



UBC CENTRE FOR
HEALTH SERVICES AND
POLICY RESEARCH

Pharmaceutical Innovation

Can health and economic goals be met?

A call for research prepared by Steve Morgan and Clare Mochrie

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The Program in Pharmaceutical Policy in the UBC Centre for Health Services and Policy Research (CHSPR) is exploring how health and economic goals of innovation policy can be reconciled. Beginning with a broad-based conference on health innovation on February 24th and 25th, 2009, CHSPR will host a series of workshops on theories, research evidence and policy experiences related to innovation policy in health care. Particular emphasis will be placed on pharmaceutical issues, with the intent to assemble a collection of essays from independent experts in 2010.

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THE UNIVERSITY OF BRITISH COLUMBIA

About CHSPR

The Centre for Health Services and Policy Research (CHSPR) is an independent research centre based at the University of British Columbia. CHSPR's mission is to advance scientific enquiry into issues of health in population groups, and ways in which health services can best be organized, funded and delivered. Our researchers carry out a diverse program of applied health services and population health research under this agenda. The Centre's work is:

- Independent
- Population based
- Policy relevant
- Interdisciplinary
- Privacy sensitive

CHSPR aims to contribute to the improvement of population health by ensuring our research is relevant to contemporary health policy concerns and by working closely with decision makers to actively translate research findings into policy options. Our researchers are active participants in many policy-making forums and provide advice and assistance to both government and non-government organizations in British Columbia (BC), Canada and abroad.

Funding and Support

CHSPR receives core funding from the BC Ministry of Health, and ongoing support from the University of British Columbia and the UBC College of Health Disciplines. This enables the Centre to focus on research that has a direct role in informing policy and health reform, and facilitates CHSPR's continuing development of the BC Linked Health Database.

Our researchers are also funded by competitive external grants from provincial, national and international funding agencies. They include the Canadian Health Services Research Foundation, the Canadian Institutes of Health Research, the Commonwealth Fund, Health Canada, the Michael Smith Foundation for Health Research, and WorkSafeBC.

Data Services: BC Linked Health Data Base

Much of CHSPR's research is made possible through the BC Linked Health Database, a valuable resource of data relating to the encounters of BC residents with various health care and other systems in the province. These data are used in a de-identified form for applied health services and population health research deemed to be in the public interest.

CHSPR has developed strict policies and procedures to protect the confidentiality and security of these data holdings and fully complies with all legislative acts governing the protection and use of sensitive information. CHSPR has over 30 years of experience in handling data from the BC Ministry of Health and other professional bodies, and acts as the access point for researchers wishing to use these data for research in the public interest.

Pharmaceutical Innovation

Can health and economic goals be met?

Introduction

Canadians spend hundreds of millions of dollars per year on pharmaceutical research and development (R&D) through governments, charitable organizations, and private investment. While the pharmaceutical industry accounts for only 2% of the Canadian economy, it is responsible for more than 10% of all Canadian R&D; and although research in other sectors has decreased in recent years, pharmaceutical R&D continues to rise.¹ From a public policy perspective, the hope is that this R&D will spur pharmaceutical innovation with benefits to population health and the economy. The degree to which these goals are both being realized, however, is the subject of increasing debate.

This paper investigates the drivers of pharmaceutical R&D and re-examines how “innovations” from this sector are defined and promoted. Our aim is to reframe these issues and stimulate a new, balanced debate on pharmaceutical innovation. We seek to outline some of the critical questions, starting with:

- Can we stimulate pharmaceutical R&D in a way that achieves our health and economic goals?
- Are the health and economic goals related to pharmaceutical innovation mutually exclusive?

We believe the answers to these questions are “yes” and “no” respectively, and are calling on independent experts to provide their insights into the issues.

Background

Canadian health and economic policy discussions are increasingly focussed on the subject of innovation. Innovation is generally seen as a critical factor for economic growth and social development. In the health care context, there is an added hope and expectation that innovation will result in new, life-saving cures and more cost-effective ways of delivering health care.

Drug therapies discovered over the past 50 years have had a phenomenal impact on the delivery of health care and the wellbeing of populations. Consider the impacts of antibiotics, anaesthetics, cardiovascular drugs and cancer treatments as

¹ Statistics Canada (2005) “Industrial Research and Development, 2001 to 2005” Science Statistics Bulletin.
<http://www.statcan.ca/>

just a few examples of health care advances made possible by pharmaceutical innovations.

The pharmaceutical industry has also become a significant sector of the Canadian economy, representing over \$9.4 billion in domestic production and accounting for approximately 75,000 jobs in 2005, the most recent year for which data is available.²

The health and economic significance of the pharmaceutical industry have enabled this sector to billions of dollars in public R&D investments and tax incentives. The expectation is that this funding will translate into innovations that improve health outcomes while simultaneously creating jobs and fuelling economic development.

It is often argued that health and economic goals related to pharmaceutical innovation work against one another instead of in harmony. Indications of disconnect, if not conflict, are found in the concurrent trends of exceptional industry profitability and decreasing numbers of breakthrough drugs.³ Globally, tensions are revealed in the disproportionate number of new drug therapies—and an estimated 90% of research funding—that target diseases of the richest 10% of the global population as opposed to those of the developing world.⁴

The potential for conflict between health and economic goals points to the need to clarify how pharmaceutical innovation is defined and to re-examine how it is promoted. It also highlights the need for policy approaches that clearly identify and reconcile the different objectives that drive this unique and important sector.

What is innovation?

Describing a product as innovative usually implies that it has some intrinsic property or quality worthy of recognition and reward. This value stems from the interaction between two key and mutually reinforcing characteristics of innovations: novelty and effectiveness.⁵

Innovations are new ideas or original reconfigurations of existing ideas. They are necessarily things that are out of the ordinary. But novelty alone is not sufficient for innovation.

New ideas do not always generate value. Indeed, many new ideas turn out to be of little practical significance. A second characteristic of innovation is therefore effectiveness. Innovations must have an impact on outcomes. Yet this too is not a sufficient condition for innovation.

² Industry Canada (2007) "Canada's Pharmaceutical & Biopharmaceutical Sectors" Sector Profile. <http://www.ic.gc.ca/>

³ National Institute for Health Care Management Foundation (2002) "Changing Patterns of Pharmaceutical Innovation" Research Foundation <http://www.nihcm.org/>

⁴ Global Forum for Health Research (2004) "10/90 Report on Health Research 2003-2004." <http://www.globalforum.org/>

⁵ Morgan et al (2008) "Toward a definition of pharmaceutical innovation" Open Medicine. <http://www.openmedicine.ca/>

New ways to replicate outcomes already obtainable do not necessarily generate value. Innovations therefore need to enable current possibilities to be surpassed through new ways of doing things. As such, innovations are neither novelty nor effectiveness in isolation, but rather represent the powerful combination of the two together: *novelty of effectiveness*.

In the context of pharmaceuticals, this two pronged definition of innovation is achieved by pharmaceutical products that safely and effectively address health care needs that would otherwise be unmet or inadequately met with existing treatments. Such treatments hold intrinsic value. The greater the unmet need, and the greater the impact on that need, the greater the value to society of the product.

How are innovations promoted?

Innovation represents a market paradox. Because ideas are a form of “public good,” their value to society is maximized when used widely and freely. Yet, in a truly “free market,” it would be entirely irrational for firms to spend time and money researching and testing an idea only to produce an innovation that competitors would invariably copy and sell at lower prices. Would-be innovators will not bother innovating in such a free market.

Particularly in sectors such as pharmaceuticals — where products are inherently information-based and the costs of research are high and uncertain — the lack of incentive to innovate in a free market is troubling. The situation is a classic instance of market failure and thus a logical place for market intervention by government.

Beyond direct investment in R&D — an important means by which governments stimulate innovation — governments also encourage private firms to invest in the R&D processes required to innovate by granting intellectual property rights over pharmaceutical inventions. Patents, in particular, provide a time limited monopoly that enables firms to set prices higher than would be possible if competing firms copied their ideas. Competing firms are only permitted to enter the market at the end of the patent, 20 years from the date on which a patent application is filed. In exchange for this initial protection from competition, the new idea is made public at the point of patent application.

Patents are not meant to guarantee that a firm will recoup the R&D costs expended on producing an invention. Rather, they are designed to give firms the opportunity to achieve sales based on the value that the market places on the patented product or process. If the idea is a truly novel and effective innovation, the market rewards may be substantial. Paybacks will be lower, however, if a patented product or process falls short, for example by failing to surpass existing technologies in a meaningful way.

The outcome-oriented nature of the market rewards provided by patents ensures that firms will be motivated to be as efficient as possible in conducting the research.

In order to maximize the outcome profitability, they will reduce any unnecessary steps or expenses in the research process. They will also prioritize those research endeavours that represent the greatest profit potential. In this way, patents can be an effective tool for addressing the paradox of innovation in normal free market scenarios.

The pharmaceutical industry, however, does not operate within a standard market.

Challenges inherent with pharmaceuticals

The rewards from patents are contingent upon the willingness and ability of consumers to pay for patented products and processes. In well-functioning markets for ordinary consumer goods, the market will provide sales revenues that are roughly in proportion to the value that society places on the goods in question.

The pharmaceutical sector is unlike ordinary economic markets in a number of ways. Owing to the nature of pharmaceuticals and their use in the pursuit of improved patient health, neither their consumers (demand side) nor their producers (supply side) adhere to classical economic assumptions about marketplaces. It may therefore be inappropriate to assume that the willingness and ability of consumers to pay for patented drugs will always be proportional to their societal value.

Unregulated consumer demand will optimally reflect the societal value of their purchases if a number of economic assumptions are met. Principal among these are that consumers must be well informed about their needs, well informed about the extent to which the goods being sold will meet their needs, able to choose not to satisfy a given need, and motivated to weigh the full costs and benefits of meeting various needs through various alternative means.

In the case of pharmaceuticals, identifying the need for a drug is a complex task. Most consumers do not possess the knowledge necessary to make an informed decision about which drug is most appropriate. And because medications involve some degree of risk, they should not be taken on a "trial and error" basis. Patients often have one shot at treatment for medical conditions.

When in need, consumers of pharmaceuticals are generally in vulnerable situations, without options to defer consumption to a time when more information or lower prices are available. Such vulnerability can alter decision-making and therefore the validity of assumptions about consumer rationality and the societal impact of trade-offs made.

Further, owing to drug insurance programs, consumers in the pharmaceutical sector (patients and their prescribing doctors) are not typically given full incentive to evaluate the costs of treatment alternatives. While this will not necessarily cause an over-consumption of medications (due to the inherent risks associated with doing so), it does mean that price differentials may not be taken into consideration when choosing between different drugs to treat a given condition.

The demand-side of the pharmaceutical sector therefore lacks the perfect information, consumer autonomy, and price sensitivity of standard markets.

Supply-side conditions in the pharmaceutical sector also depart from the norm of perfectly competitive markets. In addition to government-conferred monopolies through patents, there are significant additional barriers to entry into a market for a pharmaceutical product. Additional barriers stem from economies of scale in production and licensing costs required of would-be competitors (e.g., those seeking entry after patents expire). Such factors can disrupt the competitive structure of the market in pharmaceuticals and limit related benefits to consumers and society.

Imperfections on both the demand and supply side of the pharmaceutical market have the effect of limiting the degree of price competition between products and extending the use of marketing as a means of product differentiation. This may result in a distortion of incentives for R&D wherein excessive incentive is given for generating and then promoting products offering only incremental changes relative to existing technologies.

Stimulating Innovations for Health

Given the market anomalies present in the pharmaceutical sector, patents may generate imperfect incentives for pharmaceutical innovation. Potential shortcomings are evidenced at a local level by private R&D investments designed to imitate existing treatments with just enough distinctiveness to earn a unique patent. On a global scale, imperfect patent-based incentives for pharmaceutical innovation result in a lack of private investment targeting the development of treatments for conditions affecting populations in the developing world.

At a local level, evidence-based drug coverage policy is one form of policy intervention that can help to improve private incentives for pharmaceutical innovation. The aim of such policies is to allocate funding to those drugs that have been proven to achieve maximum health benefits for each dollar spent. While they are often seen primarily as a cost containment strategy, evidence-based drug coverage policies have the ancillary effect of prioritizing and rewarding products that demonstrate added value in the form of health outcomes.

At a global level, evidence-based drug coverage policy will have limited impact on incentives for innovation valued for its impact on the health of poor populations. This is because global inequities related to incentives for innovation stem as much from the level of resources available to purchase treatments for the poor as they do from decisions about which treatments options are chosen.

A number of alternatives have been suggested to improve incentives for addressing global health needs. For example, prizes (rather than patents) for developing certain treatments or advance commitments to purchase such treatments if and

when developed may re-direct private R&D incentives toward previously neglected diseases.⁶

Attracting Innovative Activities

While strategies motivated by the health goals of innovation focus on health outcomes, those concerned with the economic development aspects of innovation target the scientific processes of generating and developing new products. Economic development policies focus on attracting and sustaining R&D activities so as to maximize the spill-over effects for local economies.

There are a variety of factors that influence location decisions for R&D investments including intellectual property protection, tax concessions, proximity to firm headquarters, and availability, quality and cost of local technical infrastructure, including personnel.

Traditionally, governments relied heavily on intellectual property provisions as a means of attracting R&D. However, as these have been internationally standardized through the TRIPS Agreement (1995), patents and related protections are no longer an effective basis for establishing a competitive advantage and thus, for pursuing the economic goals of innovation. Viable mechanisms for attracting R&D therefore increasingly relate to the costs and productivity of doing research in a given region.

Canada's R&D tax breaks are the most generous in the OECD while Canada's level of direct public investment in R&D and scientific infrastructure is among the lowest.⁷ This combination of high indirect incentives through taxes and low direct investment in R&D has been criticized as contributing to an uncoordinated and poorly performing innovation strategy.⁸ Evidence from countries such as Switzerland, which offers no tax breaks yet has far higher R&D investment rates than Canada, would suggest that Canada's approach may be worth reconsidering.⁹

An alternative R&D strategy would be to engage in targeted direct investment with the intent to create strategic industry clusters characterized by concentrations of human capital and infrastructure in a single industry or group of related industries.¹⁰ However, it is as yet unclear which approach to attracting R&D investment will have the greatest effect in terms of stimulating valued pharmaceutical R&D in Canada.

⁶ Gallini, S Scotchmer (2002) "Intellectual Property: When Is It the Best Incentive System?" Innovation Policy and the Economy

⁷ OECD (2005) Science, Technology & Industry Scoreboard. <http://www.oecd.org/sti/scoreboard/>

⁸ Howitt (2007) "Innovation, Competition and Growth: A Schumpeterian Perspective on Canada's Economy." C.D. Howe Institute. <http://www.cdhowe.org/>

⁹ OECD STI Scoreboard Table A12.1: Rate of tax subsidies for USD 1 of R&D, 2004. OECD, STI/STP Division, April 2005.

¹⁰ Porter (1998) "Clusters and the New Economics of Competition." Harvard Business Review.

Recalibrating Pharmaceutical Innovation – a Call for Research

The pharmaceutical sector is in the midst of what is increasingly being recognized as an “innovation deficit,” characterized by increased drug costs, increased R&D investment, and decreased introduction of breakthrough treatments. This situation is at least partially a result of the market mechanisms and regulations being applied to this sector. These mechanisms will need to be adjusted if society wishes to see the billions of dollars invested in pharmaceutical R&D translate into improvements to health outcomes and quality of life. We will also need to acquire a more sophisticated understanding of the relationships, dependencies and tensions that underlie the economic and health objectives of pharmaceutical innovation.

The situation signals a call for research that reframes the questions and re-examines the issues related to pharmaceutical innovation. The agenda should recognize the dual goals of pharmaceutical innovation, understand the motives and behaviours of a for-profit industry and appreciate the highly complex and unique workings of the pharmaceutical sector. It must also acknowledge the growing urgency of the situation and the opportunity cost of waiting to refocus pharmaceutical innovation on what matters.

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Visit our website for information about our policy conference: www.chspr.ubc.ca

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