a license to a person solely because of that person’s practice of a therapy that is experimental, non-traditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that treatment is generally not effective”. It is noteworthy that the statute requires proof that the therapy resulted in harm. The state medical board bears the burden of proving the requirements of a safety risk and lack of efficacy. It should also be noted that the North Carolina harm

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349 N.C. Gen. Stat., supra note 337; Guess, ibid at 835.
350 Re Guess, ibid.
352 Ibid.
353 See Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 94.
clause specifically requires that the treatment must have posed a *greater* risk than the *prevailing* treatment. It is remarkable that the law uses the term ‘prevailing’ and not ‘conventional’ or ‘biomedical’. The ‘prevailing treatment’ at any given time may be biomedical or indigenous. This term accommodates a future in which specific indigenous therapies would be regarded and accepted by the biomedical community as the standard therapy for a given condition.

Some other US states that have amended their medical disciplinary statutes include Oregon, Alaska, New York, Oklahoma, and Washington. These amended laws are known as ‘State Medical Freedom Acts’. The Oregon statute provides that “the use of an alternative medical treatment shall not by itself constitute unprofessional conduct”. 354 According to the law, an “alternative medical treatment” is one which the “treating physician, based on the physician’s professional experience, has an objective basis to believe has a reasonable probability for effectiveness in its intended use even if the treatment is outside recognized scientific guidelines, is unproven, is no longer used as a generally recognized or standard treatment or lacks the approval of the United States Food and Drug Administration…”. 355 However, the therapy must be “supported for specific usages or outcomes by at least one other physician licensed by the Board of Medical Examiners”. 356 In addition, the therapy must not pose a “greater risk to a patient than the generally recognized or standard treatment”. 357 By its design, this liberal provision can protect physicians practicing within indigenous medical systems from liability while broadening the scope of available medical options for patients. It can also encourage the growth and development of indigenous medical systems.

According to Alaska’s legislation, the medical board “may not base a finding of professional incompetence solely on the basis that a licensee’s practice is unconventional or experimental in the absence of demonstrably physical harm to a patient”. 358 As explained above, this framing of the law arguably creates a differential standard for a finding of malpractice as between biomedicine and alternative medical systems. The New York law protects from liability physicians who choose to use “whatever medical care, conventional or non-conventional” that “effectively treats human disease, pain, injury, deformity, or physical

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356 *Ibid*.
357 *Ibid*.
358 Alaska Stat. S. 08.64.326.
condition”.\(^{359}\) It is significant that the state has established a medical disciplinary board which would have at least two physicians “who dedicate a significant portion of their practice to the use of non-conventional medical treatments”.\(^{360}\) This clearly advances integration at the decision-making level. Cohen suggests that the New York statute “broadens the scope of medicine”.\(^{361}\) According to Cohen, the law –

[p]otentially affects…other aspects of health care and health care regulation such as insurance reimbursement, medical education, and hospital staffing and disciplinary policies. For example, although insurers denying reimbursement claims for complementary and alternative medicine may claim that such treatments are “medically unnecessary” simply because they are not generally accepted by the biomedical community, the statute in fact redefines medicine to include such therapies.\(^{362}\)

Without expressly mentioning the requirement of harm, the Oklahoma legislation provides that the medical board “shall not revoke the license of a person otherwise qualified to practice allopathic medicine within the meaning of this act solely because the person’s practice or a therapy is experimental or nontraditional”.\(^{363}\) In Washington, “the use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed”.\(^{364}\)

In Canada, there have also been statutory reforms to prevent the automatic finding of liability where a physician administers an indigenous or experimental treatment. While the Canadian statutes are not as liberal as some of the US statutes, there is at least some attempt – through the improved version of the problematic harm principle – to limit the liability of physicians who practice integrated medicine.\(^{365}\) For example, both the *Medicine Act of Ontario, 1991*\(^ {366}\) and the Alberta *Medical Profession Amendment Act, 1996*\(^ {367}\) require a finding that the therapy adopted by the physician poses a greater risk of harm than the traditional therapy for the

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\(^{359}\) N.Y. Educ. Law S. 6527(4)(e).


\(^{361}\) Cohen, *Legal Boundaries and Regulatory Perspectives*, supra note 16 at 95.

\(^{362}\) *Ibid.*


\(^{365}\) See sub-section 6.3.1 above where the Canadian provisions and how they may be further amended in the interpretation process are discussed.


medical condition. In *Ravikovich v. College of Physicians and Surgeons of Ontario*, the Disciplinary Committee of the College of Physicians and Surgeons of Ontario endorsed the harm principle even though it found the physician guilty of professional misconduct based on his alleged administration of non-scientific therapies.

The Disciplinary Committee’s limiting assessment of the therapies utilized by Dr. Ravikovich through Western scientific standards is clearly at odds with Oregon’s amended medical disciplinary statute which permits physicians to administer alternative treatments that may not fall within the Western conception of scientific validity. It will be recalled that the Oregon statute defines an ‘alternative medical treatment’ as one which –

…the treating physician, based on the physician’s professional experience, has an objective basis to believe has a reasonable probability for effectiveness in its intended use even if the treatment is outside recognized scientific guidelines, is unproven, is no longer used as a generally recognized or standard treatment or lacks the approval of the United States Food and Drug Administration…

Another Canadian statute that has amended its rules regarding the practice of indigenous or alternative medicine by healthcare professionals is the British Columbia *Health Professions Act, 1996*. Under the title ‘alternative medicine’, section 25.4 provides that:

[T]he college must not act against a registrant or an applicant for registration solely on the basis that the person practises a therapy that departs from prevailing medical practice unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice.

It is noteworthy that ‘the college’ in the above provision includes the British Columbia College of Chiropractors, the College of Dental Surgeons of British Columbia, the College of Surgeons and Physicians of British Columbia, the College of Pharmacists of British Columbia, as well as to any other college “continued under” section 15(1) of the Act. Given that the definition of ‘college’ in the Act is inclusive of the College of Chiropractors, it is evident that ‘prevailing medical practice’ as used in the Act includes both indigenous or alternative medical standards

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368 *Ravikovich*, supra note 249.
372 Section 15.1, *ibid.*
and biomedical practice. This is quite a significant amendment and certainly serves as a step towards levelling the practice fields between the medical professions. These and other amended US statutes, which require more than the mere occurrence of harm to establish liability, are progressive steps towards broadening the concept of medicine and healthcare to reflect the evolution in consumer healthcare behaviour.

6.4.1.5. Defences to Professional Liability

A number of defences are available to both integrated healthcare providers and practitioners of indigenous medicine. Generally, these defences include the Respectable Minority, Clinical Innovation, Assumption of Risk and Informed Consent defences.\(^{373}\)

1. Respectable Minority Defence (or the Two Schools of Thought Doctrine)

The respectable minority defence (also known as the two schools of thought doctrine) may be invoked in defence of a healthcare provider where there are members of the professional community who also practice the given therapy or mode of treatment adopted by the practitioner. According to the two schools of thought doctrine, a medical practitioner who administers a therapeutic procedure or treatment which a respectable minority within the profession would administer under related circumstances is not liable for malpractice.\(^{374}\) This implies that physicians may adopt other alternative approaches to diagnosis and treatment, provided that the chosen approach is accepted by a respectable school of thought, even though that school of thought is a minority school within the medical community.\(^{375}\) However, it is not clear what constitutes a ‘respectable minority’. In Oregon, for example, a chosen therapy must be “supported for specific usages or outcomes by at least one other physician licensed by the Board of Medical Examiners”.\(^{376}\)

In the determination of what constitutes ‘a respectable minority’ in the US, two tests are applicable: (1) the treatment should be supported by a considerable number of physicians, or (2) the treatment would have been adopted by a reasonable and prudent physician under the same

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\(^{373}\) For a fuller discussion of these four defences, see Cohen, *Legal Boundaries and Regulatory Perspectives*, supra note 16 at 58-60.

\(^{374}\) *Hood v. Phillips*, 554 S.W.2d 160. See also Cohen, *Legal Boundaries and Regulatory Perspectives*, *ibid* at 58 [“Hood v. Phillips”].

\(^{375}\) *Ibid*.

or similar circumstances.\textsuperscript{377} In \textit{Jones v. Chidester},\textsuperscript{378} the Pennsylvania Supreme Court was of the opinion that the test for liability under the “two schools of thought doctrine” would depend on whether the physician “followed a course of treatment advocated by a considerable number of recognized and respected professionals”.\textsuperscript{379} The court’s reasoning reflects an attempt to combine the “quantitative and qualitative standards”\textsuperscript{380} of the respectable minority test generally applied. In \textit{Hood v. Phillips},\textsuperscript{381} the Texas Supreme Court held that the standard to be applied “whether the mode or form of treatment is experimental, outmoded or rejected” is that a “physician who undertakes a mode or form of treatment which a reasonable and prudent member of the medical profession would undertake under the same or similar circumstances shall not be subject to liability for harm caused thereby to the patient”\textsuperscript{382}.

Whether the determination of what constitutes ‘respectable minority’ will be made with reference to qualitative or quantitative standards is a decision that may vary from state to state or from province to province. Regardless of the standard employed, it appears quite likely that in the case of indigenous medicines, the court will look to whether the therapy has some, if not all, of the qualities that define a system of medicine. For example, is the therapy practiced by a clearly identifiable group of indigenous medical providers who advocate the logic of the theory? Are there some members of the biomedical profession who consider the theory valid? Are there practice guidelines that define the standards of care within that system?

\textit{II. Clinical Innovation Defence}

The defence of clinical innovation protects physicians who employ innovative medical techniques in critical medical conditions.\textsuperscript{383} However, it is not clear that this defence offers much protection to physicians practicing in the area of indigenous and integrated medicine.\textsuperscript{384} This is because the defence is available only to physicians who have not breached ethical rules such as the requirement for institutional review board approval for experimental or research-

\begin{footnotes}
\footnotescaption{S.S. Sanbar, \textit{Legal Medicine} (Philadelphia: Mosby/Elsevier, 2007) at 110 [‘Sanbar’].
\footnotetext{377}{Sanbar, supra note 377 at 110.}
\footnotetext{378}{\textit{Jones v. Chidester}, 610 A.2d 964. Pa., 1992.}
\footnotetext{379}{\textit{Ibid.}}
\footnotetext{380}{Sanbar, supra note 377 at 110.}
\footnotetext{381}{\textit{Hood v. Phillips}, supra note 374.}
\footnotetext{382}{\textit{Ibid.}}
\footnotetext{383}{Cohen, \textit{Legal Boundaries and Regulatory Perspectives}, supra note 16 at 58.}
\footnotetext{384}{\textit{Ibid.}}
\end{footnotes}
based medical procedures. Furthermore, an experimental procedure has to be conducted according to the standards of the profession. The clinical innovation defence would not be available to the practitioner if he or she performed the operation or administered the treatment negligently. The facts of *Colton v. New York Hospital* present an interesting illustration of this point.

In *Colton*, the plaintiffs sued the defendant hospital and its physicians for a botched experimental kidney transplant in which one brother donated his kidney to another. While the recipient brother, Dudley, died after the operation from complications arising from an ailing liver, the donor, Donne, went into shock, accompanied by acute renal failure and life-threatening infections. He also became deaf from the antibiotics the physician had administered to him. Before the operation, the brothers had supposedly waived their rights to sue the physician and the hospital by signing a detailed form to that effect. The physician and the hospital contended that they were “absolved from any and all liability, damages, lawsuits, and causes of action arising out of or in connection with” the operations on the brothers.

The court held that while an agreement not to sue over an experimental procedure was enforceable, it could bar an action against a defendant only where the defendant physicians conducted the operation in a “proper” and “non-negligent” manner. It is important to note that the court was of the view that an experimental procedure, is “ordinarily…in and of itself a departure from customary and accepted practice (and thus possibly actionable as malpractice)”. This implies that under the right conditions – that is where the researcher or experimenter has not been negligent and has obeyed all applicable rules, including ethical research standards – the law can approve an experimental treatment or procedure that is ordinarily outside approved medical standards. Under this rule, it is hoped that the courts will extend the protection of the law to medical developments within the area of indigenous medicine and to clinical innovations commonly termed ‘complementary and alternative medicine’ in North America.

In view of the increasing popularity and importance of these forms of medicine to population health, it can be expected that medical-legal doctrines, such as the clinical

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innovation defence, may evolve to recognize developments within indigenous and integrated medicine. An indication of such legal evolution may be found in *Gemme v. Goldberg*[^388] where the physician neglected to inform the patient that corrective surgery was not mandatory because there was an option of a more comprehensive treatment plan. The court upheld the patient’s claim of lack of informed consent, while noting that the jury could have found that the physician was in breach of the duty to obtain informed consent “by failing to disclose a viable alternative that might have produced a less perfect result but may have represented a safer or less invasive procedure”.[^389] Therefore, as these treatments and procedures increasingly become recognized therapies for given medical conditions, practitioners who ignore safe and effective indigenous therapies and rely exclusively on biomedical care might be accountable for medical malpractice – for providing healthcare below the evolved standard of care.[^390]

### III. Assumption of Risk Defence

The assumption of risk defence is available to a physician where an informed patient has given consent to assume the risks attendant to a given medical procedure. The patient’s consent relieves the physician of liability for a treatment or medical procedure and its known risks.[^391] Usually, the patient opts for the treatment with full knowledge of the risks involved.[^392] Thus this defence is associated with the informed consent principle because the validity of the defence is based on the physician’s disclosure of the relevant risks and benefits of the procedure to the patient.[^393] The assumption of risk doctrine may constitute a shield against malpractice for practitioners who have employed indigenous therapies after consulting with the patient.[^394] The decisions in *Schneider v. Revici*, *Boyle v. Revici*, *Charell v. Gonzalez* and *Shorter v. Drury*[^395] illustrate the workings of this principle.

[^389]: Ibid.
[^390]: Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 59.
[^392]: Ibid.
[^393]: Ibid.
[^394]: Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 64.
In *Schneider v. Revici*, the plaintiff opted to forgo conventional cancer therapy in favour of the defendant’s alternative treatment. The patient signed a consent form absolving the physician of liability and accepting knowledge of the possibility that the therapy might fail. Although the defendant attempted to treat the patient with his “non-invasive” and “non-toxic” therapy, he also recommended surgery. Eventually, the patient underwent a bilateral mastectomy and a long period of chemotherapy. She sued the physician for malpractice, fraud and lack of informed consent. The court of first instance held that while Revici was not liable for malpractice, he was 50 percent negligent in the circumstances. However, the US Court of Appeals for the Second Circuit held that the patient’s decision to forgo conventional therapy in favour of an alternative procedure constituted an express assumption of risk, which is an absolute defence to malpractice. This defence should have completely negated the physician’s liability. The appellate court remanded the case for retrial, noting that the lower court should have instructed the jury to consider the express assumption of risk defence. The court further observed that:

> We see no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment. While a patient should be encouraged to exercise care for his own safety, we believe that an informed decision to avoid surgery and conventional chemotherapy is within the patient’s right to ‘determine what shall be done with his own body’.  

Similarly, in *Shorter v. Jury*, the court held that the assumption of risk doctrine creates a defence to malpractice liability. In this case, a Jehovah witness signed an agreement absolving the hospital from liability based on her rejection of blood transfusion. While noting that the agreement did not protect the physician from liability arising from his own negligence, the court upheld the patient’s right to assume the risks arising from her rejection of blood transfusion. In another case, *Charrell v. Gonzalez*, the New York Supreme Court upheld the jury’s finding that the patient had implicitly accepted the risk of injury when she opted to undergo the alternative therapy. Based on this finding, the jury allocated 51% of the blame to the physician and 49% of the patient. The court held that “even though [the physician] had not given appropriate

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396 *Schneider v. Revici*, ibid at 995 citing *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (1914) [‘*Schloendorff*’].

397 *Charrell v. Gonzales*, supra note 395.
information regarding the risks of his procedure, “it was within the province of the jury”, based upon available evidence that the patient had independently obtained adequate information “to conclude that there was an implied assumption of risk.”\textsuperscript{398} The court reached a similar decision in \textit{Boyle v. Revici} where the US Court of Appeals for the Second Circuit held that while the plaintiff had not signed a consent form, the jury could still consider the assumption of risk defence. The court noted that patients can make an informed decision to “expressly assume the risk of malpractice and dissolve the physician’s duty to treat a patient according to the medical community’s accepted standards”.\textsuperscript{399}

However, it must be noted that this defence does not protect the physician who practices a therapy that is outside his or her scope of practice.\textsuperscript{400} The law generally requires that only professionals trained in particular medical procedures can perform those procedures.\textsuperscript{401} It is part of the physician’s duty of disclosure to inform the patient of the limits of his or her medical expertise. This disclosure is material to patients’ informed decision-making.\textsuperscript{402} The appropriate course of action is for the physician to refer the patient to a qualified professional or specialist.\textsuperscript{403} In line with this generally accepted legal position, the ethical norms imposed by the court in the practice of chiropractic require that chiropractors have a duty of reasonable care:

1. to determine whether the patient presents a problem treatable through chiropractic;
2. to refrain from further chiropractic treatment when a reasonable chiropractor should be aware that the patient’s condition will not be responsive to further treatment; and
3. if the problem is outside the chiropractor’s skill, training and expertise, to inform the patient that the condition is not treatable through chiropractic.\textsuperscript{404}

Similarly, Quebec’s Code of Ethics for Physicians provides that “in practicing his profession, a physician must take into account the extent of his capacities and knowledge as well as their

\textsuperscript{398} \textit{Ibid} at 233.
\textsuperscript{399} \textit{Boyle v. Revici}, \textit{supra} note 395 at 1063.
\textsuperscript{400} Iyioha, “Informed Choice”, \textit{supra} note 252 at 25.
\textsuperscript{401} See, for example, Ontario’s \textit{Regulated Health Professions Act}, \textit{supra} note 59 which prohibits non-health professionals and health professionals acting outside their scope of practice from treating or advising people about their health when it can be foreseen that serious harm may occur. Based on this provision, an integrated healthcare practitioner who administers a therapy outside his or her area of competence can be held liable for malpractice: Iyioha, “Informed Choice”, \textit{supra} note 252 at 25.
\textsuperscript{402} \textit{Ibid}.
\textsuperscript{403} \textit{Ibid} at 26.
\textsuperscript{404} \textit{Kerman v. Hintz}, 418 N.W.2d 795, 802-3 (Wis. 1988).
limits and the means at his disposal; whenever necessary, he should enter into consultation or refer his patient elsewhere”. 405

Where a physician exceeds the appropriate scope of practice, “there is a strong possibility” that he or she would be treated as a specialist in the given area of practice. 406 In such a case, the applicable standard of care is that which applies to the professional school of the specialist. Therefore, the optimal decision for a physician is to refer the patient to the appropriate specialist who can best administer the indigenous or alternative treatment that the patient seeks. 407

IV. Informed Consent

The doctrine of informed consent serves as both a defence against physician liability and as a protective mechanism for the patient. The doctrine upholds an individual’s “right to determine what will be done with his or her own body”, and “protects the patient’s bodily integrity by requiring the physician to disclose all information pertinent to the patient’s decision to submit to a particular medical procedure”. 408 A physician who ensures that the patient is provided with all necessary information related to the patient’s medical condition and the proffered treatment is protected from liability. Thus, the doctrine operates in favour of the physician as a defence against liability because the patient voluntarily submits to the procedure based on knowledge of all the benefits and risks attendant to the procedure.

The doctrine of informed consent also constitutes an instrument for healthcare reform in the area of integrated medical practice. Specifically, it can be employed to influence the type of healthcare delivered to consumers. The next subsection – the healthcare consumer level – examines how the doctrine can contribute to pushing integrated healthcare from the fringe to the core of the healthcare system.

405 R.R.Q., 1981, c. M-9, r.4, art. 2.03.16.
408 Schloendorff, supra note 396.
6.5. The Healthcare Consumer Level: Informed Consent and Other Imperatives

Respect for patient autonomy is the foundation of the concept of informed consent. The doctrine requires healthcare practitioners to obtain the consent of their patients based on full disclosure of all information relevant to specific diagnostic or therapeutic procedures before they can carry out such procedures.\(^{409}\) Hence, a key implication of the doctrine is that patients should have sufficient information necessary to make proper decisions.\(^{410}\) The doctrine of informed consent requires physicians “to disclose and ensure that patients (or authorized surrogates) comprehend all information material to the patient’s decision to undergo or reject a specific medical procedure”.\(^{411}\) The legal requirements embodied in the principle are designed to protect patients against “non-consensual” medical interference with their bodies.\(^{412}\)

The modern law on informed consent in Canada derives from United States’ jurisprudence, which was formulated in the judgement of Cardozo J. in the case of Schloendorff v. Society of New York Hospital.\(^{413}\) The most modern framing of the law in Canada has its root in the Canadian Supreme Court cases of Hopp v. Lepp,\(^{414}\) and Reibl v. Hughes,\(^{415}\) where the court redefined liability arising from failure to inform before consent as negligence rather than assault. This ‘redefinition’ applies to situations where the risks or alternatives to the procedure are not outlined.\(^{416}\) The court also recognized that in the determination of what information is material to satisfy the informed consent obligation, the expectations of the patient are determinative.\(^{417}\)

Before considering what information is ‘material’, it is pertinent to note that the law of informed consent has its root in biomedical practice.\(^{418}\) Therefore, though the general law on informed consent as developed in case law and indicated in some Acts, such as the Ontario


\(^{411}\) Cohen, Beyond Complementary Medicine, supra note 79 at 37.

\(^{412}\) Ibid.


\(^{416}\) Note that assault remains the cause of action where the nature of the procedure is misunderstood.


\(^{418}\) See generally Cohen, Beyond Complementary Medicine, supra note 79 at 37-45.
Health Care Consent Act,\textsuperscript{419} and the Nigerian National Health Act,\textsuperscript{420} stipulates that the patient is entitled to be informed about alternative approaches to prescribed medical treatments, it remains unclear whether indigenous medicine falls within the class of ‘alternatives’ required by law.\textsuperscript{421} Rather, what is apparent from the case law and statutes is that the class of ‘alternative therapies’ that are legally acceptable fall within ‘conventional or biomedical alternative therapies’.\textsuperscript{422}

6.5.1. What Constitutes Material Information?

It is settled law that the doctrine of informed consent is not to be treated as a matter of procedure, but must involve substantive discussions of all information material to the patient’s decision whether or not to undergo a particular medical procedure. According to Picard and Robertson:

\begin{quote}
It is now well established that the duty of disclosure is not confined to risks, but extends to other material information which a reasonable patient would want to have. In particular, the patient must be informed of any available alternatives to the treatment being proposed, as well as the material risks associated with those alternatives.\textsuperscript{423}
\end{quote}

In Reibl v. Hughes, the Canadian Supreme Court stated that the nature of information to be disclosed to the patient must be “material, special, or unusual risk”.\textsuperscript{424} The decision of the court effectively made the reasonable person in the plaintiff’s position the determiner of what constitutes material information. Earlier in Hopp v. Lepp, the court had already rejected the opinions of medical professionals regarding what is material as the determinative standard. According to Justice Laskin:

\begin{quote}
…[S]ince a particular patient is involved upon whom surgery is to be performed or particular therapy administered, and it is a duty of disclosure to him that affects the validity of his consent, evidence of medical experts of custom or general practice as to the scope of disclosure cannot be decisive, but at most a factor to be considered.\textsuperscript{425}
\end{quote}

\begin{flushright}
\textsuperscript{419} Health Care Consent Act, S.O.1996, c. 2.
\textsuperscript{420} Section 23, National Health Act, 2008, supra note 12.
\textsuperscript{421} Iyioha, “Informed Choice”, supra note 252 at 9.
\textsuperscript{422} Ibid.
\textsuperscript{423} E. Picard and G.B. Robertson, Legal Liability of Doctors and Hospitals in Canada (Toronto: Carswell, 1996) at 129-130.
\textsuperscript{424} Reibl v. Hughes, supra note 415.
\textsuperscript{425} Ibid. Emphasis supplied.
\end{flushright}
Thus, while the Canadian Supreme Court did not reject the medical professional standard of disclosure in totality, it clearly highlighted the close connection between the patient’s opinions regarding what is material and the underlying objectives of the informed consent obligation itself, which is to protect the patient’s autonomy as well as his or her bodily integrity. In the context of indigenous and other new and experimental treatments, the court’s retention of the medical professional standard of materiality alongside the more dominant standard of the reasonable or prudent patient can help provide patients with a balanced perspective of what a particular procedure involves. In other words, a patient who is keen on knowing about and trying out a new procedure may benefit from the physician’s knowledge and opinion of the risks and benefits of the procedure.\(^{426}\)

Irrespective of whether the standard of disclosure is that of the medical profession or the patient, the court in *Fergusson v. Hamilton Civic Hospital*\(^{427}\) has noted that in determining whether the duty to inform has been met, the court will need to know whether the patient has been informed of the importance of the treatment, the known risks and side-effects of the treatment, the limits of relevant knowledge, alternative goals of treatment and reasonably accessible alternative means of pursuing those goals.\(^{428}\) Under section 11(3) of the Ontario *Health Care Consent Act, 1996*,\(^{429}\) the items for which information should be provided include:

(i) the nature of the proposed treatment;

(ii) the expected benefits of the proposed treatment;

(iii) the material risks and side-effects of the proposed treatment;

(iv) *alternative courses of action*;

(v) the likely consequences of not having the proposed treatment; and

(vi) the answers to any questions the patient has regarding the proposed treatment.\(^{430}\)

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\(^{426}\) See Iyioha, “Informed Choice”, *supra* note 252 at 14 (footnote 27).


\(^{428}\) *Ibid.*

\(^{429}\) *Health Care Consent Act, supra* note 419.

The question turns on what constitutes “alternative courses of action” as stipulated in paragraph (iv) above. Fundamentally, the question is whether ‘alternative courses of action’ can be interpreted to include therapies that are non-biomedical. Evidently, the legal and medical jurisprudence in this area indicate “the primacy of conventional or biomedical alternative treatment”.431

Section 23(1) of Nigeria’s National Health Act432 provides that:

(1) Every health care provider shall give a user relevant information pertaining to his state of health and necessary treatment relating thereto including:-

(a) the user’s health status except in circumstances where there is substantial evidence that the disclosure of the user’s health status would be contrary to the best interests of the user;

(b) the range of diagnostic procedures and treatment options generally available to the user;

(c) the benefits, risks, costs and consequences generally associated with each option; and

(d) the user’s right to refuse health services and explain the implications, risks, obligations of such refusal.433

It is not clear whether “the range of diagnostic procedures and treatment options generally available” as indicated in paragraph (b) include indigenous Nigerian medicine. However, it can be inferred from the similarities between Nigerian and British law on the issue that the operative standard is that of the medical profession. It is noteworthy that English courts have expressly rejected the doctrine of informed consent as a “transatlantic doctrine”434 “liable to import all of the horrors of American malpractice litigation”.435 The Nigerian National Health Act provides no indication that indigenous alternatives are part of the requirement of section 23(1)(b). What is more obvious is that the Act incorporates a biomedical conception of the law of informed consent, in which the interpretation of “the range of diagnostic procedures”, “treatment options”, or ‘alternatives’ often tilts towards what the biomedical community believes to be the standard treatment.

432 Section 23(1), National Health Act, 2008, supra note 12.
433 Ibid. Emphasis added.
435 Dickens, supra note 413 at 129.
Generally, the opinion of the Canadian and US courts appears to be that the patient need not be informed of just any available alternative. This was the decision in the Alberta case of *Santos v. Traff*, where the court stated that there is “no duty to advise of fringe or dangerous alternatives”. According to the court:

> Common sense suggests that failure to advise of alternatives might be applied most successfully against a doctor who uses the fringe alternative, or one not generally accepted by the medical profession as within the standard of care, and fails to inform of the medically mainstream alternative.

Similarly, in *Moore v. Baker*, the court inquired whether the alternative treatment preferred by the patient was accepted by the medical community. *Moore v. Baker* involved a malpractice claim which arose from the physician’s failure to disclose the existence of chelation therapy as a possibly safe and effective alternative to a carotid endarterectomy. The patient had a blockage in her carotid artery, which impeded the flow of oxygen to her brain. A blood clot developed after surgery. Although the physician reopened the wound, the clot had irreversibly damaged the plaintiff’s brain.

The plaintiff sued for malpractice, relying on the relevant Georgia statute that required physicians, prior to a surgical operation, to inform patients of the risks and alternatives generally recognized and accepted by reasonably prudent physicians. In determining whether the physician incurred any liability under the Georgia statute based on his non-disclosure of chelation therapy, the court examined the evidence on the acceptance of chelation therapy by members of the medical community, and held that the plaintiff had not shown that reasonably prudent physicians recognized and accepted chelation therapy as a viable alternative to a carotid endarterectomy.

The decisions in *Santos* and *Moore* both suggest that the acceptance of an alternative treatment plan is based on its recognition by the medical community as a viable therapy, which according to the *Santos* case, is a treatment “generally accepted by the medical profession as

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*Santos v. Traff* (1999) ABQB 630 [‘*Santos v. Traff*”].


Emphasis mine.
within the standard of care.” This decision differs from the opinion of the Canadian Supreme Court in *Hopp v. Lepp*, where the court reasoned that “since a particular patient is involved upon whom particular therapy is to be administered, and it is a duty of disclosure to him that affects the validity of his consent, *evidence of medical experts of custom or general practice as to the scope of disclosure cannot be decisive*.” Although the Supreme Court was not considering the specific case of alternative therapies, nevertheless the “patient-oriented approach” espoused by the court disallows “the imposition of a rigid standard of materiality that is wholly dependent on the opinions of the medical profession”.

In *Seney v. Crooks*, an Alberta court was unwilling to read into the physician’s obligation to disclose alternative options an extended duty to disclose non-standard or “fringe” alternatives. The question before the court in *Seney* was the extent of the physician’s duty to inform his patient of alternative therapies in order to empower the patient to reach an informed decision. The physician argued against the overextension of the duty on the reasoning that to overextend the duty to inform of alternative therapies would be to place an “unpredictable and monumental” responsibility upon the medical profession. He rested his contentions on the questions whether (1) “it would be necessary to inform of every possible alternative available, whether or not generally considered reliable by the profession, (2) each professional need to become knowledgeable on, and inform patients of, alternative medicine practices such as chiropractic treatment or holistic medicine treatments, and (3) if the treatment performed complies with the local standard, why should it be negligence to fail to inform of another”.

While it is arguable that the third question contradicts the informed consent obligation because the doctrine imposes on the physician the duty to disclose all relevant alternative medical options to the patient, what appears to be indubitable is that the alternative options to be disclosed must be supported by evidence of safety and efficacy. Apparently, the courts have not held physicians to an unequivocal duty to disclose the risks and benefits of alternative

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441 *Santos v. Traff*, supra note 436.
442 *Hopp v. Lepp*, supra note 414.
445 Ibid at paras. 57-58.
therapies as part of the obligation of informed consent. Physicians’ refusal to disclose untested and unproven therapies is based on the lack of scientific evidence to validate such therapies. Furthermore, physicians may be wary that liability may arise from disclosing therapies with unproven efficacy or undefined risks.

Against this background and in the light of the Canadian Supreme Court’s decision in Hopp v. Lepp which negates a wholesale adoption of the biomedical standard of disclosure, it is necessary to examine whether and how indigenous medical alternatives can be read into a physician’s obligation to disclose viable medical alternatives. The next subsection considers some statutes and case law that support an expansion of the physician’s duty to disclose alternative therapies to embrace a broader duty to disclose alternative options outside biomedicine.

6.5.2. Expanding the Rule

The expansion of the informed consent doctrine to cover therapies traditionally outside biomedicine can have important implications for medical practice. The extension of the traditional boundaries of the doctrine can be implemented by both the courts in the course of legal interpretation and by consumers who exercise their right to be informed of viable alternatives. Where physicians are obligated to meet patients’ demands for information about indigenous therapies, the informed consent obligation can serve as a bridge to integrated care. Thus, an expansion of the informed consent principle to accommodate integrated healthcare can create a reformed principle whereby informed consent moves away from “doctrinal rigidity and toward its ideal of dialogue”. While no court has yet recognized the existence of a duty to disclose the risks and benefits of indigenous therapies as part of the informed consent obligation, some statutes and emerging case law appear to favour the incorporation of indigenous medical alternatives into the doctrine.

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447 Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 44-45. See also Iyioha, “Informed Choice”, supra note 252 at 17.
448 Cohen, Beyond Complementary and Alternative Medicine, ibid at 38.
449 Ibid at 37.
450 Ibid at 39.
451 Ibid at 41.
452 Ibid at 44-45.
For example, section 11(2) of the Ontario *Health Care Consent Act* provides as follows:

(2) A consent to treatment is informed if, before giving it,

(a) the person received the information about the matters set out in subsection (3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and

(b) the person received responses to his or her requests for additional information about those matters.\(^{453}\)

The matters set out under subsection 11(3) include (i) the nature of the treatment, (ii) the expected benefits of the treatment, (iii) the material risks and side-effects of the treatment, (iv) alternative courses of action, (v) the likely consequences of not having the treatment, and (vi) the answers to any questions the patient may have about the treatment.\(^{454}\) As earlier noted, paragraph 11(3)(iv) above does not provide any information regarding the categories of ‘alternative courses of action’ acceptable in law. The medical profession’s Disciplinary Committee, as well as the courts, has often reached the conclusion that the alternative courses of action stipulated in section 11(3) do not involve scientifically unproven diagnostic and therapeutic practices.\(^{455}\) It is now clear from the law that the chosen therapy must have some evidence of efficacy and safety.

There are statutory indications of the type of alternative courses of action that could be subsumed under section 11(3) of the Ontario *Health Care Consent Act*. For example, it will be recalled that section 5.1 of the *Medicine Act of Ontario, 1991*\(^ {456}\) provides that “[a] member shall not be found guilty of professional misconduct or of incompetence … solely on the basis that the member practices a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient's health than the traditional or prevailing practice.”\(^ {457}\) Clearly, section 5.1 of the Act permits physicians to adopt non-biomedical therapies provided the therapy does not pose greater risk to the patient’s health. Notably, the 1996 *Medical Profession Amendment Act* of

\(^{453}\) *Health Care Consent Act, supra* note 419.

\(^{454}\) *Ibid.*

\(^{455}\) Iyioha, “Informed Choice”, *supra* note 252 at 18.

\(^{456}\) *Medicine Act, supra* note 14.

Alberta limited the ability of the Alberta College of Physicians and Doctors to control the provision of alternative services by its members. The provision of section 34(3) of the Act is similar to section 5.1 of the Medicine Act of Ontario.

Section 11(2)(a) and (b) of the Ontario Health Care Consent Act provides further opportunity for an expansive interpretation of ‘alternative courses of action’. Sub-section (2)(a) outlines the required standard of disclosure as what a reasonable person in the same circumstances as the patient would require in order to make a decision about the treatment. Where a patient in exercise of his or her rights under the sub-section requests information about legitimate non-biomedical alternative treatments, there appears to be no legal or ethical ground under which a physician (who under the circumstances is expected to be acquainted with such information) can deny the patient of the recognized alternatives. Based on the texts of section 11(2)(a) and (b) and on the preceding arguments regarding what could legitimately be subsumed under ‘alternative courses of action’, a physician has an obligation to inform of non-biomedical alternative therapies where a patient inquires about them, or can otherwise be taken to be interested in information about such therapies. However, the information requested by the patient must be within the physician’s area of expertise. Furthermore, medical and legal ethics require that the physician’s disclosure be accompanied by details of the risks involved in the alternative therapy, including (where appropriate) the fact that the therapy may have no established scientific validity.

Where the patient does not request information about alternative courses of action, section 11(2)(a) requires the physician to provide information regarding the matters outlined under subsection (3) that a reasonable person in the patient’s circumstances would need to know. This provides an avenue for the physician to consider whether to disclose information about an indigenous therapy known to be effective for the patients’ condition. The physician is expected to weigh the circumstances of the case in determining whether the given therapy was one which ought to have been brought to the knowledge of the patient. Thus, if by its nature the ‘alternative’ therapy is such that a reasonable person in the same circumstance as the patient

458 Medical Profession Amendment Act, supra note 236.
460 Ibid.
461 See ibid at 18.
462 Ibid.
463 Ibid at 19.
would need to be informed about in order to make a decision about the treatment, and if the therapy is one, which – by virtue of its acceptance by the majority or a reasonable minority of the medical community – a physician is expected to be informed about, then the physician should be required to make such disclosure.

This approach could push the rigid boundaries of the informed consent rule towards greater acceptance of integrated medicine. The argument for a disclosure of the expanding range of available treatments and procedures whether biomedical, indigenous or simply experimental, is founded on the deep respect of the law for patient autonomy and the right to bodily integrity. Informed consent – the principle that patients have the right to all information material to their medical decision making is premised on the law’s predilection towards protecting both patient autonomy and bodily integrity. The patient’s entitlements to these rights can be further guaranteed through the extension of the principle of informed consent to other non-conservative medical means of achieving the same goals. As one commentator has noted, “this right arguably transcends majoritarian medical views of certain therapies and should include the right to receive information about non-conventional therapies that are not fully accepted, yet are supported by a material and credible body of evidence”.

The US cases of Schneider v. Revici, Boyle v. Revici, Gemme v. Goldberg and Charrel v. Gonzalez support this extended interpretation of informed consent. In Schneider, Boyle, and Gonzalez, the courts found that the patients could exercise their rights to reject biomedically-approved methods in favour of unconventional therapies. However, such decision must be supported with adequate information about the risks and benefits of the procedure. In Gemme v. Goldberg where the physician did not inform the patient that corrective surgery was optional and that there was an alternative treatment plan, the court upheld the patient’s claim of lack of informed consent, stating that the jury could have

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464 Ibid.
466 Cohen, Beyond Complementary Medicine, supra note 79 at 38.
468 Cohen, Beyond Complementary Medicine, supra note 79 at 38.
469 Schneider v. Revici, supra note 396; the court also cited Schloendorff, supra note 396; Boyle v. Revici, supra note 395; Gemme v. Goldberg, supra note 388; Charrell v. Gonzalez, supra note 395.
470 See ibid. See Schneider v. Revici, ibid at 995.
471 Boyle v. Revici, supra note 395 at 1063.
determined that the physician was in violation of his duty under the informed consent rule by his failure “to disclose a viable alternative that might have produced a less perfect result but may have represented a safer or less invasive procedure”. 472

An expanded informed consent obligation could be instrumental to ridding medical practice of paternalism, which “defines, adjudicates, and resolves legal dilemmas by adopting the opinions of biomedical experts, remote insurance adjusters, judges, and other parties” – opinions that are based on purportedly objective criteria such as certain levels of acceptance, forms of documentation, and judgments about medical necessity. 473

As the law continuously struggles to balance patient safety and patient autonomy, 474 an expanded interpretation of informed consent, which ensures patients are provided with information about the available choices and their risks and benefits – regardless of whether those choices are allopathic or indigenous – can reconcile patient safety and patient autonomy in medical matters. In this process, practitioners – especially dual or integrated healthcare practitioners can avoid legal liability by staying informed about the existing evidence on the safety and efficacy of various indigenous therapies. 475

6.6. Healthcare Clinic Level

Medical integration at the level of the healthcare clinic involves practitioners of the different medical paradigms collaborating, where necessary, to achieve the best health outcomes for patients. In this setting, the favoured therapy is that which offers the best care to the patient whether the therapy is conventional or indigenous. 476 Medical practice in the integrated healthcare clinic is directed at providing the best treatment or combination of treatments that work best for the patient rather than at emphasizing philosophical differences between medical systems. While practitioners may work collaboratively as a team in the integrated health clinic, they may also work independently as specialists. In either case, they may refer patients to one another.

472 Gemme v. Goldberg, supra note 388 at 326.
473 Cohen, Legal Boundaries and Regulatory Perspectives, supra note 16 at 115.
475 Crouch, et al., supra note 241 at 176.
As is the case with other levels of the healthcare system, legal rules are implicated in this evolving clinical relationship between biomedical and indigenous medical providers. A key legal issue is the duty to refer. The legal duty to refer requires a healthcare provider to recommend a patient to the appropriate specialist where the patient’s medical needs are beyond the professional skills of the provider. The requirement ensures that medical professionals do not exceed professional practice boundaries. It is noteworthy that the legal rules governing referral between medical practitioners developed within the biomedical system. The legal duty to refer itself is designed to encourage referrals between allopathic healthcare providers. As such, these rules have not been favourable to integrated healthcare delivery and have impeded patients’ access to indigenous treatments.  

However, a collaborative relationship between the practitioners of the different medical cultures achieved in part through referrals could be a progressive step towards a system of integrated healthcare. Referral between medical systems would also be in the best interest of patient safety.

According to the standard legal position, while a physician may not incur liability for referring a patient to a specialist or another healthcare practitioner, liability may arise in the following instances: (1) “[I]f the decision to refer itself reflects a lack of due care and results in patient injury” (direct liability); (2) “liability attaches under a theory of vicarious liability if the treating practitioner is viewed as an agent of the referring physician” – in this case, “the practitioner’s negligence can be imputed to the referring physician”; (3) “the courts will impose joint and several liability on the referring physician and treating practitioner on the theory that the two providers, although acting independently, have inflicted an indivisible injury on the patient”; (4) “the court will regard the physician’s duty as one of continuing care and responsibility, which is not extinguished by referral to the complementary and alternative medicine provider but requires ongoing supervision and oversight”.

Summarily, medical referrals between providers attract one of four liability types. The providers may share direct, vicarious, joint and several, or continuing liability for medical errors depending on their working relationship and on the interpretation of this relationship by the court. The operation of each of these liability types is examined within the context of indigenous medical care.

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477 Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 47.
478 Ibid at 47-48.
6.6.1. Direct Liability

Direct liability could arise where the patient’s medical condition is not treatable through the indigenous or alternative therapy to which the physician has referred a patient – especially where the physician is expected to know of the specific conditions treatable by the alternative procedure.\textsuperscript{479} As is the case with malpractice law generally, where the patient is able to establish a nexus between the negligent referral and the injury, the referring physician may be directly liable for malpractice. Cohen suggests that “the prospect of direct liability, whether clear or remote, suggests that physicians should increase their knowledge of the potential benefits and pitfalls of different complementary and alternative therapies and the ways these therapies might interface with existing conventional modalities within their specialty”.\textsuperscript{480}

6.6.2. Vicarious Liability

A physician may be vicariously liable for malpractice where his or her “actual agent, employee, or assistant” acts negligently.\textsuperscript{481} These agents are usually under the direct supervision and control of the physician.\textsuperscript{482} This rule is particularly pertinent in an integrated healthcare centre where providers practice independently and where a physician refers a patient to an indigenous or alternative medical practitioner who works within the same centre.\textsuperscript{483} In another instance, a physician may become vicariously liable for referring a patient to a practitioner who is incompetent.\textsuperscript{484} Physicians are expected to exercise due care and diligence in making referrals, and would be wise to ensure that a therapy is safe and efficacious before making a referral to the practitioner of the said therapy. Physicians – especially when employed in an integrated clinic under a partnership – may also be found liable for the misconduct of a member of the partnership.\textsuperscript{485}

\textsuperscript{479} Ibïd at 48.
\textsuperscript{480} Ibïd.
\textsuperscript{481} Ibïd at 50.
\textsuperscript{482} Ibïd.
\textsuperscript{483} Studdert, et al., “Medical Malpractice Implications of Alternative Medicine” supra note 228 at 1613.
\textsuperscript{484} Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 50.
6.6.3. Joint and Several Liability

Where a patient is injured after independent treatments by two or more physicians, the court may find the physicians jointly and severally liable on the reasoning that the physicians’ negligent actions caused the patient an “indivisible” harm, whether or not the physicians acted in concert or as a team.\footnote{486} Although every attending practitioner is to be held liable for all of the damages suffered by the patient regardless of the differing quantum of fault of each practitioner, some courts have insisted that the apportionment of liability must be based on fault.\footnote{487}

6.6.4. Continuing Liability

Finally, the courts may find that the referring physician has a continuing duty with respect to care of the patient on the ground that the physician’s duty is not extinguished after referral to the designated practitioner, especially in cases where the therapy offered by the latter is “adjunctive to medical care”.\footnote{488} Cohen has noted that:

The relationship between referring physician and complementary and alternative medicine provider bears some resemblance to the relationship between surgeon and physical therapist. For example, even though the chiropractor is a licensed, independent provider, one can imagine referral to a chiropractor for services analogous to those provided by the physical therapist.\footnote{489}

This type of relationship was confirmed in one of the interviews conducted in Canada. On enquiry regarding referral practices within the centre, the practitioner stated that “the Naturopathic doctor [supervises] the nutritionist to make sure that what they are recommending is safe for the client that the Naturopath is referring to the nutritionist”.\footnote{490} Generally, different integrated health centres with particular reference to modes of practice, hierarchy of providers, and referral patterns appear to be structured to avoid malpractice liability. The next subsection examines referral practices and organization of roles within some integrated health centres in Canada and Nigeria.

\footnote{486} Cohen, Beyond Complementary and Alternative Medicine, supra note 79 at 52.  
\footnote{487} Ibid.  
\footnote{488} Ibid at 54.  
\footnote{489} Ibid.  
\footnote{490} Iyioha, International Research, supra note 49.
6.6.5. Case Studies on Organizational Practices

The practitioners interviewed in Canada who are wary of malpractice liability have attempted to sever the chain of responsibility within their integrated health centres (IHCs).\textsuperscript{491} In other cases, the centres were more interested in fostering a team approach to treatment than in formulating regulations regarding provider relationships in the interest of averting malpractice charges. In some other cases, while there was clearly an attempt to make every provider responsible for his or her patient through separate malpractice insurance for instance, there was still an interest in ensuring that there was a collaborative relationship within the centre.\textsuperscript{492} For example, according to one practitioner:

Every practitioner here is responsible for their clients regardless of their scope of practice... All of our practitioners are responsible for their own practice insurance, they are responsible to be operating within the limitations of their own scope of practice, they are not supposed to be going outside that scope; so, there isn’t really a lot of the relationship of one person working under somebody else. There isn’t a lot of hierarchy…it’s more of a team approach.

However, this practitioner did concede the existence of supervisory relationships between different providers where necessary, such as between the Naturopath and the Nutritionist in the example cited above, where the Naturopath needs to ensure that the nutritionist’s recommendations are safe for the client.\textsuperscript{493} This supervisory relationship does not foreclose a team approach within the centre, and may in fact be deemed an aspect of the collaborative relationship. Accordingly, the Integrative Health Institute in Toronto strives to operate as a truly integrated clinic, emphasizing partnership and collaboration before and beyond liability concerns that may arise from a shared, continuing responsibility over patient care.\textsuperscript{494} According to a Co-Director of the Institute:

As a team here, we try to be a little different than just a multidisciplinary clinic where you have different practitioners all working in our own little silos… So, we foster team work by open communication and open dialogue with our practitioners. We have monthly meetings where we discuss challenging cases… We try to keep the chain continuous… There is referral when one practitioner is convinced that the patient needs the care of another specialist, for example, a counsellor or naturopath….

\textsuperscript{491} Ibid.
\textsuperscript{492} Ibid.
\textsuperscript{493} Ibid.
\textsuperscript{494} Ibid.
Some other centres have also attempted to foster a collaborative approach to healthcare delivery by establishing partnerships or other forms of alliances with biomedical centres. For example, the *Pax Herbal Clinic and Diagnostic Centre* in Ewu, Edo State of Nigeria, operates a partnership with a teaching hospital, the *Irrua Specialist Hospital*, situated in Irrua, Edo State. The Director of the *Pax Herbal Clinic*, Fr. Anselm Adodo, describes the arrangement as follows:

[T]here is referral – on very many occasions. There is referral back and forth between the practitioners. At the moment, there is a committee between this clinic and the Irrua Specialist hospital on partnership whereby they bring some patients here, lets say for Asthma or whatever, and we treat them and their doctors supervise the treatment and keep [the] records. Then, some of the illnesses we are able to handle very well they bring them [patients] here. Then, [they] open a [small] clinic there for our products, they assign two doctors officially – one would have an office there to [go] through the documents.

The Director further disclosed the plan to draw up a formal agreement to govern the activities of the partnership:

…[W]e are making it more practical. We are drawing [up] an MOU [Memorandum of Understanding] before Christmas [2009] to guide our activities…and that is a very big step forward for herbal medicine in Nigeria.

For some other practitioners, the emphasis is first on how best the patient can interact and benefit from the centre. Thus, both referral and the structure of the centre itself revolve around the patient’s choices. For example, while there is a referral tradition within the *Integrated Cancer Care Centre* in Vancouver – usually with the patient’s consent, the choice of practitioner or specialist is usually made by the patient after the latter is introduced to the spectrum of medical services available at the Centre. This arrangement does not emphasize any particular organizational structure over another, nor does it categorize practitioners expressly as ‘conventional’ or ‘Complementary and Alternative’. There is clearly an attempt to achieve a non-hierarchical system within which every practitioner is simply recognized as capable of delivering qualitative healthcare. A Co-Director of the Centre, Hal Gunn, differentiates the structure of the Centre from other integrated health centres:
There is a spectrum of possible integrative centres and along that spectrum, on the one hand, there is the practitioners who have come together each with their own specific field of training and each functioning as an expert around their treatment. What can happen in those kind of centres is each of them sees a patient, they come together to discuss what the treatment plan is and treat the patient according to that collaborative treatment plan.

At the other end of the spectrum, there is a recognition that it is not so much on us being the experts and telling patients what to do but us creating an environment of safety and empowerment and engagement, providing people with information, allowing them to choose which practitioners they would like to see, and then having those practitioners just be respectful of it – collaborating with the patients. Inspire Health is at this end of the spectrum. We are less interested in being the experts and telling the patients what to do; we are more interested in empowering people and providing people with options and information and allowing them to make the choices that feel right for them.

The other distinctive model identified during the interview process was the independent system, which comprised an organization of integrated healthcare providers each of whom practiced independently from the other. Within this setting, the attempt is to sever the chain of responsibility between providers. The *Qi Integrative Health Institute* in Vancouver emphasizes the independent status of each provider within the Institute. The Clinical Director of the Institute, Kim Schutter, noted that “everyone practices independently” and when prompted confirmed that the providers may be seen as simply “sharing a common space”.

While this organizational structure might be aimed at limiting the incidence of vicarious or continuous liability, other arrangements within an integrated healthcare centre may remain susceptible to any of the other liability types. For example, there remains a referral tradition within the *Qi Integrative Health Institute*. The Clinical Director expressly noted that “we refer patients to one another”. Furthermore, the Director discussed the occasional existence of team work between practitioners where it is in the best interest of the patient:

“We have sessions where we offer acupuncture and massage therapy exactly at the same time… So, there are two practitioners working on the patient at the same time… With chiropractic, we treat the same people and schedule appointments based on our opinions as practitioners… We work together that way to deliver the best care we can give…”

While the practice of each provider could certainly lead to legal consequences within medical malpractice law, the less clear-cut legal question within this working relationship is how the court would apportion liability between the providers in case of a medical injury. Notably, while the question of ‘how’ liability will be apportioned may be unclear, what is at least certain
is that one or the other of the liability types applies as between the providers. On this note, Cohen has observed that “efforts to create the illusion of clinical and legal separation between such providers, or to characterize the affiliation as one of independent contractors with no liability for each other’s negligent acts, may not necessarily succeed”.

Beyond constituting somewhat intricate systems in themselves, each of the organizational structures described above differs from the other in a number of ways, and this further complicates any attempt at defining the duty and standards of care required in each setting. In *Jennings v. Burgess* the court noted the importance of legislative intervention in this area:

> Recent developments in the health care industry have diffused the chain of medical authority for the sake of containing costs and increasing profits. … Unless the Legislature acts in a comprehensive way to address this issue, courts will be forced to re-think traditional notions of duty and standards of care, leading to fundamental doctrinal shifts gauged both to protect victims of medical malpractice and to shield physicians from frivolous malpractice claims.

Indeed, the law must evolve to address new developments in medical practice in this area – especially given that more models of clinic organization might be identified in a large-scale study. Perhaps, as models vary, so would the liability types, as well as the ability of patients and providers alike to obtain justice. The legal system would have failed in its responsibility if it neglected to address the current development.

### 6.7. Healthcare Institutions Level

The legal issues that may arise at the level of the healthcare institution are similar to those at the level of the healthcare clinic. Medical integration at healthcare institutions will involve a “combination of different professional services such as “surgery, long-term care, maternity, emergency medicine, and palliative care” with indigenous medical providers working as part of the medical team in various wards.” At this level, indigenous medicine is accepted as “integral to the mission, goal, and action plan of the institution,” and the practitioners of both systems

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496 *Jennings v. Burgess*, 917 S.W.2d 790 (per Gonzalez, J.).
497 Ibid at 796.
498 Iyioha, “In Search of Law’s Residence”, *supra* note 26 at 275 citing Tartaryn and Verhoef, *supra* note 17 at VII.104.
499 Boon *et al.*, *supra* note 476 at 53.
are aware of the importance of referral and collaborative work where the medical case so demands. Knowledge transfer between the professions is imperative at this level, as is the case at the practitioner level. The legal rules discussed above under the healthcare clinic are operative here as well.

6.8. Professional Healthcare Organization Level

Professional healthcare organizations “set the general philosophical milieu and explicit standards of conduct” which allow its members to practice in particular ways.\(^{500}\) The healthcare organization can permit members to make referrals to, and communicate\(^{501}\) at different levels (including at the educational and professional levels) with, professionals outside the biomedical field. This will enhance the relationship between practitioners. As discussed at the practitioner level, state and provincial medical practice laws need to be amended to incorporate the new evolution in healthcare delivery. For example, professional organizations can ensure that medical liability insurance incorporates the provision of indigenous medicine.\(^{502}\)

While some states and provinces in the US and Canada have already amended their medical practice laws to accommodate physicians’ practice of indigenous medicine, other states and provinces, including regulatory bodies in Southern nations, can ensure that similar amendments are introduced in their jurisdictions. These laws can absolve physicians of liability when they incorporate indigenous therapies into practice in a non-negligent manner. However, such laws would be most effective in promoting integrated medical practice if they are drafted to account for the inherent differences between medical systems and, as such, ensure that the standard of care for a finding of malpractice is linked to a breach of the applicable standards within a given healthcare profession rather to a detached finding of harm.

Finally, it is important that organizations of indigenous medical providers incorporate into the organizations’ regulations rules regarding referral between healthcare professionals. This will deter indigenous medical providers from exceeding professional boundaries – especially where the provider has no expertise in the area of a given medical condition. Beyond

\(^{500}\) Tartaryn and Verhoef, supra note 17 at VII.104; see also Iyioha, “In Search of Law’s Residence”, supra note 26 at 275.

\(^{501}\) Ibid.

\(^{502}\) Boon et al., supra note 476 at 53.
strengthening inter-professional relationships, this will also entrench an integrated system of healthcare in which patient safety is given as much importance as patient autonomy.
CHAPTER 7. CONCLUSION: THE NEW HEALTHCARE STATE – A LEGAL THEORY

Our discussion … adopts a critical perspective that ‘stands apart from the prevailing order of the world and asks how that order came about … [It] does not take institutions and social power relations for granted but calls them into question by concerning itself with their origins and how and whether they might be in the process of change … [It] is a theory of history in the sense of being concerned not just with the past but with a continuing process of historical change’.

Mykitiuk and Dagnino, “TRIPs and Its Implications for Healthcare” citing Robert Cox (and Timothy J. Sinclair), Approaches to World Order.¹

Legal process ideally respects the patient’s search for health as a process at the juncture of social, political, economic, and personal events… Legal rules reflect essential social values and culturally accepted models of health care. As these values and models continue to unfold, legal rules, too, will evolve to embrace a more expansive and empowering vision of health care and the healing process.

M.H. Cohen, Complementary and Alternative Medicine, Legal Boundaries and Regulatory Perspectives. ²

7.1. Introduction

The contentions and theories offered in this study emerge from the statistics on healthcare delivery worldwide and from an examination of the resources, history, culture, and healthcare behaviour of certain Southern communities. As established in the introductory chapter, evidence from North American and Southern health economies reveals that states are witnessing increased healthcare expenditure, and continuously have to consider the fiscal sustainability of their health systems when making policy decisions. While there have been a number of healthcare reform proposals to address the problem of rising costs in jurisdictions such as the US, Canada and Nigeria, these proposals may be more appropriately described as health insurance reform initiatives. This is because the data on healthcare delivery reveals far more structural problems than merely insurance-related fiscal problems. Simply stated, the healthcare equity question is a systemic issue that must be addressed through a comprehensive


strategy that extends beyond insurance reform. This study proposes that the first step towards comprehensive healthcare reform is to restructure health governance to allow for the development of an integrated healthcare system. The preceding chapters outlined some legal issues involved in this process.

This concluding chapter presents a summary analysis of the research outcomes in the preceding chapters, and synthesizes the outcomes to delineate the emergent theoretical framework which states that are interested in medical integration may adopt. The theoretical framework, depicted through the integrated governance theory, offers a method of thinking about law and legal institutions and their role in strengthening or creating productive institutions for the benefit of society. In this thesis, the specific concern is with how this theoretical framework can engender reform within the healthcare institution.

As outlined in chapter one, two studies by the Fraser Institute and Health Canada reveal that 74% of Canadians utilize ‘complementary and alternative medicines’, while 71% use Natural Health Products. The Health Canada study further establishes that 81% of Canadians believe that the use of Natural Health Products will increase over the next ten years. In a broader jurisdictional context, the World Health Organization (WHO) reports that more than 80% of the peoples of the global South rely on indigenous and alternative medicines for their healthcare needs. The legal and public health scholarship further confirm that many countries in both the North and South, including the US and Canada, face rising healthcare costs and diminishing returns in healthcare investments.

However, the African continent more than any other region of the world faces a crisis of inequitable healthcare delivery that is driven by workforce shortages and inefficient management of material and human resources in health, as well as geographical disparities in access to healthcare and rising out-of-pocket expenditures for health products and services. Beyond the major equity problems engendered by the rising costs of biomedical care and the continuous reliance on biomedical and technological resources, the shortage in healthcare personnel constitutes one of the most devastating problems for African healthcare systems.


4 Health Canada Report, ibid.
noted in the introductory chapter, the WHO has observed that in the struggle against various global healthcare crises, there has been limited focus on the people who actually deliver health services.\(^5\) It has been noted that Africa faces an ominous crisis in human resources for healthcare delivery.\(^6\)

However, as was further observed in the introduction, some of the problems that have beset the healthcare systems of Southern states are associated with flawed governance, political unrests, economic upheavals, and legacies from a colonial past. In fact, the scholarship often identifies the former problems collectively as an outcome of the colonial experience itself. The failings of the modern state in Africa are usually attributed to this colonial legacy, with the controversy centering on the disparity between the institutional structure and mandates of the Westphalian state and the customary institutions of governance in many pre-colonial states. As asserted in the introduction, the frail healthcare system in many of these formerly colonized states may be said to be one casualty of the flawed governance regimes in these states. This critical viewpoint on the impact of colonialism on governance regimes in formerly colonized states does not preclude the argument that governance reform, at least in the area of health systems, will be best engineered by the state. The argument that the state is the best institution to engineer medical integration emerges from the understanding that the state is the central feature of governance today.\(^7\) An appreciation of the centrality of the state to governance and of the authority and resources of the state institution is essential to understanding why the state must be involved in health governance reform in the interest of integrated medicine.

### 7.2. Configuring Integration: A Synthesis of Research Outcomes

Part of the primary objectives of this study has been to identify the legal issues that are associated with the concept of integrated medicine and to devise an approach to health governance reform which would create the appropriate environment for the development of an integrated health system. As established in the introductory chapter, integrated medicine is interconnected with law and necessarily relies on law and the institutional power of the state for

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\(^6\) Ibid.
\(^7\) See generally, Boaventura de Sousa Santos, Toward a New Legal Common Sense: Law, Globalization and Emancipation 2d ed. (London: Butterworths, 2002).
its realization. The state and the legal order play a central role in health systems because of
law’s ability to create and reinforce institutions. Law, as has been argued, is the state’s primary
instrument for systematic institutional reform.

Beyond shaping its laws to create the desired institutions, the state must synchronize the
necessary human and material resources needed to achieve institutional reform. As noted above,
the choice of the state as a central actor in the creation of an integrated health system is based
on the legal and material resources available to the state institution. This proposition in no way
ignores the diminishing influence of the state in some Southern territories. Rather, while
acknowledging that the Westphalian state has failed to deliver on many of its post-colonial
promises, the proposition is founded on the knowledge that the prevailing socio-economic
conditions in many Southern states render impracticable the idea of a privately managed health
system through the micro-governance system or a health system managed by the state alone
through the macro-governance system. Given the dearth of key healthcare resources and the
need to contain and diffuse healthcare costs, the state is more likely to achieve its objectives in
healthcare delivery by endorsing an integrated approach to health governance in which formerly
excluded actors are able to contribute through diverse medical approaches and financing
schemes to the development of the healthcare system.

Furthermore, the state has the responsibility to regulate or monitor the private delivery of
healthcare in the interests of cost reduction and maintenance of safety standards. Quality control
may not be achieved in a system dominated and governed primarily through private initiatives.
Additionally, the state is in a position to liaise with non-state actors, such as the World Health
Organization and health maintenance organizations, which make significant contributions to
national health systems.

Perhaps, the greatest influence of the state in creating a system of integrated healthcare
lies in its policymaking power. Through its policymaking power, the state can legalize or
delegitimize institutions. This power has been instrumental to placing biomedicine in a position

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8 A. Seidman and R.B. Seidman, State and Law in the Development Process: Problem-Solving and Institutional Change in the Third World (New York: St. Martin’s Press, 1994) at 38 [‘Seidman and Seidman’].
9 Ibid.
of dominance over other healthcare institutions. State policy on healthcare, as noted in chapter two, is itself dominated by biomedical principles and standards. The governance of health systems through a biomedical worldview has been instrumental to impeding the development of other approaches to healthcare delivery. As new states emerged from previously colonized territories, they endorsed the biomedical approach to healthcare delivery along with its institutions and laws. While this in one way could be interpreted as progressive, these states – especially emergent states in the African region – failed to make equal legal provisions for the development of their indigenous healthcare institutions. This failure to govern the indigenous healthcare system has been detrimental to the interests of consumers in underserved Southern societies because the indigenous healthcare institution was and continues to be the primary source of healthcare for the populations.

The failure of the states to create a conducive policy environment for the growth and development of indigenous healthcare systems reflects a fundamental misunderstanding of how governance regimes can influence the success or failure of a health system. Fundamentally, the conventional approach to health systems governance does not acknowledge the dissonance between the health laws and policies operative in the regions and the economic, social, cultural, geographical, and other material realities on ground. In the adoption of Western institutions and legal norms in African and some other Southern countries, there has been little acknowledgement that the emergent state has limited human and technological resources to provide sustainable healthcare based on the biomedical model for a large population. There is also no recognition that the new state has a unique socio-economic structure that is historically different from the imposed capitalist system.

In many cases, this transposition of laws and institutions has yielded opposite outcomes to the intended goals. As outlined in chapter two, scholars have observed that legal and institutional transplants are hardly successful. This is because legal subjects ultimately choose how to act in response to the law as well as to economic, political, social, and other subjective factors peculiar to their own countries and living situations.\(^{12}\) The subjective factors arise primarily from the particular customs, history, technology and other non-legal circumstances operative in a specific country.\(^{13}\) For example, a look at Nigeria’s history and traditions reveals

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\(^{12}\) Seidman and Seidman, supra note 8 at 45.

\(^{13}\) Ibid.
a long-standing allegiance to the practice and patronage of indigenous medicine. As has been noted, there is patronage of indigenous medicine by indigent consumers even where the costs of a particular therapy far outweigh its biomedical counterpart. The shape of the indigenous health system was akin to the social health insurance system. However, the incursion of capitalism into the Nigerian economic landscape has largely reshaped the structure of the indigenous health system along the capitalist profile of biomedical practice.

Also noteworthy are the opinions held by Nigerian healthcare consumers about different medical systems. Consumers have tended to identify biomedicine as a system more closely tailored to treating chronic diseases and other medical conditions requiring advanced technological care. On the other hand, the indigenous healthcare centre constitutes the primary healthcare unit for a majority of consumers who have limited financial and geographical access to biomedical care. As the research conducted in Nigeria reveals, community members are convinced that the development of the indigenous medical sector will address the inequities in the healthcare system. Thus, besides the history and tradition that have shaped the patronage and commitment to indigenous medicine, consumer patronage in more recent times is being shaped by the limited range of conditions treatable through biomedicine as well as the inadequacies in the conventional healthcare system for conditions amenable to biomedical care. It is necessary to emphasize that ‘access’ encompasses geographical and financial access. Many consumers have difficulties finding a hospital in their localities; and when they find one, the costs of the services and products are often unaffordable. Furthermore, the right technologies necessary for some diagnoses and treatments are not always available. In a world increasingly reliant on technological medicine for specific conditions, costs are bound to increase. Thus, while the law and healthcare institutions that support a biomedical approach to healthcare delivery are designed to achieve particular outcomes, the financial and technological realities in the regions do not allow the realization of the expected outcomes.

Analyzed through critical legal theory, this conflict between law and institutions on the one hand and the realities (social, economic, historical, geographical, cultural and available resources) on the other hand is manifest in the theoretical differences between positivism and the natural law jurisprudence. While the positivistic tradition is prescriptive and favours a governance system based entirely on written rules and quantifiable patterns of evidence that may not accord with societal experiences, the latter legal tradition represents a bridge between
the conflict between law/institutions and factual circumstances. This study adopts the position that the positivistic legal tradition is inexcusable where it produces unfair outcomes or worsens extant conditions.

Therefore, this study necessarily construes the conflict between the two traditions as an index of a failure of governance – that is, the failure of states (whose approach to governance is more allegiant to the positivistic tradition) to create laws that are cognizant of the history, resources, values, lifestyle and general circumstances of the legal subjects to whom they apply. As has been argued, healthcare laws and policies need to reflect the lived experiences and healthcare behaviour of legal subjects if the healthcare objectives of the state are to take root and produce the desired institutional changes. The state’s approach to health systems governance must also evince recognition of favourable patterns of practitioner-consumer healthcare behaviour and legitimize a new healthcare institution that can better ameliorate the conditions that foster inequities in healthcare delivery.

The state, as observed in chapter two, comprises both legal rules and the acts of the officials who make and implement the rules.14 The rules and the acts of officials who execute the rules constitute fundamental tools for institutional reform. As argued in chapter three, the actions of policymakers and the pronouncements of judicial officers in healthcare litigations are pathways towards legal reform. Judges must make pronouncements for a more open and participatory healthcare decision-making process. The public needs to know how and on what grounds decisions are made. The task of the court in its interpretive role is not to reify commonly held and non-evidence-based assumptions about the safety and efficacy of alternative therapies. Rather, the court needs to ground its decisions on valid and comprehensive evidence. In this regard, the court must exercise its inherent role to ensure fairness in law and policymaking. This requires the court to inquire whether policymakers have factored the appropriate considerations into the decision-making process.

For example, policymakers must ground policies on evidence. Towards this end, they need to support more studies on indigenous and alternative medicines, while engaging researchers in aspects of the decision-making process to ensure that health research is used in

14 See *ibid* (at 41) where the authors state that “the state comprises, not only the rules of law, but also the behaviours of “all the officials who formulate and implement them”.
policymaking.\textsuperscript{15} Notably, policymakers and researchers must embrace a broader definition of evidence beyond the conventional Randomized Controlled Clinical Trial model of evidence. As argued in chapter three, it is necessary for researchers to begin to adopt a composite research paradigm that recognizes that indigenous medical philosophies constitute an integral part of most indigenous therapeutic regimen.

Furthermore, policymakers need to embrace a broader range of evidence that are equally necessary to determine whether or not a particular medical system should be regulated and integrated into the state or national healthcare delivery system. As enunciated through the questionnaire research conducted in Nigeria, evidence of safety and efficacy are only two of several important considerations that should be factored into the health policymaking process. Beyond the evidence of safety and efficacy, it is equally important for policymakers to consider evidence of cost-effectiveness, cost-minimization and cost-utility of indigenous and alternative therapies as well as the availability of biomedical options. As evident in the case law, some patients turn to alternative therapies when they fail to find relief within biomedicine. Some other patients, as seen in the case of Herzig, are often left to choose between alternative medicine and imminent death.

Additionally, it is necessary for policymakers to encourage research into the socio-cultural demographics of indigenous and alternative healthcare consumers. According to Health Canada, eight in ten Canadians believe that it is important to respect the role that natural health products play in some cultures.\textsuperscript{16} Indeed, a significant majority of Canadian immigrants depend wholly on alternative healthcare approaches indigenous to their home cultures. Policymakers also need to consider the availability of human and material resources in healthcare delivery. The pertinent questions within this consideration would include, ‘how can alternative healthcare providers contribute to addressing the disparities in healthcare delivery’? ‘To what extent can alternative healthcare providers contribute to reducing the wait-times within a healthcare system’?

\textsuperscript{15} John Lavis, et al., “Examining the Role of Health Services Research in Public Policymaking” (2002) 80:1 \textit{The Milbank Quarterly} 125 at i. According to the authors, “policymakers need to establish accountability mechanisms to access other information besides “citable research” (defined as research information published in publicly available forms, such as books, journal articles, working papers)”.

\textsuperscript{16} \textit{Health Canada Report}, supra note 3.
Research outcomes from Nigeria confirm that there are longer wait-times in biomedical clinics than in indigenous healthcare centres. It was established that while 63% of respondents spent between one to four hours in the waiting room in biomedical healthcare centres, 82% of respondents spent thirty minutes or less in the waiting room at an indigenous healthcare centre. Furthermore, 40% of respondents who favoured medical integration, insurance coverage for indigenous medicines and involvement of IMPs in community healthcare delivery explained that these initiatives would address the problems of financial and geographical access to healthcare in the communities. Collectively, these types of health systems research evidence that address the relationships between modalities, the users of the modality, and the external factors that impact on accessibility provide a comprehensive evidential framework for appropriate policy decisions on indigenous and alternative medicines.

However, as was further observed, policymaking and government supervision may be impossible where Indigenous Medical Practitioners (IMPs) and Integrated Healthcare Practitioners (IHPs) have little interest in conforming to regulatory standards. As interviews conducted in Canada have shown, the disinterest in formal regulation among Canadian IHPs lies in the government’s attempt to regulate alternative medicines and natural health products as drugs. Practitioners have expressed fears that the regulation of alternative medicines using biomedical criteria would limit the number of IMPs or IHPs who can practice alternative medicine and reduce the autonomy of those who are able to practice within the system. These fears are founded on the likelihood that if natural health products are regulated as drugs, pharmaceutical corporations that are more primed to bear the costs of the RCT model of regulation would dominate the market for natural health products through the protection of patents. In some Southern jurisdictions, such as Nigeria, the research shows that the lack of interest in the regulation process is more associated with the IMPs’ dissatisfaction with the patent system, which does not grant protection to indigenous medicines, than with the issue of autonomy.

As recommended in chapter four, states can reform the patent system to recognize the efforts of IMPs and IHPs who have invested material resources and creativity into products of indigenous therapeutic knowledge. Research outcomes from Nigeria were analyzed in chapter four to counter the popular assumption that indigenous medicines belong to the public domain, and are unoriginal. Contrary to the popular discourse, the outcome of the small-scale research
conducted in Nigeria reveals that only 39% of those surveyed had knowledge of the ingredients used in the preparation of NHPs. Of this percentage, 75% had either prescribed the product for themselves or had it prescribed by a family member or friend. Thus, for 75% of the respondents, knowledge of the materials used in the preparation of the medicines is directly traceable to their participation in the collection and preparation of the materials. It was also discovered that only 40% of respondents could have correctly administered the product without the directions of an IMP. For 60% of the respondents, the knowledge (or vague knowledge) of the constituents of the medicinal product did not translate to knowledge of administration.

There was further evidence from the opinions provided by Canadian and Nigerian respondents on the secrecy surrounding indigenous medical practice that indigenous medical practice is a specialized field of knowledge rather than lay practice or public domain knowledge. Through qualitative interviews with IMPs in Nigeria, it was shown that the very nature of indigenous medical practice in Nigeria provides explanation for the cryptic approach to indigenous medical practice, and offers further evidence that indigenous medical knowledge is possessed by a closed group of professionals. The Nigerian society has a large community of professional herbal practitioners, and among this diverse group of practitioners, there is common knowledge that innovation and competition are vital to a successful and profitable practice. Hence, practitioners are constantly on guard to protect their innovations through trade secrets. These research outcomes collectively negate the popular assertions about the nature of indigenous medicines. As has been suggested, these outcomes support the proposal for an amendment of the patent system to grant juridical protection to indigenous medicines and natural health products.

The choice of the patent system as an appropriate protective mechanism lies with the international recognition accorded to this system of intellectual property protection. The amended law can extend juridical protection to products of indigenous therapeutic knowledge while it maintains the standards of the TRIPS Agreement. The suggested model in chapter four retains the basic framework of the current patent law in order to comply with the minimum requirements of the TRIPS Agreement. As was noted in chapter four, nothing in the Agreement limits the right of states to exceed the basic requirements of the law. Thus, states may consider extending patents for products of indigenous therapeutic knowledge beyond the 20 years (minimum) requirement established by the TRIPS Agreement. This amendment would not
breach the TRIPS Agreement; it would ensure that IMPs have an extensive time-frame to commercially exploit a product derived from indigenous therapeutic knowledge that has been a family resource for generations. However, it was also suggested that the derivative products must meet certain basic requirements to be eligible under a reformed patent law. As enunciated in chapter four, they must comprise of an inventive mixture of diverse constituents, or a previously undiscovered knowledge of the medicinal propensities of a given natural resource, and they must not be obvious to the average specialist in the field.

It is important to note that an amended patent law necessarily conforms to the legal theory espoused in this research – that legal norms must reflect the socio-cultural, economic and other material realities of the people they are meant to govern. The experiences of Nigerian IMPs and the needs of Nigerians suggest that such an amendment of the patent law will go a long way towards resolving the ongoing controversy between the regulators and the practitioners of indigenous medicine. It is also noteworthy that this suggestion is a specific response to the Nigerian experience. Other jurisdictions in Africa and beyond may find this to be a constructive proposal or find other initiatives to be better suited to their regional needs. In the Canadian case, the recommendation that policymakers and regulators must embrace a broader concept of medical evidence in the interest of population health is equally applicable to addressing the concerns of IMPs regarding the regulation of NHPs as drugs. An integral approach to medical research in which the tenets of the biomedical and alternative medical paradigms are equally recognized can resolve the misgivings that Canadian IMPs have about the regulatory system.

However, while state healthcare reform through law and policymaking may be slow in coming, the courts can accelerate healthcare reform through judicial interpretation. Elsewhere, I have argued that law has an emancipatory capacity located within both the ‘associative power’ of legal subjects and legal hermeneutics. Legal hermeneutics involves the deconstruction of legal rules through inventive interpretation. The theoretical position that law ought to reflect prevalent and commonly accepted societal norms should also apply to judicial interpretation of extant healthcare law and policies. As expatiated in chapter six, through creative interpretation and expansion of the legal meanings and definitions now

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attached to certain medico-legal principles, such as negligence, informed consent, standard of care, and scope of practice, the courts can ensure that relevant healthcare laws and policies reflect society’s changing attitudes in the patronage of healthcare services and products.

Each of the above reform initiatives – policymaking, legislative reform and judicial interpretation – has been analyzed at the six levels of the health system. As explained in chapters five and six, strategic health governance reform at each of the six levels of the health system captures an aspect of the integrated system of health governance. Integrated health governance, which provides a foundation for a systemic partnership between the biomedical and indigenous medical systems, is described in chapter six as a participatory decision-making and administrative process that incorporates the contributions of state officials, private enterprises, consumer interests and a broad range of healthcare actors into healthcare management at every level of the health system, while acknowledging the limitations inherent in both public and private health governance.

In this sense, integrated governance may be conceived as a democratic governance system that in part embodies the tenets of a functional theory of law and society – that law and its administration must be representative of the aspirations of its subjects and facilitate the realization of policy goals by harnessing all human and material resources available to a people. It will be recalled that the functional conception of law locates legal validity and justice within the purposes or social function of law. Law, within this postulation, is required to meet societal needs and expectations if it is to be able to promote justice in human relations as well as within governance regimes. In the context of this study, this implies that the legal process must be reformed to recognize new trends in consumer healthcare behaviour, and to regulate and integrate valid medical systems and approaches into the conventional healthcare delivery system.

There are several reasons why a functional conception of healthcare laws in the context of integrated medicine is imperative. One of the most important reasons is that of patient safety. Indigenous and alternative medical practice is presently ill-equipped to take on the large number of consumers who patronize the system. The system also lacks “the organization and the means”, as well as the “self-criticism” necessary for growth and development. Further, the

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19 Ibid.
lack of legal regulation for such a widely patronized medical system merely perpetuates the conditions for charlatans to flourish.\textsuperscript{20} Regulation and integration can prevent the practice of indigenous medicine by unqualified persons. An associated problem is the spate of self-prescription among patrons of IMS. According to the data from the research conducted in Nigeria, only 33\% of respondents had taken an NHP on the prescription of an herbal practitioner (28\%) or physician (5\%). The research showed that 51\% of respondents used an NHP on the recommendation of a family member or friend, while 16\% had prescribed the product for themselves. This situation merits urgent legal attention.

Beyond patient safety and the advantage of cost reduction which scholars have associated with integrated medicine, there is an increasing reliance on indigenous and alternative medicines for the treatment and management of critical ailments. There continues to be heavy reliance on indigenous medicines in the South and increasing desperation among patients who have limited access to biomedical care within both urban and rural regions. Furthermore, Canada’s growing multicultural heritage might mean a greater reliance on indigenous and alternative medicines in coming years. As noted above, 81\% of Canadians surveyed in Health Canada’s Study on the usage of natural health products among Canadians believe that the use of NHPs among Canadians will increase in the next ten years. It is hoped that the conservative judicial approach to the interpretation of impugned laws in this area would be replaced once the courts acknowledge that the health policymaking process is neither democratic nor are the resultant laws supportable under the \textit{Charter’s} fundamental justice clause.

As further discussed, a functional conception of law requires law to reflect commonly accepted and progressive societal norms while redirecting future conduct towards conformity with newly prescribed norms. For there to be meaningful law reform in the latter regard, new norms and aspirations should not conflict with the historical, social, cultural, economic and other material realities of the citizenry so much that they become unattainable. Thus, the instrumental use of law to create new norms, as has been proposed, must be tailored towards (re)creating new institutions or patterns of behaviour that do not complicate the pre-existing problems within a given society. In this process, an integrated approach to governance requires

\textsuperscript{20} \textit{Ibid} at 303.
that the state consider the experiences and interests of its citizenry as part of the law and policymaking process.

For example, while scholars are agreed that the lack of insurance coverage for indigenous and alternative medicines “represents a serious inequity”,21 yet policymakers ought to consider whether it is expedient to extend insurance coverage to indigenous medicines in a community where members pay for indigenous medical services in diverse ways (deferral, contingent payment, services rendered, goods supplied, etc.). The decision-maker needs to consider the impact of the new payment method on affordability of products and services. Policymakers would need to consult the expected beneficiaries of such a policy to confirm whether their interests would be better served through an extension of coverage in the given circumstances. While data from the research conducted in Nigeria suggests that 56% of respondents from both the urban and rural regions supported a payment scheme for indigenous medicines through the NHIS, a comprehensive study that investigates the opinions of community members on a proposed restructuring of the current flexible payment methods might produce new insights into community preferences, which would be useful for policymaking.

Finally, a functional conception of law and society has the potential to help avert the type of failings identified within African healthcare systems in the 1990s. It will be recalled that this was the period when the World Bank foisted on African health economies capitalist policies and strategies for health governance that were incompatible with local systems and institutions and the way of life of the people they were meant to govern. As has been noted, such approaches to governance have tended to worsen the conditions they were intended to improve. Indeed, the instrumental use of Western colonial laws to create new societies and socio-economic institutions in some formerly colonized territories has more often failed to improve the targeted institutions. In no other institution has this outcome been more obvious than the healthcare institutions of those shifting regions of the world often denoted as the ‘Third World’.

This study targets this conflict – that is the discrepancy between the legal framework that supports the dominant models of health governance and the lived experiences of legal subjects. Importantly, the foregoing discussion about health governance reform must be understood in the context of the proposition that a certain type of approach to health governance is mandatory.

for states to achieve equity in healthcare through the integrated healthcare system. Health systems governance is often facilitated through law and policymaking, as well as through policy implementation. Thus, governance reform necessarily implicates law reform. This thesis suggests that law reform itself must be preceded by a theory of governance. Beyond dictating the shape of policies and laws that would appropriately undergird the proposed model of governance, a theory ensures that the emergent laws and policies are grounded on the lived experiences of legal subjects. This thesis proposes Integrated Governance as a feasible theory. This theory, as set out in the body of this research, advances a democratic health policymaking system while effectively synchronizing material and human resources in the improvement of healthcare delivery. The equitable healthcare system created through the integrated governance approach is the integrated healthcare system.

7.3. Integrated Medicine and Improved Healthcare Access: A Legal Theory

The introductory chapter presents a précis of the case for integrated medicine based on the available data on healthcare delivery worldwide. The data reiterated above is further supported by statistics on the number of IMPs available to serve healthcare consumers in different African states. As outlined in chapter 1, there are about 900,000 IMPs registered with the Association of Folk Medicine Practitioners in Nigeria, while there are under 35,000 physicians serving the country’s population of over 140,000,000. It is important to emphasize that these practitioners conduct their practice in a region that is under a human resources in health crisis.

Public health scholars have suggested that in light of the unlikely fiscal sustainability of the current healthcare system, it is crucial for policymakers to focus on the insight, experience, and expertise of both indigenous/alternative medical providers and biomedical professionals. In this sense, integrated medicine may be construed as a population health strategy, not only to improve financial access and such other barriers resulting from or associated with the dearth of human resources in healthcare, but also to reduce the burden of disease and improve population health.

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22 As noted in chapter 1, there are more than 700,000 IMPs in South Africa, more than 450,000 registered members of the Senegalese Melango Union, and about 50,000 healers registered with Zimbabwe’s National Traditional Healers: see Report of the Joint United Nations Program on HIV/AIDS and Folk Medicine in Africa (1998).

As suggested in the introductory chapter, that part of the world often described as the ‘developing’ or the ‘Third World’ is at a stage in its growth where it must search within its own resources for solutions to its healthcare problems. While the pursuit of progress in medical technologies must necessarily continue in the interest of patients with medical conditions that are not amenable to indigenous care, Southern nations should consider reducing their dependence on foreign aid through an integrated approach to healthcare delivery. This proposal has the support of the World Health Organization.

However, while the WHO has consistently affirmed that an integration of medical systems will improve the current limited access to healthcare in underserved populations, there has not been any comprehensive effort to address the legal vacuum in the proposals for integration. While it is necessary to conduct further research on the manner in which law reform might advance integrated medicine, this thesis has attempted to lay out a trajectory for law reform in this area. Figure 7.1 captures the approach outlined in this study.

Figure 7.1: Trajectory for Medical Integration

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24 Ibid.
The trajectory involves a number of synchronized processes: dialogues between practitioners, organization of their professional groups, and negotiation between practitioners and the state. Furthermore, both practitioners and consumers can contest laws and practices that are deemed unfair and incompatible with constitutional or other legal rights. While contestation may not be a quick approach to institutional reform, it could certainly be a catalyst highlighting the need for systemic reform. Beyond these, however, the primary reform initiatives in the integration process are legislative and institutional reforms which involve the adoption of the integrated governance model at every level of the healthcare system, and in which each level interacts with the other as well as with broader interest groups of patients and providers.

This interaction will be manifest in health systems where consumers are able to discuss openly their use and interest in indigenous and alternative medicines with their biomedical healthcare providers; consumers’ values and interests are incorporated into law and policymaking; and healthcare practitioners of the different medical paradigms are able to communicate and collaborate with each other without fear of legal sanctions. Interaction between the systems will also be evident where healthcare clinics and institutions are able to administer integrated healthcare to patients and create a collaborative working environment for their providers without concerns about prohibitive legal rules; and where healthcare organizations and associations recognize practitioners’ ongoing acceptance and practice of integrated medicine through amended state medical practice laws. A conducive policy environment at the national or federal level as well as at the state or provincial levels, established through updated legal rules facilitates interaction between the levels.

This interaction, therefore, is achieved largely through a legal framework (comprising both legislation and court judgments) that reflects accepted norms as well as the expectations of societal members, and accordingly allows the coordination of healthcare resources in a manner that meets societal needs. Such a legal framework neither adopts and applies transplanted norms without due consideration of the impact of the laws on the lives of legal subjects given established patterns of behaviour nor does it interpret local practices as deviations from a foreign rule regardless of the authenticity of those practices. Fundamentally, the Integrated (or Integral) Governance theory approximates to a theory of law that conceives law as an embodiment of the intersecting norms and influences of culture, history, and the experiences of a people. The experiences are themselves conditioned by the available resources for a people’s
survival and are influenced by human and technological resource constraints, and political, economic, social, and geographical factors.

This legal theory specifically associates fair law and policy with democratic lawmaking that is contextualized to acknowledge and account for the tripartite intersecting norms identified above – the cultural, historical and experiential. In this manner, this theory offers a different view from the conventional, positivistic approach to policymaking at least in the field of health law and policy, in which medicine is assumed to be a field of knowledge capable of producing a fixed conclusion that is wholly scientific and entirely dissociated from the broader social milieu. This conventional paradigm also presumes that the solutions to health problems lie wholly in the area of medical treatment, while broader policy questions about social change towards health promotion are unaddressed. Within the preexisting paradigm, the problem of healthcare access may generally be normatively defined as purely scientific and fiscal without more.

However, the theoretical view of law proposed in this study reframes healthcare and health law and policymaking as phenomena that necessarily intersect with the identified tripartite norms and the associated political, economic, social, geographical and resource constraints. The impact of law on the lives of legal subjects depends on the extent to which these constraints or influences are reflected in its provisions. The legal subject, who in the present analysis is the healthcare consumer, has a greater chance of finding a healthcare expert and at a lower cost if states were to embrace a broader vision of healthcare delivery supported by this expanded theory of law in which law creates functional societal institutions and is itself created by legal subjects guided by the totality of their experiences past and present.

It remains necessary for large-scale studies to investigate how this legal vision, embodied within the integrated governance theory, might operate in actuality. Further research might also reveal other models of integrated health centres and the type of legal issues or complications that arise from the models. At the present, it is hoped that the broader legal vision advocated in this thesis will advance the objective outlined at the outset: that of a journey towards medical independence for underserved populations.

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25 Mykitiuk and Dagnino, supra note 1 at 311.
26 Ibid.
27 Ibid.
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APPENDIX: BEHAVIOURAL RESEARCH ETHICS BOARD APPROVAL CERTIFICATES

The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road, Vancouver, B.C. V6T 1Z3

CERTIFICATE OF APPROVAL - MINIMAL RISK

<table>
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<tr>
<td>Mary Anne Bobinski</td>
<td>UBC/VP Academic (Academic Units)</td>
<td>H08-02767</td>
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INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

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Other locations where the research will be conducted:
Medical professionals at the Integrated Cancer Care Centre, Vancouver, will be interviewed in their private offices. In Nigeria, interviews will be conducted with indigenous healthcare providers and key government officials in the health industry at their respective offices and questionnaires will be distributed at random to adult/competent consumers of indigenous and orthodox medicines at various locations: university campuses, offices and business centres across the geopolitical zones in Edo State, Southwest of Nigeria.

CO-INVESTIGATOR(S):
Inehobhude Oghobere Yioha

SPONSORING AGENCIES:
UBC Dean of Law

PROJECT TITLE:
Survey of Patterns of Use, Cost, and Governance of Indigenous Medicine and Choice of Intellectual Property Protection for Herbal Medicines in Nigeria

CERTIFICATE EXPIRY DATE: December 18, 2009

DOCUMENTS INCLUDED IN THIS APPROVAL:

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The application for ethical review and the document(s) listed above have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.
Approval is issued on behalf of the Behavioural Research Ethics Board and signed electronically by one of the following:

Dr. M. Judith Lynam, Chair
Dr. Ken Craig, Chair
Dr. Jim Rupert, Associate Chair
Dr. Laurie Ford, Associate Chair
Dr. Daniel Safi, Associate Chair
Dr. Anita Ho, Associate Chair
CERTIFICATE OF APPROVAL - MINIMAL RISK AMENDMENT

PRINCIPAL INVESTIGATOR: Mary Anne Bobinski
DEPARTMENT: UBC/VP Academic (Academic Units)
UBC BREB NUMBER: H08-02787

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

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Other locations where the research will be conducted:
Medical professionals at integrated Healthcare Clinics and Centres in Ontario and British Columbia will be interviewed in their private offices. Interviews will be conducted with Nigerian experts and integrated healthcare providers and key government officials in the health industry through phone interviews. Questionnaires will be distributed at random to adult/competent consumers of indigenous and orthodox medicines at various locations: university campuses, offices and business centres across the geopolitical zones in Edo State, Southwest of Nigeria.

CO-INVESTIGATOR(S):

Rehoboth Otihor tlwch

SPONSORING AGENCIES:

UBC Dean of Law

PROJECT TITLE:

International Research on Usage, Financing and Governance of Indigenous and Integrated Medicine and the Construction of Intellectual Property Regime for Herbal Medicines

Expiry Date - Approval of an amendment does not change the expiry date on the current UBC BREB approval of this study. An application for renewal is required on or before: December 18, 2009

AMENDMENT(S):

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Dr. Laurie Ford, Associate Chair
Dr. Anita Ho, Associate Chair
The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road, Vancouver, B.C. V6T 1Z3

CERTIFICATE OF APPROVAL - MINIMAL RISK RENEWAL

PRINCIPAL INVESTIGATOR: Mary Anne Bobinski
DEPARTMENT: UBC/VP Academic (Academic Units)
UBC BREB NUMBER: H08-02767

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

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CO-INVESTIGATOR(S):
Irehobude Obihoro Iyoha

SPONSORING AGENCIES:
UBC Dean of Law

PROJECT TITLE:
International Research on Usage, Financing and Governance of Indigenous and Integrated Medicine and the Construction of Intellectual Property Regime for Herbal Medicines

EXPIRY DATE OF THIS APPROVAL: November 17, 2010

APPROVAL DATE: November 17, 2009

The Annual Renewal for Study have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.

Approval is issued on behalf of the Behavioural Research Ethics Board

Dr. M. Judith Lynam, Chair
Dr. Ken Craig, Chair
Dr. Jim Rupert, Associate Chair
Dr. Laurie Ford, Associate Chair
Dr. Anita Ho, Associate Chair
The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road, Vancouver, B.C. V6T 1Z3

CERTIFICATE OF APPROVAL - MINIMAL RISK AMENDMENT

PRINCIPAL INVESTIGATOR:  DEPARTMENT:  UBC BREB NUMBER:
Mary Anne Bobinski  UBC/VP Academic (Academic Units)  H08-02767

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Other locations where the research will be conducted:

Medical professionals at Integrated Healthcare Clinics and Centres in Ontario and British Columbia will be interviewed in their private offices by the co-investigator. Interviews with Nigerian experts and integrated healthcare providers and key government officials in the health industry will be conducted in their private offices by a research assistant. Questionnaires will be distributed at random to adult/competent consumers of indigenous and orthodox medicines at various locations: university campuses, offices and business centres across the geopolitical zones in Edo State, Southwest of Nigeria.

CO-INVESTIGATOR(S):

Ireohbude Otihor Lyihoa

SPONSORING AGENCIES:

UBC Dean of Law

PROJECT TITLE:

International Research on Usage, Financing and Governance of Indigenous and Integrated Medicine and the Construction of Intellectual Property Regime for Herbal Medicines

Expiry Date - Approval of an amendment does not change the expiry date on the current UBC BREB approval of this study. An application for renewal is required on or before: November 17, 2010

AMENDMENT(S):

AMENDMENT APPROVAL DATE: December 3, 2009

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The amendment(s) and the document(s) listed above have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.

Approval is issued on behalf of the Behavioural Research Ethics Board
and signed electronically by one of the following:
Dr. M. Judith Lynam, Chair
Dr. Ken Craig, Chair
Dr. Jim Rupert, Associate Chair
Dr. Laurie Ford, Associate Chair
Dr. Anita Ho, Associate Chair