# Negotiating Trust in the Canadian Blood System: Governance and the Politics of Public Accountability in the Wake of the Tainted Blood Scandal

by

### JAY FIDDLER

### B.A. Carleton University, 1997 M.A. The University of British Columbia, 2004

## A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

### DOCTOR OF PHILOSOPHY

in

## THE FACULTY OF GRADUATE STUDIES (Sociology)

## THE UNIVERSITY OF BRITISH COLUMBIA (Vancouver)

May 2011

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#### Abstract

Blood and its derivatives are critical public health resources. Therefore, the ability to ensure a sufficient and safe supply of blood is a central role for governments and blood organizations. The challenges involved in ensuring this complex resource became evident following the contamination of blood supplies in the 1980s and 1990s with the Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV). In Canada, this became known as the "tainted blood scandal", with approximately 2000 people infected with HIV and more than 160,000 people infected with HCV through contaminated blood products. This crisis resulted in the loss of public trust in the Canadian blood system and in those responsible for its management. The public outcry led blood experts and governments to adopt more efficient ways of anticipating and managing emergent threats to blood safety by implementing the precautionary principle. These efforts also aimed to retain their legitimacy and rebuild public trust by integrating formal mechanisms of stakeholder engagement in risk governance.

By using stakeholder engagement as a case study, this study focuses on the institutional processes of rebuilding trust in the Canadian blood system following the tainted blood scandal. The analysis describes competing ideas about trust, risk and responsibility in the blood system and traces the influence of stakeholders groups such as the hemophilia community and other blood consumer organizations. The findings suggest that stakeholder engagement primarily serves the interests of the blood operator by enhancing its reputation as a responsible manager of the blood system. It also diverts attention away from the role of the state in managing blood risk through expert systems

ii

and a policy of strict adherence to the precautionary principle. The analysis also demonstrates that stakeholder engagement can also serve as an alternative form of power and influence for hemophilia consumers. As victims of tainted blood, these consumers are able to play a unique role in endorsing blood safety and thus helping to rebuild reputation and public trust. However, because of this role they may also become an organizational risk if their interests are not reflected in blood policy.

#### Preface

Smith, AP, Matthews, R., Fiddler, J. (2011) Blood donation and community: Exploring the influence of social capital. *International Journal of Social Inquiry*. Vol:4 No:1 January 2011. This publication derived out of a study entitled "The Social Determinants of Blood Donation: Examining the Role of Social Capital, Ethnicity, and Trust." Parts of this publication, particularly the historical context of the blood system, appear in Chapter 2 were written by me. The study was conducted over four different research sites (Surrey, Vancouver, Richmond and Kelowna), each with a Canadian Blood Services blood donor clinic. I did interviews with 42 participants (out of 103) and approximately 25 hours of participant observation in two different sites (Kelowna and Vancouver). Along with the other co-investigators, I helped to establish the data analysis codes derived from interview data, document data and participant observation and then analyze the data for write up.

UBC Behavioural Research Ethics Board certificates #B04-0554 (for the 'Sponsored Agency of the Canadian Institutes of Health Research) and certificate #04-0024 (for the Bayer Blood Partnership Fund).

Smith, A.P. and J. Fiddler. (2009). Making the Gift of Life Safer: The Canadian Tainted Blood Scandal. (pp. 491-505). In Health, Illness and Health Care in Canada. 4th edition. B. S. Bolaria and H.D. Dickinson (Eds.). This book chapter provides an overview of the tainted blood scandal and its regulatory consequences. My contribution centers around the sections outlining the history of the Canadian tainted blood scandal and the procedures and policies subsequently put in place to manage blood risk. I also contributed to the theoretical framework, which is outlined in the section titled "Blood and the Risk Society." Material for this chapter comes from Chapters 2 and 3 of my dissertation. The data derives from a review of the existing literature, not from interview data.

Tab	le of	Contents

Abstract	ii
Preface	iv
Table of Contents	v
List of Tables	ix
List of Figures	x
Acknowledgements	xi
Chapter One: Governing Risks and Trust through Stakeholder Participation	1
Chapter Two: Setting the Stage: Responding to Tainted Blood and Public	
Distrust	10
A Historical Overview of Blood Contaminations in North America	11
Emergence of Acquired Immunodeficiency Syndrome (AIDS)	11
Emergence of Hepatitis C (HCV)	14
The Krever Inquiry: Recommendations for a New Canadian Blood System	15
Blood Consumers: The Hemophilia Population in Canada	19
The Current Canadian Blood System: Two New Blood Operators	20
Rethinking Blood Safety: Governing Risks, Public Accountability and Trust	22
Public Accountability and Precaution	25
Gaps in the Literature	28
Overview of the Dissertation	30
Chapter Three: Theorizing Stakeholder Participation in Risk Governance	33
Conceptualizing Blood Risks in the Risk Society	34
Access Points and Trust Building	37
Governmentality and the Stakeholder Society	40
A Governmentality Perspective on Governing	41
Public Participation as a Strategy of Government	43
Risk as a Strategy of Government	45

Governmentality and the Blood System	46
Risk, Culture and Moral Responsibility	49
Summary and Conclusions	54
Chapter Four: Methodology and Context: The How, the What and the Who	57
The How: Research Methods	57
Interview Participants: Description of Sampling Frame	58
Expert Advisory Committee on Blood Regulation (EAC-BR)	61
Canadian Blood Services (CBS)	64
Interview Protocol	67
Document Collection	70
Data Analysis	73
Summary and Conclusions	77
Chapter Five: Public Participation in Regulatory Risk Governance: Representatives of Governmental Responsibility for Blood Safety	79
Situating the EAC-BR in the Regulatory Environment: Tainted Blood and the	82
Creating a New Pegulatery Environment	05 ۸۷
Redefining Risk and Responsibility in the Canadian Blood System	04 86
Concentualizing Risks and Responsibilities	80 97
Precaution as a Representation of Responsibility	, o 80
Precaution Trumps Sufficiency and Cost	09
Establishing Law Participation in Regulatory Blood Decision Making	
The Bole of Access Points to Expert Risk Management Bodies	06
I av Membershin on the EAC-BR: Redefining Public Participation	100
Lay Members: Representing History and Trust through Responsibility	100
Providing Public Perspectives on Scientific Decision-Making	101
Expert Knowledge and the Challenge of Lay Participation	108
The Role of Blood Consumers on the EAC-BR	112
Summary and Conclusions.	123
Chapter Six: Consumer Stakeholder Participation in Canadian Blood Services Legitimacy, Public Trust and the Power of the Blood Consumer	<b>:</b> 127
Canadian Blood Services: Tainted Blood, Justice Krever and the Making of a New Blood Operator	121
	131

Overview of Canadian Blood Services Mandate	133
Stakeholder Participation in Canadian Blood Services	134
The National Liaison Committee (NLC)	136
Stakeholder Influence in Canadian Blood Services	137
Rebuilding Trust through Moral Capital: The Role of Consumer Stakeholders	138
The Expertise of Consumer Stakeholders	143
Points of Tension and Reputational Risk	145
Points of Tension: Risk Priorities	149
Prioritizing Risk Containment Above the Issue of Cost	154
Consumer Inclusion as a Form of Risk Management	160
Trust, Risk Management and Blood Sufficiency	161
Consumer Stakeholders as Endorsers of CBS	164
Summary and Conclusions	168

Chapter Seven: Science, Precaution and Stakeholder Interests: An Examination of the Men Who Have Sex With Men (MSM) Blood Donor	
Deferral Policy	172
The Politics of Blood Safety: An Overview of the MSM Deferral Policy	175
Identifying At Risk Populations: Key Players and Controversies	175
Challenges to the MSM Policy	179
Stakeholder Positions on the MSM Policy	
Contrasting Views on Discrimination and Rights	
Different Views on Science, Uncertainty and Acceptable Risk	188
Acceptable Risk and Precaution	191
Different Views on Trust and Sufficiency	196
Reviewing the MSM Policy: Examining Stakeholder Influence	198
Regulatory Reviews of the MSM Policy	200
Regulatory Positions on Policy: Science and Visible Precaution	201
Public Intolerance of Blood Risk	
CBS Reviews of the MSM Policy	
Access Points and Contingent Trust	210
The Relationship Between CBS and Health Canada	
Impact of Regulatory Responsibility on CBS	
Acceptable Risk, Consumer Endorsement and Trust	

Summary and Conclusions	
-------------------------	--

Chapter Eight: Conclusion	
Building Trust: Responsibility, Precaution and the Role of Moral Capital	
Trust, Precaution and Certain Publics	
Building Trust: The Unique Role of Hemophilia Consumers	
Moral Capital and Trust as Power in the Stakeholder Society	
Limitations	
Future Research	
Implications of Engaging the Public in Risk Decision-Making	
References	
Appendix A – Contact Letter	
Appendix B – Interview Questions	
Appendix C – Documents Analyzed	

### List of Tables

Table 4.1, Total Number of Interviews with Canadian Blood Service and Expert	
Advisory Committee – Blood Regulation	61

## List of Figures

Figure 4.1, He	alth Canada Organi	ational Chart	
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#### Acknowledgements

This dissertation would not have been possible without the support of my family – both biological and chosen. First, I have to thank my parents, Brenda and Wayne, and my sister, Jerri. They have provided unfailing support for me over the years, including places to stay and a great boat for our yearly fishing trip.

I want to thank Edge for all his support, particularly in the early stages of this research when I was trying to balance school and the many health challenges I faced with the diagnosis of Stills Disease. He was always there to help out, including having to carry me up the stairs and deal with my medications when I was unable to do so. I could not have made it through graduate school without you.

I want to thank Gord for all his love and support over the past five years. You have been an amazing resource in all ways possible. Thank you for listening to me while I rambled on about the blood system and the nature of risk and trust. Even when it must have bored you to tears and confused you beyond words, you were there to provide feedback and keep me on track.

Thanks to my advisor, Ralph Matthews for his support, input and encouragement. I also want to thank my committee members, André Smith and Rich Carpiano for their support and input over the past few years. Your guidance has helped to strengthen the analysis and, ultimately, the dissertation.

Thanks must also go out to the other graduate students that have provided support over the years. From late night phone calls to a much-needed glass of wine, you made all the difference. In particular, I want to thank Laura Huey, Marnie Westerman and Billy Flynn for giving me their encouragement and making me laugh when I needed it most.

xi

Last, but not least, I want to thank the participants who agreed to be part of this research. Their honesty and trust is the foundation of this study. Without them, this study would not have been possible. They agreed to speak with me about issues that were very personal and for that, this research is richer. I hope that I have appropriately and honestly captured your thoughts and experiences.

#### **Chapter One:**

#### **Governing Risks and Trust through Stakeholder Participation**

Blood and its derivatives are critical public health resources and serve as key factors in saving millions of lives each year. With the advent of new medical procedures to treat a host of diseases and illnesses, human blood usage is on the increase in most nations (Canadian Blood Services [CBS], 2005). For this reason, the ability to ensure a sufficient supply of safe and available blood for citizens is a critical role for governments and blood organizations. The challenge of ensuring the safety and sufficiency of this complex resource became increasingly evident following the contamination of blood supplies in the 1980s and 1990s with Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV). These viruses infected hundreds of thousands of individuals across the world (Krever, 1997; Wilson et al., 2001). In Canada, this was one of the worst public health disasters in the country's history and became known as the "tainted blood scandal." More than 2000 people throughout Canada were infected with HIV and more than 160,000 people were infected with HCV (Krever, 1997) through contaminated blood products. The hemophilia population was one of the hardest hit communities as they were reliant on blood products that were created using thousands of pooled donors. It is estimated that over 1000 hemophiliacs were infected with HIV and many more with HCV (Canadian Hemophilia Society [CHS], 2010).

In the aftermath, Canada, as with many Western nations, established a special commission to examine what factors contributed to these contaminations, and to recommend changes necessary to ensure it never happens again (Krever, 1997; Weinberg et al., 2002). Led by Justice Horace Krever, the inquiry, known as the Krever Inquiry. reviewed all activities of the blood system, including the events that surrounded the contamination of the blood supply. It also compared the organization and effectiveness of current and past blood systems in Canada and similar systems in other counties with voluntary donation systems (Krever, 1997). In addressing the shortcomings that led to the tainted blood scandal, and laving out the foundations for a new blood system in Canada. Justice Krever centered on two fundamental and inter-related areas: safety and accountability. Indeed, a distinguishing characteristic of Justice Krever's recommendations was his decision that the new blood system should have the mandate and authority to put safety first by clearly establishing lines of accountability for decision making to the public (Krever, 1997). He put forth fifty recommendations that were to serve as the basis of the new blood system. In doing so, he identified key changes required to ensure a safer and sufficient supply of blood and blood products as well as to increase public accountability and trust in the blood system. This led to fundamental changes in the governance of the blood system and renewed efforts to enhance the use of scientific evidence and a precautionary approach to decision-making in the development of risk management policies (Wilson, McCrea-Logie & Harvey Lazar, 2004; Wilson et al., 2007).

In Canada, this meant that the Red Cross, which had been responsible for running the Canadian blood system, was forced to withdraw from the collection and distribution of blood. Two new blood operators, Canadian Blood Services (CBS) and Héma Québec (HQ) were created to take over blood collection. CBS is responsible for managing all aspects of

the blood system outside of Québec, with HQ responsible for managing the blood system in the province of Québec (Wilson et al. 2004).<sup>1</sup> In addition to the creation of two new blood operators, the Krever Inquiry recommended clearer lines of accountability and responsibilities for blood safety between the federal, provincial/territorial governments and the two blood operators (Wilson et al., 2004; Wilson et al., 2007). While these are complex and will be discussed further in *Chapter 2*, in general, the federal government is responsible for blood safety, the provincial/territorial governments are responsible for funding the blood system and the blood operators are responsible for the collection, management and processing of blood and blood products (Wilson et al., 2004).

In response to public outrage and the collapse of public trust and confidence in blood safety, it became increasingly evident to policy makers and blood operators that practices to manage risk could no longer be focused solely on issues of contamination and the technical management of contamination risks (Ezekiel, 2006; Krever, 1997; Ponte, 2006; Weinberg et al., 2002). As most Western systems relied on voluntary donors to ensure a sufficient supply of blood and blood products, re-establishing public trust and accountability for blood safety also became a key concern (Hergon et al., 2005; Krever, 1997; Ponte, 2006; Wilson et al., 2004). For that purpose, blood systems implemented a variety of accountability measures, with a key one being *public participation*, or the inclusion of stakeholders into decisions about blood safety (Hergon et al., 2003; Krever, 1997; Ponte, 2006; Wilson et al., 2004).

In Canada, public participation became a key feature of the blood system and is formally embedded in the governance structures at the regulatory level and within each of

<sup>&</sup>lt;sup>1</sup> For the purposes of this study, I will focus specifically on the CBS as it covers the majority of the country and I am not restricted by language issues.

the blood operators (Ezekiel, 2006; Krever, 1997; Wilson et al., 2003). Participatory processes were implemented to provide a way to incorporate into blood safety decisions the concerns and experiences of a diversity of stakeholders, including: members of the public, health professionals and blood consumers or users (Ezekiel, 2006; Wilson et al., 2004). While there are many different stakeholders involved in the Canadian blood system, and there are differences in participatory processes between the regulator and the blood operators, particular effort has been made to ensure the involvement of consumer stakeholders or representatives of blood consumer groups such as the Canadian Hemophilia Society (Wilson et al., 2004; Wilson et al., 2007).

At the regulatory level, public participation is characterized by the inclusion of lay members on the Expert Advisory Committee for Blood Regulation (EAC-BR) (Health Canada, 2006). Lay members are those that represent the community at large or the public (Health Canada, 2006). At the time of this study, the lay members included one representative from the Canadian Hemophilia Society (CHS), one member from St. John's Ambulance and one member representing the general public. Within CBS, public participation processes involve a diverse stakeholder list, including: members of the general public, blood donors, medical professionals, representatives from other health/disease organizations such as arthritis and blood consumers; including the hemophilia and thalassemia populations.

The inclusion of stakeholders caught the attention of social scientists and health policy researchers, who were concerned about the implications of such changes to the governance arrangements of blood systems on blood systems (Berner, 2007; Boven, 'tHart & Peters, 2001; Feldman & Bayer, 1999; Hergon et al., 2005; O'Neill, 2003; Ponte 2006; van Zwanenberg & Millstone, 2005). Some of this work has highlighted the complexity of

balancing issues of blood safety, precaution, and the technical aspects of risk management, with those of public accountability and public trust (Hergon et al., 2005; Ponte, 2006; Rousell, 2003; Wilson et al., 2004). Of particular relevance, their commentaries underline the increasing reliance that governments and blood operators place on public participation processes to demonstrate accountability and re-build public trust in blood safety. As noted by Hergon et al. (2005), in their research on the French blood system, "the participation of all interested parties in policy decision making is an essential part of the method for managing potential risks because it responds to social demands for transparency and accountability in the face of blood safety issues" (p. 279).

There is generally a consensus that public participation has been important in rebuilding public trust and support (Ezekiel, 2006; Krever, 1997; O'Neill, 2003; Wilson et al., 2007). However, several researchers have argued that the need to re-establish public trust and confidence in blood safety also prompted governments and blood operators to implement precautionary risk measures that are financially costly and negatively impact blood safety by reducing the supply of blood available (Farrell, 2006; Hergon et al., 2006; O'Neill, 2003; Wilson et al., 2004). As Wilson et al. (2007) point out, precautionary measures established in the Canadian blood system to manage risks have increased costs but "only marginally improved the safety of the blood supply" (p.182) and threatened the sufficiency of the blood supply. These researchers argue that such measures are reflective of government and policy makers' "risk aversion," (Wilson et al., 2007) driven by an awareness of the legal and public health consequences of risk policy decisions. Recent comments have suggested that the inclusion of stakeholders, namely consumer stakeholders, have been particularly influential in prioritizing certain types of risks and promoting precautionary blood safety policy and measures to policy makers (Hergon et al.,

2006; O'Neill, 2003; Ponte, 2006). As O'Neill (2003) states, "the problem is that often the measures taken to ensure trust of blood recipients in the system will undermine the trust of blood donors" (p. 372).

Although recent research rightly draws attention to the impact of participatory processes on blood system decision-making, particularly the influential role of consumer stakeholders in risk decisions, less attention has been devoted to explaining how their roles are viewed by governments, regulatory bodies and blood operators, and what factors shape the conceptualization of stakeholders and their roles. Research has also not paid sufficient attention to understanding how the prioritization of certain stakeholders, namely consumers, could impact the participation of other stakeholders. For example, if consumer stakeholders hold a prioritized role in blood system decision-making, what role do other stakeholders, such as members of the general public, as well as those representing other disease groups or health professionals, have in blood system decision-making? Additionally, despite the consensus that stakeholder participation is important for trust building, there is little understanding of how stakeholders build trust, what mechanisms stakeholders use to promote public trust in blood safety and whether there are differences in this regard between the various stakeholders. There is also a clear absence of any conceptual analysis of participatory processes, which significantly limits our understanding of how these processes operate and their consequences. Finally, little has been written about the influence of stakeholders on blood operators as most attention has focused on governments and regulatory bodies.

Underlying this study is the assumption that stakeholder involvement in the Canadian blood system provides an opportunity for a more comprehensive analysis of their participation. While the responsibilities of the federal and provincial levels of government

and CBS have been well documented (Wilson et al., 2004; Wilson et al., 2001), little attention has been paid to study the impact of participatory processes on blood system decision-making. Drawing upon analysis of 27 in-depth interviews conducted with a range of stakeholders, including members of the EAC-BR and participants within CBS, as well as textual analysis of organizational and regulatory documents, this study examines the integration of participatory processes into the governance structures of the blood system following the tainted blood scandal and the Krever Inquiry. It investigates the involvement of stakeholders in blood safety policy decisions, examining the mechanisms through which stakeholders are integrated into the blood system, the way various stakeholders, regulatory experts and CBS representatives understand decisions about risks and safety, and the implications of these participatory processes on maintaining a safe, sustainable and sufficient supply. Of particular interest is the manner in which stakeholders understand the precautionary principle as a safety measure and its potential impact on donor motivation and the sufficiency of the blood supply. In investigating participatory processes, this research also compares the role of consumer stakeholders to that of other stakeholders involved in blood policy decisions, and seeks to determine whether there are differences in their influence on blood policy.

Studying the nature and function of public participation in blood system decisions is sociologically significant because the topic taps into issues of trust, risk, morality and responsibility, as well as the relationship between civil society and the state. To fully explain the role of stakeholders in blood safety policy decisions, I use a conceptual framework that draws upon aspects of the *risk society*, the notion of governmentality, particularly the recent comments on the *stakeholder society*, and cultural analyses of risk. Each of these perspectives enables an analysis of how risks are conceptualized and how

participatory processes function as sources of legitimacy for governments and organizations, as well as for stakeholders themselves.

It has been widely acknowledged that there is a growing awareness among citizens of their exposure to risks (Lupton, 1999; Petersen, 2003). At the same time, there is a declining trust in scientific expertise, largely because some of the greatest environmental and health risks in society have either been caused by scientific and technical developments, or by the failure of science, experts and governments to protect us (Beck, 1992; Giddens, 1990; Petersen, 2003). As a result, trust becomes a key issue for policy makers. Trust plays a critical role in facilitating collective action and provides the basis for legitimizing the actions of government and organizations (Giddens, 1990; Gilson, 2003). In response, there has been an increasing push to implement public participation processes as a way to provide support and legitimacy for risk decisions (Petersen, 2003; Power, 2003). This contemporary relationship between "citizens and the state is mirrored in the newlyemergent notion of the stakeholder society" (Petersen, 2003, p. 194). Here, the relationship between agencies of the state and stakeholders is based on the idea of *mutual obligation*, with an expectation that stakeholders serve as *sources of legitimacy* if they are to have a say in the agencies of the state (Petersen, 2003).

Drawing upon these ideas, I will show how participatory processes, particularly the inclusion of consumer stakeholders, are conceptualized as potential mechanisms for policy makers and the blood operator to legitimize blood safety decisions. This legitimacy, in turn, serves to help increase public trust and support for the blood system. However, these participatory processes are situated within a context of a recent and remembered history of contamination, tainted blood trials, the Krever inquiry and renewed responsibilities for blood safety. I argue that these were, and continue to be, socially, culturally and

historically significant events that frame the Canadian blood system. This shapes stakeholder participation in the blood system by influencing who is involved and the roles that they play, as well as re-defining how risks are interpreted and managed in new governance structures.

At the same, as I will show, while participatory processes function as a way to serve the interests of governments and the blood system, they also serve as alternative forms of power and influence for consumer stakeholders, their communities and causes. The ability of blood consumers to draw upon their historical experiences as victims of tainted blood to legitimize the work of governments and CBS means they are able to maintain support for their own interests, place and value in the system. Therefore power is not simply top down, or even something that works through the populace. There are ways that power comes from below, allowing consumer stakeholders to extract concessions they feel are important for their groups. This has important implications on the participation of other stakeholders, such as health professionals, and for the blood system in general.

This research contributes to a more comprehensive understanding of how public participation processes have been integrated into the Canadian blood system, and the implications of these processes on blood policy. In particular, it adds a dimension to the existing literature by providing a Canadian perspective, particularly one that focuses on organizational issues. To date, research has focused on the involvement of stakeholders at the regulatory level. While valuable, it does not fully account for the roles of stakeholders in blood safety decisions within blood operators. This study addresses this gap in knowledge by exploring how stakeholders, particularly consumers, are able to shape blood safety policies of Canadian Blood Services.

#### **Chapter Two:**

#### Setting the Stage: Responding to Tainted Blood and Public Distrust

This study is concerned with the integration of participatory processes into governance structures of the Canadian blood system following the tainted blood scandal and the Krever Inquiry, and the implications of these processes for ensuring a safe, sufficient and sustainable blood supply. This chapter provides a brief review of the events surrounding the tainted blood scandal and the decisions subsequently made to safeguard the Canadian blood supply in the early days of the contamination. This review highlights the historical and institutional factors that influenced the management of risk and led to contamination of the blood supply. It will also help to contextualize the current blood system and illustrate changes to the management of risk, particularly how processes of public accountability have been implemented.

Next, I will review relevant blood literature that highlights the changes that have occurred in the way that blood systems manage risk and accountability. This review provides a backdrop to identify areas of focus and gaps in the existing literature. In particular, it draws attention to the involvement of stakeholders in risk decision-making, the roles these stakeholders play in regulatory and CBS governance structures, and how their involvement shapes the management of risk.

#### A Historical Overview of Blood Contaminations in North America

In the late 1970s and the 1980s the Canadian blood supply, along with that of most Western nations, became contaminated with two infectious viruses: Human Immunodeficiency Virus (HIV), which causes Acquired Immune Deficiency Syndrome (AIDS) and the Hepatitis C virus (HVC). More than 1,000 persons in Canada were infected with HIV through the blood supply. For these individuals, the development of AIDS from HIV was invariably fatal. HCV infected tens of thousands of persons in Canada, with many going on to develop chronic hepatitis, cirrhosis of the liver and liver cancer (Krever, 1997). Individuals became infected through the blood supply either in a hospital for surgery or through factor concentrates, such as Factor VIII, made from the pooled plasma of thousands of donors and used to treat hemophilia. Additionally, partners who had already been infected with one or both of these viruses unknowingly also infected other people. Below I will briefly outline the timeline of each virus and the measures taken by governments and blood operators in the U.S. and Canada to identify and manage these contamination risks.

#### **Emergence of AIDS**

Acquired Immune Deficiency Syndrome (AIDS) first emerged in North America in the early 1980s. However, in the early stages of recognition, it was called GRID, which stood for Gay Related Immunodeficiency, as most of those affected were gay men. In late 1980 and early 1981, the Centers for Disease Control (CDC) in the U.S. received reports of homosexual men suffering from *Kaposi sarcoma* (KS) and *Pneumocystic carinii pneumonia* (PCP). By late 1981, there were over 70 cases reported and by the end of 1981, the CDC was investigating 160 cases of GRID (Krever, 1997). By 1981, GRID (renamed AIDS in 1982) was seen not only in gay men, but also injection drug users and heterosexual women (Krever, 1997; Shiltz, 1987). By early 1982, a "cluster" of KS and PCP cases was identified among American homosexual men. The same year, the *Morbidity and Mortality Weekly Report*, published by the CDC, reported three cases of PCP in American hemophiliacs treated with factor VIII, which is a antihemophilic factor given to people with hemophilia (Schiltz, 1987, p. 206). These cases supported an emerging theory that an infectious agent was responsible for AIDS and that it was contaminating the blood supply (Krever 1997). This prompted the U.S. Food and Drug Administration and the U.S. National Hemophilia Foundation to recommend that blood not be collected from the populations considered most at risk for AIDS: Haitians, homosexuals, intravenous drug users, and individuals with signs and symptoms of AIDS.

In early 1983, U.S. blood banks began to implement measures to prevent those individuals considered high risk for AIDS from donating blood (Bayer, 1999). Most of these measures centered on educating the public and these specific populations to refrain from donating blood. For example, pamphlets were distributed describing the groups at high risk of contracting AIDS, the symptoms of AIDS, and requesting individuals belonging to those groups and/or having the symptoms of AIDS not to donate blood (Krever, 1997). Additionally, blood clinic staff began to directly question individuals to determine whether they belonged to a high risk group or had the signs and symptoms of AIDS, and if so, excluded them from donating blood (Krever, 1997; Smith and Fiddler, 2008).

The March 1982 *Canada Diseases Weekly Report*, which was a publication of the Bureau of Epidemiology, Laboratory Centre for Disease Control of the federal government, published the first reported case of a homosexual man infected with PCP

(Krever, 1997). By August of that year, eight cases of AIDS were reported to the Health Protection Branch in Canada and in October, twelve more cases of AIDS were reported: seven among homosexual men, five in persons from Haiti, and one in a person from Africa (Gilmore & Sommerville, 1999, p. 32). By December, a Montreal study concluded that hemophiliacs treated with factor VIII had immune deficiencies similar to those of nonhemophilia patients infected with AIDS. At this point, the Canadian Bureau of Biologics called upon the Canadian Red Cross and the Canadian Hemophilia Society to monitor the disease among hemophiliacs so as to track the early impact on this population (Krever, 1997).

Although many recommendations to reduce infections in the Canadian blood supply arose in early 1982 (such as surrogate testing and donor screening) many were not instituted until the mid to late 1980s, or not at all. Canada lagged well behind many countries in the implementation of such critical safety policies (Krever, 1997). As noted above, the U.S. instituted donor screening early in 1983. Yet, the Canadian Red Cross' only real response was to issue two press releases describing the groups at risk of contracting AIDS and asking members of those groups not to donate blood. Following that effort, the Red Cross developed a pamphlet that described AIDS, which was to be handed out at blood clinics. Yet, even this pamphlet was not distributed until 1984 and when it was, there was little accountability to ensure that all blood clinics were handing it out (Krever, 1997). In addition, as noted by Krever, (1997), blood donor recruitment staff "had little involvement in, or understanding of, the issues raised by AIDS and volunteers in the blood donor program were ill-suited to deliver a message concerning homosexuality that would result in the exclusion of donors" (p. 291).

In the end, it was not until 1986 that the pamphlet was revised to include a description of those high-risk groups unable to donate blood. Moreover, despite the fact that HIV was identified in 1984, and the HIV antibody test was available early in 1985 and being used by many countries including the U.S. and Australia, Canada did not begin testing until late November of 1985. Research has shown that, had testing been implemented as soon as it was available, approximately 133 people would not have been infected with the HIV virus (Krever, 1997).

It was in these early days that stakeholders, particularly hemophilia consumers and their health care providers, began advocating for the Red Cross to be more accountable and cautious in their risk decision-making (Krever, 1997). However, despite their involvement in helping to monitor the impact of these contaminations on blood user populations, consumers and other members of the public were not included in the decision-making processes. There was no mechanism to allow these groups, particularly those who were being severely impacted, to have input in risk decision-making (Ezekiel, 2006; Picard, 1995). As we will see in the upcoming discussion on the *Commission of Inquiry on the Blood System in Canada*, the lack of public accountability and access to risk decisionmaking became a central concern of the inquiry and was addressed by Justice Horace Krever in the final recommendations of his report.

#### **Emergence of Hepatitis C (HCV)**

The risks of transmitting hepatitis through blood have been known for many years. In 1965, Hepatitis B was discovered in Australia. By 1972, the Canadian Red Cross had implemented a test for Hepatitis B. In 1974, scientists postulated that there was another form of Hepatitis in existence, referring to a non-A, non-B Hepatitis. While the virus had not yet been identified, in 1981 a report published in the *New England Journal of Medicine*  suggested that testing blood donations for ALT (a liver function test) would decrease the occurrence of post-transfusion non-A, non-B Hepatitis by 40 percent (Krever, 1997). In addition to ALT testing, research in the early 1980s showed that testing for the anti-HBc (antibody to the core of the Hepatitis B virus) would further reduce the incidence of non-A, non-B Hepatitis. However, in the early days, both the U.S. blood operators and the Canadian Red Cross recommend against the implementation of surrogate testing for non-A, non-B Hepatitis, arguing for the need for further evidence.

While Germany was the first nation to implement surrogate testing in 1984, U.S. blood fractionators began testing in late 1985. It was not until 1986 that the U.S. Food and Drug Administration, the American Association of Blood Banks and the American Red Cross recommended that both ALT and anti-HBc testing of blood donations be implemented. Despite the implementation of testing in the U.S., Germany and other countries, the Canadian Red Cross continued to recommend against surrogate testing for non-A, non-B Hepatitis until further evidence of efficacy could be established. In July 1988, the same year that the virus for non-A, non-B Hepatitis was discovered (later known as HCV), factor concentrates, such as Factor VIII, began to be heat treated, however surrogate testing was still not implemented. It was not until June 1990 that the Canadian Red Cross implemented HCV antibody testing. Three years later, two Canadian researchers showed that, had Canada implemented surrogate testing earlier, there would have been significantly less post-transfusion Hepatitis in Canada (Krever, 1997).

#### The Krever Inquiry: Recommendations for a New Canadian Blood System

In response to the national blood crisis and public outrage, the subcommittee on Health Issues of the Parliamentary Standing Committee on Health and Welfare, Social Affairs, Seniors, and the Status of Women held hearings between November 1992 and April 1993. Its mandate was to determine the circumstances that resulted in the contamination of blood and blood products. The Committee concluded that the Canadian blood system did not respond in a timely and adequate manner to the threat of HIV/AIDS (Krever, 1997). However, they were unable to determine the reasons for this delay, thereby recommending a more robust public inquiry to investigate the circumstances that surrounded the contamination of the national blood supply (Krever, 1997). In September 1993, the federal, provincial, and territorial Ministers of Health, with the exception of Québec that held their own review, recommended that a public inquiry be established. Led by Justice Horace Krever, the inquiry was tasked to review all activities of the blood system, including the events that surrounded the contamination of the blood supply, as well as compare the organization and effectiveness of current and past blood systems in Canada and similar structures in other counties with voluntary donation systems (Krever, 1997).

Justice Krever heard testimonies of experts and members of the public, particularly consumer stakeholders representing the hemophilia population (Kirp, 1999). First, he held "organizational hearings," which brought together federal and provincial governments, the Red Cross, the Canadian Blood Agency, Connaught Laboratories, which was the major supplier of blood products in Canada at the time, as well as other organizations such as the Canadian AIDS Society and the Canadian Hemophilia Society, to represent organizational interests and perspectives. In addition, three sets of public hearings were held that brought the voices of the public, including those infected or affected by the contamination of the blood supply, to the inquiry. These hearings addressed a range of issues including: personal experiences of those infected by HIV or HCV, historical relations or actions between the blood operator, private pharmaceutical companies and governments that

contributed to the contaminations as well as recommendations for a new blood system (Krever, 1997).

In addressing the shortcomings that led to the tainted blood scandal, and laying out the foundations for a new blood system in Canada, Justice Krever centered on two fundamental and inter-related areas: safety and accountability. Indeed, a distinguishing characteristic of Justice Krever's recommendations was his decision that the new blood system should have the mandate and authority to put safety first by clearly establishing lines of accountability for decision making to the public, particularly the consumer public (Krever, 1997). He put forth fifty recommendations that were to serve as the basis of the new blood system. In doing so, he identified key changes required to ensure a safer and sufficient supply of blood and blood products as well as to increase public accountability and trust in the blood system. These included a recommendation to centralize decisionmaking by creating a system with a publicly accountable administrative structure – with its CEO reporting to a Board of Directors that included public representatives – and with a focal point of accountability lying with the CEO. Along with recommending a more accountable governance structure, Krever stated that the functions of the new blood system - collection and processing of blood and blood products should be tightly regulated by Health Canada in order to ensure a safe blood supply (Krever, 1997). In addition, Krever (1997), recommended that to ensure blood safety, the blood supply system be governed by the precautionary principle, a "public health philosophy, which rejects the view that complete knowledge of a potential health hazard is a prerequisite for action" (p.1048). Finally, he made specific recommendations for the inclusion of a broad range of stakeholders, particularly consumers or blood users, at all levels of the blood system (Krever, 1997).

As this research is primarily concerned with public participation processes and the roles of stakeholders in the Canadian blood system, it is relevant to outline in more detail the specific recommendations that Justice Krever established regarding public engagement and accountability in the new blood system. In responding to what he saw as a central gap in the decision-making process of the Red Cross, Krever (1997) recommended, "the public must have access to information about the policy, management, and operations of the blood supply system and be represented in the decision-making" (p. 91). To do so, he made specific recommendations for the implementation of public participation processes within the new blood operator responsible for English Canada, as well as the regulatory system.

At the level of the blood operator, Krever (1997) recommended that, in order to address the lack of confidence and openness in the blood operator, the Board of Directors include representatives from the consumer community and blood donors. Additionally, he outlined the creation of committees that would serve an advisory role to the Board of Directors, including those for safety (both scientific and technical) and liaison, stating that, "to promote the principle of openness, all committees should have as members representatives from consumer groups and the public" (Krever, 1997, p. 1055).

At the regulatory level, Krever again made specific reference to the involvement of the public. In his recommendation regarding the creation of an Expert Advisory Committee to help in risk assessment, Justice Krever spoke of the need to include consumer representatives as one aspect of interest and expertise. In addition to the formal inclusion of consumers, he also spoke of the importance of the regulator in being open and accessible to the public (Krever, 1997). For him, this meant ensuring that reports and regulatory documents that emerge from the work of the committees, which are not confidential, were accessible to the public.

#### **Blood Consumers: The Hemophilia Population in Canada**

As with many nations, in Canada the hemophilia population was severely impacted by the contamination of blood in the 1980s and 1990s. Over 1,000 Canadian hemophiliacs were infected with HIV, tens of thousands more with HCV, and many were infected with both viruses (Gilmore & Sommerville, 1999). For example, by the end of 1982, 56% of hemophiliacs in Montreal were infected with HIV; by 1988, 74% of hemophiliacs were infected with HIV (Gilmore & Sommerville, 1999). As this study is examining the role of stakeholders, with a particular focus on consumers, it is worth providing a brief overview of the disease, treatment and history of hemophilia.

Hemophilia is a heredity disorder found almost exclusively in men. This disorder is characterized by excessive bleeding, as blood does not clot normally. Hemophilia is caused by an absence of one of two proteins, known as the coagulation factors VIII and IX, or by a deficiency in the functioning of one of those factors. There are two types of hemophilia: hemophilia A and hemophilia B. The former, also called classic hemophilia, is the most common and is related to the lack of factor VIII. It affects fewer than 1 in 10,000 people or around 2,500 Canadians. The latter, hemophilia B, also known as Christmas Disease, is characterized by a lack of factor IX. This type of hemophilia affects approximately 1 in 50,000 people or about 600 Canadians (Canadian Hemophilia Society, 2009). While found almost exclusively in men, women can be affected. It also found to affect all races and ethnic origins.

To understand the infections from tainted blood, one has to understand what treatments existed for hemophilia in the 1970s and 1980s. In the late 1960s, concentrates containing factor VIII and IX were available to treat hemophilia. This allowed

hemophiliacs to treat themselves at home, rather than having to go into hospitals. However, these clotting factors put hemophiliacs at risk of HIV and HCV as they were made of pooled blood from potentially thousands of donors. Therefore, any single unit could contaminate the entire pool and thus the product. Moreover, because of the lack of plasma derived from donors in Canada, about half of the factor concentrate used in Canada was manufactured in the United States from paid donors. Research has shown that these donors had higher rates of hepatitis and HIV than voluntary donors (Krever, 1997).

While blood transfusion recipients also experienced high rates of infection during the 1980s and early 1990s, they were not organized and had no broader group representation. In contrast, the Canadian Hemophilia Society, which had been established in 1953, served as an important source of expert and lay information on all issues related to hemophilia. For this reason, they could respond to these contaminations as an identifiable community, playing a key role in collecting evidence of the infections in their populations and calling for a full-scale investigation into the process that led to the contamination of the Canadian blood supply (Kirp, 1999).

#### The Current Canadian Blood System: Two New Blood Operators

In 1998, two new not for profit organizations, Canadian Blood Services (CBS) and Héma-Québec (HQ), assumed the responsibility of managing the blood system from the Red Cross. CBS took over responsibility for the blood supply for all of English Canada, following a Memorandum of Understanding (MOU) that was signed by representatives of all of the provinces/territories (except Québec) and which made the organization responsible for collecting, processing, and distributing transfusion-ready blood and blood products. HQ was incorporated as a non-profit organization on March 27, 1998, with

responsibility for the blood supply system within the province of Québec. While these are different organizations, both are regulated by Health Canada and must meet the same national regulatory standards. It is important to state that this research focuses solely on CBS, with no examination of HQ (Wilson et al., 2004). Therefore, in the sections below, I will only speak to the role of CBS, even though there may be mirrored responsibilities within the other blood operator.

As recommended by the Krever Inquiry, there are distinct roles and responsibilities for CBS and the various levels of governments involved in the blood system. The federal government, through Health Canada, is responsible for regulating the safety of the blood system by identifying potentially dangerous pathogens and the populations in which such pathogens are evident. The provincial and territorial governments are responsible for funding and ensuring the delivery of blood services, with CBS responsible for collecting, testing, manufacturing, and distributing blood and blood products (Wilson, et al. 2004).

In responding to Krever's recommendations, public participation processes have been formally implemented in the Canadian blood system. At the regulatory level, public participation occurs mainly through the inclusion of lay representatives on the Expert Advisory Committee on Blood Regulation (EAC-BR). This is the regulatory body that "provides the Biologics and Genetic Therapies Directorate with timely advice on our federal responsibilities within the national blood system related to blood, blood components, blood products, and associated issues" (EAC-BR, 2006, para. 2).

While there exists a range of public participation strategies that operate within CBS, two of the central mechanisms established to engage stakeholders include the National Liaison Committee (NLC), as well as the inclusion of two consumers (or patients) on the Board of Directors (Ezekiel, 2006). In the past six years, "key stakeholders,"

particularly blood consumers, such as those representing the Hemophilia Society, have been included in each major risk decision facing the CBS, including variant Creutzfeldt-Jakob disease (vCJD) and the West Nile virus (Ezekiel, 2006).

#### Rethinking Blood Safety: Governing Risks, Public Accountability and Trust

The management and organization of blood systems has been a point of interest for social scientists since the 1970s, with the publication of Titmuss' (1974[1997]) *The Gift Relationship: From Human Blood to Social Policy*. This text is widely recognized as one of the first and most influential organizational studies on the governance of blood safety and the relationship between structures of the state and the practices of the blood system. His work was so influential it served as a basis for the reorganization of the American blood system from one that was market-based, to a voluntary system, and has served to underlie almost all voluntary blood systems (Healy, 1999; Farrell, 2006).

More recently, social scientists re-focused their attention to study new risk governance arrangements in contemporary blood systems, providing important insights on the changes to the regulation and management of blood systems (Berner, 2007; Boven, tHart & Peters, 2001; Feldman & Bayer, 1999; Hergon et al., 2005; O'Neill, 2003; Ponte, 2006; van Zwanenberg and Millstone, 2005). At the same time, the loss of trust and confidence that most governments and blood operators experienced following contaminations of their blood supplies has served to frame much of the risk management literature and guided the development of blood policy and practice in most nations (Ezekiel, 2006; O'Neill, 2003; Weinberg et al., 2002; Wilson et al., 2004). Out of this loss of trust, attention has been drawn to the increasing reliance on public participation

processes, particularly the inclusion of stakeholders in decision-making, and to their role in helping to demonstrate accountability for blood safety and re-build public trust.

A continued reliance on voluntary blood donation is crucial for establishing trust in blood safety. At the same time, if members of the public do not trust blood systems, they will not be blood donors, resulting in an insufficient supply of blood and blood products. Therefore, the blood system operators see paying attention to public perceptions of risk and including stakeholders as key to re-establish public trust and confidence in blood safety and those responsible for blood systems (Hergon et al., 2005; O'Neill, 2003; Ponte, 2006; Wilson et al., 2004). As Hergon et al. (2005) note, the participation of "all interested parties" is seen as an essential aspect of risk management as it contributes to "confidence in experts, transfusion institutions, and public authorities and this confidence in turn renders risks, particularly those considered uncertain, more acceptable" (p. 276). Moreover, policy decisions "derived from a collective development process make subsequent legal action difficult, if not impossible" (Hergon et al., 2005, p. 279).

There is wide agreement on the value of participatory processes for re-building trust and support. However, there is also an acknowledgement of the challenges that arise in balancing the technical requirements of risk management with that of public trust and confidence. One complexity often raised that is particularly relevant to this research is the issue of scientific uncertainty and the application of the precautionary principle to the management of risks (Ponte, 2006; Rousell, 2003; Wilson et al., 2003). In contemporary blood systems, decisions about risk and blood policies are guided by the precautionary principle, which rejects the view that complete knowledge of a public health hazard is a prerequisite for action (Wilson et al., 2003). The use of this principle was originally applied in the context of environmental policy as a way to enable governments and policy

makers to mitigate potential risks to the environment despite the lack of conclusive proof of the risk and its extent (Wilson et al., 2003).

Increasingly, the precautionary principle has been applied to health policy decisions and, since the contamination of blood systems with HIV and HCV, the precautionary principle has been used as a "guiding principle in managing infectious risks to nations' blood systems" (Wilson et al., 2003, p. 89). In the context of blood systems, the use of the precautionary principle also serves to demonstrate public accountability for blood safety while at the same time re-building public trust and confidence (Hergon et al., 2005; Wilson et al., 2007). However, as we will see, these processes are complex and influential in shaping blood safety policies (Rousell, 2003; Wilson et al., 2003).

Several researchers have raised concerns about the impact of a wholesale application of the precautionary principle on blood systems (O'Neill, 2003; Ponte, 2006; Weinberg et al, 2002; Wilson et al., 2007). One issue concerns the financial burden of implementing the safety measures needed to deal with an increasing number of theoretical risks (O'Neill, 2003; Ponte, 2006; Weinberg et al, 2002; Wilson et al., 20007). Following Krever's recommendations, the federal regulator in Canada is not responsible for the costs of operating the blood system – that is a provincial and territorial responsibility (Wilson et al., 2007). It has been suggested that because of this arrangement, there is no motivation for the regulator to take into account cost effectiveness when mandating new safety measures. This lack of motivation could potentially jeopardize the future financial viability of the system if federally mandated safety measures end up being too costly for the provinces and territories to bear (Wilson et al., 2007).

Researchers have also expressed concerns about the impact of an increasing number of deferrals on the sufficiency of the blood supply (Hergon et al., 1995; O'Neill,
2003; Ponte, 2006; Wilson et al. 2004, 2007). For example, CBS lost approximately 3.5% of its donor basis when it deferred donors who lived or travelled to Western Europe between 1980 and 1996 because of the "theoretical risk" of exposure to variant Creutzfeldt-Jakob disease (vCJD) (Wilson et al., 2001). This is a human form of Bovine Spongiform Encephalopathy (BSE) also known as mad cow disease. Until 2004 it was considered a theoretical risk since researchers had found no definitive evidence that vCJD could be transmitted by blood (Canadian Blood Services, 2009b).

As these examples demonstrate, in order to understand the role and impact of stakeholders in contemporary risk governance arrangements, it is also necessary to attend to issues of scientific uncertainty. In this context, it is important to examine how participatory processes and the conceptualization of stakeholders are established in the context of the precautionary principle and the need to manage uncertain or theoretical risks.

### **Public Accountability and Precaution**

In modern blood systems, the emergent and unpredictable nature of contamination risk presents a unique problem to be managed by governments and blood operators (Hergon et al., 2005; Ponte, 2006; Roussel, 2003; Wilson et al., 2007). To address this, governments and blood organizations have relied on an approach to risk decision-making known as the precautionary principle. The use of the precautionary principle is generally justified under two conditions: a lack of scientific certainty about the nature and severity of the risk, and the potential for the risk to cause "serious and irreversible damage" (Ewald, 2002, p. 284). Originally developed as an approach to deal with environmental threats such as global warming, the precautionary principle now guides the management of a much broader range of risks, including health risks (Moreno, 2003; Wilson et al., 2003). As a

strategy to manage theoretical risks – those risks carrying potential rather than actual or known threats - the precautionary principle favours the use of safety measures when such risks have the potential to cause significant harm (Chiavetta et al., 2003; Ewald, 2002).

Not surprisingly, research on blood system risk management has discussed the precautionary principle in relation to issues of public accountability and trust (Ewald, 2002; O'Malley Weir, & Shearing, 2000; Wilson et al., 2003). In these discussions, researchers often note that the adoption of this principle has had a significant impact on how blood systems make decisions about risks. In modern blood systems, the precautionary principle has served to create new responsibilities for governments. regulators and blood operators with regard to blood safety (Rousell, 2003; Wilson et al., 2003). As noted by Roussel (2003), whereas previously politicians and blood system administrators could claim that some risks were beyond their control, in the new climate, precaution and prudence serve to symbolize responsibility on the part of decision-makers and politicians, and, thus, legitimate an increased responsibility of the state in managing potential risks to citizens. In that context, "scientific uncertainties have henceforth to be translated into public health policies or other systematic measures to show that all the precautions have been taken to be close to zero risk" (Roussel, 2003, p. 128). While Roussel's work focuses on the French blood scandal, her analysis equally provides an important framework by which to view the changes in the roles and responsibilities for risk and uncertainty in the Canadian blood system.

In his report, Justice Krever (1997) recommended that the Canadian blood system adopt a precautionary approach to risk decision-making, addressing a key criticism of the Red Cross, which was that it delayed excluding people at high risk for HIV from donating until there was sufficient evidence to confirm HIV as a blood-borne pathogen. Justice

Krever found that the Red Cross could have prevented many cases of infection had it deferred high-risk donors on a precautionary basis instead of waiting for scientific confirmation of the HIV threat. Like France, the behaviour of Canadian blood system administrators was criminalized and major changes regarding the roles and responsibilities to the management of risk occurred. This led to an increase in the regulation of risk along the lines of precaution and prudence, and an increased role for the federal government as the sole party responsible for blood safety (Wilson et. al, 2004). In this context, safety is a priority. Thus, the management of risk must now consider theoretical risks, such as vCJD and West Nile, in the event that "a potential disease-causing agent is or may be blood borne, even when there is no evidence that recipients have been affected" (Wilson et al., 2003, p. 90).

The formal involvement of stakeholders into risk governance arrangements in Canada forces us to ask what roles they play in precautionary decision-making, and the implication of their involvement. This is particularly important in light of research suggesting that the inclusion of consumers, in an effort to build trust, plays an important and influential role in precautionary decision-making (O'Neill, 2003; Ponte, 2006). For example, in her article "Politics of Blood Donation in the Era of Mad Cow Disease," O'Neill (2003) suggests that, in a desire to maintain public credibility and trust, governments and regulatory bodies implement precautionary risk measures to ensure the trust of recipients, or consumers. For her, as with Ponte (2006), this reflects only one aspect of trust – that of the recipient. The problem with this is that in developing trust with one aspect of the public, the system risks losing it with another important public – the donors. This loss of trust raises the possibility of it contributing to a different risk – an insufficient supply of blood and blood products.

### Gaps in the Literature

These arguments underline how political and historical factors mediate precautionary risk management decisions, providing important insights on how issues of blood safety and public accountability are addressed in contemporary blood systems. Of particular relevance to this study are recent comments suggesting that stakeholders, particularly consumer stakeholders, have been able to shape blood safety decisions because of the perceived influence they have in helping re-establish public trust and confidence in how risks are identified and managed (Hergon et al., 2006; Ponte, 2003). However, some aspects of this issue require further examination.

First, while research rightly draws attention to the increasing roles of stakeholders in blood system decision-making, less attention has been paid to understanding how governments, regulatory bodies and blood operators view stakeholders. What is missing is a more nuanced examination of the factors that influence state and public conceptualizations of stakeholders, as well as their roles in shaping decisions about risk. In the pages that follow, I will address this question by identifying and describing the various stakeholders within the blood system and their roles, as well as investigating the factors that shape these participatory processes. As we will see social, structural and cultural factors, including the tainted blood scandal and the Krever Inquiry, influence who is involved, how they are involved and what roles stakeholders play in blood safety decisions.

A second problem that arises in much of the literature centers on the role of participatory processes in re-establishing trust. There is a consensus about the value of participatory processes on helping to re-establish public trust in blood systems. However,

within existing research, there is little understanding of how stakeholders build trust and the differences in this regard across the various stakeholders. Moreover, little attention has been paid to understanding how trust is conceptualized and the differences between the various stakeholders in this regard. I will investigate how stakeholders build public trust, paying particular attention to the practices and mechanisms used by stakeholders, particularly consumer stakeholders, to promote public trust in blood safety.

Third, research has rightly drawn attention to the unique role of consumer stakeholders in blood system decision-making. However, researchers have paid little attention to how the involvement of consumers may shape the participation of other stakeholders. If consumers and their perspectives on risk are prioritized as a way to ensure their support and trust, what roles do other stakeholders, such as members of the broader public, as well as those representing other disease groups or health professionals, have in bringing forth their perspectives and experiences? Moreover, what impact does this have on the blood system?

These questions lead us into a fourth issue arising from the literature, namely, the lack of conceptual analysis of participatory processes. As a result, there is very little understanding of how participatory processes function in practice and their consequences on blood system decision-making. As I will show, there is a need to examine how participatory processes serve as a form of mutual benefit between policy makers, the blood operator and stakeholders, particularly consumer stakeholders. I argue that by serving as a source of legitimacy for decisions regarding blood safety, consumer stakeholders, particularly those representing the hemophilia population, are able to extract concessions that are in the interests of their community. In this way, participatory processes need to be examined as alternative forms of power and influence for consumer stakeholders.

Finally, little has been written about the influence of stakeholders on blood operators. With the exception of comments by Wilson et al. (2004) when discussing public participation, existing research focuses on the regulatory and governmental level and largely ignores the significant role that the blood operator plays in risk decision-making. This is particularly relevant from a Canadian viewpoint as the blood operator can introduce safety measures that exceed those set by the regulator (Wilson et al., 2004). Given that stakeholder participation is integrated into CBS decision-making structures, it is important to understand the influence of these stakeholders on shaping that organization's response to potential risks.

### **Overview of the Dissertation**

This study examines the integration of participatory processes into the governance structures of the blood system following the tainted blood scandal and the Krever Inquiry, by investigating the involvement of stakeholders in blood safety policy decisions. It examines the implications of these participatory processes on maintaining a safe, sustainable and sufficient supply, the mechanisms through which stakeholders are integrated into the blood system, and the way various stakeholders, regulatory experts and CBS representatives negotiate decisions about risks and safety. Of particular interest is the manner in which stakeholders understand and advocate for the precautionary principle as a safety measure, and the potential impact of this on donor motivation and the sufficiency of the blood supply. In investigating participatory processes, this research also compares the role of consumer stakeholders to that of other stakeholders involved in blood policy decisions, and seeks to determine whether there are differences in their influence on blood policy. In *Chapter 3*, I discuss the conceptual framework that guides my analysis through an exploration of the literature on the risk society and on governmentality, paying particular attention to recent analyses of the stakeholder society, and of risk. These perspectives will be used to provide a better understanding of how participatory processes function as sources of accountability and legitimacy in a blood system that balances competing interests, responsibilities and roles. In *Chapter 4*, I present the methodology that guides the empirical analysis. There, I discuss the collection of data, including organizational and regulatory documents, as well as my interview strategy. I also speak about the analysis of the data and the limitations of qualitative methods.

Chapters 5 through 7 contain the findings of this study. In Chapter 5, I explore how stakeholders have been included at the regulatory level of the blood system, through an examination of the role of lay representation on the Expert Advisory Committee for Blood Regulation (EAC-BR). I argue that the role of lay members on the EAC-BR can be understood as an important way to incorporate non-expert public perspectives on blood risks, build trust, and fulfill a governmental responsibility to be transparent and accountable. However, I situate lay representation in the context of a recent history of contamination and a renewed responsibility for the regulator of blood safety. As I show, this has resulted in a more technocratic approach to risk management that prioritizes scientific evidence and scientific expertise and influences who is able to participate as a lay member on the EAC-BR. Here, risks are constructed mainly around issues of contamination and trust, and are associated with good scientific decision-making and adherence to the precautionary principle. Therefore, lay representation serves mainly to demonstrate accountability for a science-based and precautionary approach to risk decision-making. This raises important questions about the role of stakeholders in

scientific decision-making and has implications for the integration of public participation in regulatory policy decision-making.

In Chapter 6, I examine the role of stakeholders in CBS through interviews with CBS management, members of its Board of Directors and members on the National Liaison Committee. I argue that, within CBS, the need to re-build trust and ensure a safe and sufficient supply of blood requires different roles for stakeholders, particularly consumer stakeholders. Unlike at the regulatory level, these roles center on actively and publicly building and maintaining public trust and legitimizing decisions of CBS, particularly in relation to blood safety. CBS considers trust to be fragile and dependent on the public endorsement of CBS blood safety policies by stakeholders, particularly consumer stakeholders. Consumer stakeholders, in particular hemophilia consumers, draw upon their historical experiences and participate actively in CBS, thus legitimizing the organization's policies. From a CBS perspective, this type of endorsement also serves to encourage the public to donate blood voluntarily. This role affords consumer stakeholders a level of influence on risk management policies, which allows them to request that more emphasis be placed on certain aspects of risk, particularly precaution and science in the identification of risks. I suggest that this has an impact on how other stakeholders see their participation in decisions about risks and blood safety.

*Chapter 7* examines the *men who have sex with men* deferral policy. This policy highlights the complexities of defining who is a stakeholder, what their roles are, and what impact they have in the identification and management of risks to the blood system.

*Chapter 8* concludes with an examination of the implication of these findings within the larger context of democracy, civil society and the roles of citizens in risk governance.

## **Chapter Three:**

#### **Theorizing Stakeholder Participation in Risk Governance**

In this chapter, I discuss the conceptual framework that guides this examination of participatory processes in the Canadian blood system. As noted in the previous chapter, research on blood systems has drawn attention to the complexity of balancing issues of blood safety, precaution, and the technical aspects of risk management, with those of public accountability and public trust (Hergon et al., 2005; Ponte, 2006; Rousell, 2003; Wilson et al., 2004). However, much of the previous research does not address the impact of participatory processes on the blood system, nor does it fully consider the role of consumers in blood safety policy decisions. Moreover, prior research lacks an analysis of trust and the conceptualization of stakeholders in relation to issues of accountability and legitimacy. In contrast, the conceptual framework developed below provides a basis for enhancing our understanding of how participatory processes function and their consequences on policy decisions.

In the following discussion, I draw upon aspects of the literatures on the risk society, specifically Giddens' (1990, 1991) analysis of trust and *access points*. In addition, I incorporate the Foucauldian concept of *governmentality*, particularly recent comments on the *stakeholder society* (Macintyre, 1999; Petersen, 2003). Finally, I incorporate Douglas' (1990, 1992) cultural analyses of risk. Together these perspectives will serve to provide a conceptual framework to this study, which as noted, will allow for a broader understanding

of the integration of public participation into the governance structures of the Canadian blood system, how these processes function and their impact on the blood system.

## **Conceptualizing Blood Risks in the Risk Society**

The contamination of Western blood supplies in the 1980s and early 1990s, and the ongoing issues facing policy makers over the need to address actual and potential risks. have been called a "textbook example of the risk society" (Beck, 1992, p. 48). This is not surprising as many of the issues facing blood system policy makers epitomize examples of what theorists have described as the risk society. These events exemplify the breakdown in Western societies of the prevention and management of risks that has led citizens to become increasingly aware of their exposure to risk, to the point where such awareness has become an all-pervasive aspect of industrial society. Unlike pre-modernity, in which risks were considered supernatural and thus beyond the control of humans, in late modernity, many risks are generated by humans and represent a failure of science and technology. Additionally, rather than being confined to specific locals, risk in late modern society are global in nature, thus having wide spread effects (Beck, 1996; Giddens, 1991). For Giddens, the development of social institutions and experiences of risk in late modern society are characterized by three key features. The first is the reorganization of space and time across multiple contexts both past and present. The second being "disembedding mechanisms", such as expert systems, that serve to "lift out social relations from local contexts of interaction across indefinite spans of time-space" (Giddens, 1990, p.21). This third feature is institutional and individual "reflexivity" (Giddens, 1990).

Giddens (1991) sees the reorganization of space and time as a primary influence on the way citizens understand the management of risks in modernity. In pre-modernity, most

citizens experienced the world as it unfolded in specific localities. In contrast, the rise of technologies of communication and transportation in late modernity has unified experience across space and time and established "a single world, a sense of awe as humanity facing problems and opportunities together, which never existed in pre-modernity" (Giddens, 1991, p. 27). The contaminations of most Western blood supplies with HIV and HCV demonstrate the broad and unifying reach of risks in contemporary societies. Countries were not able to respond individually to blood systems risks, nor were any countries immune to contamination problems. For example, in Canada the contamination of our blood supply resulted from both our national donors as well as through the purchasing of plasma from American donors (Krever, 1997).

The reorganization of space and time acts as a disembedding mechanism, lifting out social relations from their local contexts and restructuring them on the basis of standardized and abstract forms of knowledges. This reorganization requires the use of other disembedding mechanisms, namely "symbolic tokens", such as money and means of political legitimacy, as well as expert systems or what he terms, "abstract capacities" (Giddens, 1990, p. 22). By symbolic tokens, Giddens (1990) means "media of interchange which can be passed around without regard to the specific characteristics of the individuals or groups that handle them at any particular juncture" (p. 22). In the Canadian blood system, the association between voluntary blood donation and altruism can be understood as a symbolic token. However, in the context of this study, I draw upon the notion of symbolic token to help explain the roles of stakeholders in the blood system. I will demonstrate how consumer stakeholders utilize their historical experiences as victims of the tainted blood scandal to provide legitimacy for decisions about blood risks. In this way, these experiences serve as symbolic tokens of safety and good decision-making by policy

makers and CBS. Additionally, I use the notion of symbolic token as a way to understand the implementation of the precautionary principle and its role in trust.

The second disembedding mechanism, which Giddens (1990) refers to as expert systems or "abstract capacities", are understood as "systems of technical accomplishment or professional expertise that organize large areas of the material and social environment in which we live today" (p. 27). Like other technological activities in modernity, the expert management of risks is a standardized practice that cuts across local contexts and displaces local forms of knowledge. Because these systems rely on complex technical knowledges that are not accessible to non-experts, citizens have no choice but to trust that these systems operate according to plan in protecting them against harm. Trust is also necessary because these systems are neither present in immediate time and space nor unavailable for local scrutiny.

At the same time, Giddens cautions, while we are forced to rely on expert knowledge, the involvement of human action in the development and identification of modern risks has brought about challenges to the validity of this knowledge in the eyes of the public (Giddens, 1990). This "reflexivity" as Giddens (1991) calls it, means that individuals and institutions reflect on their circumstances and consider the "contingent nature of expert knowledges and social activity, [such as their] susceptibility to revision and change [or] contradiction" (p. 85). The contradictory nature of expert knowledges, and past failure to respond to uncertain risks, such as discussed earlier with the past blood contaminations, has lead to greater uncertainty and a declining trust in scientific expertise. This is a problem as trust is key to managing uncertainty in situations that are perceived to be inherently risky. As Giddens (1991) states, "what is seen as acceptable risk – the

minimizing of danger – varies in different contexts, but is usually central in sustaining trust" (p. 35).

Giddens' discussion of expert knowledge and reflexivity is particularly relevant for this study. In light of the past failure of blood policy makers to anticipate the impact of HIV on the blood supply and recipients of blood, expert bodies, at the regulatory level and within the blood operators, have been established to ensure blood safety. However, because of the past failings of the blood system, the public has lost trust and confidence in the experts making decisions (Ezekiel, 2006). This means blood systems have had to implement measures that bridge experts and interested publics. Giddens' notion of "access points" is particularly useful in understanding such measures and the roles they play in the Canadian blood system.

### **Access Points and Trust Building**

For Giddens (1990), in late modern societies, trust is "not in individuals, but in abstract capacities such as symbolic tokens and expert systems, both of which depend on trust." (p. 26). Indeed, from Giddens' (1990) perspective, trust is "involved in a fundamental way with the institutions of modernity" (p. 26). The contingent nature of expert knowledge means that expert systems need to provide access points to increase acceptance and gain public trust (Giddens, 1990). These access points provide a way for individuals to directly confront those responsible for the development and/or implementation of abstract systems of expertise. Central to the development of trust through these access points is the ability for representatives to display trustworthy characteristics during encounters (Giddens, 1990). Often, these take the form of educational campaigns to demystify the complex practices of expert systems or consultations and engagement with members of the public in policy and decision-making

processes. Without those access points, expert systems run the risk of losing legitimacy and alienating the members of the public they seek to govern (Giddens, 1990). For Giddens (1990), the mechanisms used to produce trust in expert systems of late modernity are, most often, reliant upon the connection, or what he terms access points between the lay public and expert systems, as well as information sources such as media.

Participatory processes in the blood system can be understood as access points whereby lay individuals, specifically past victims of tainted blood, such as hemophilia consumers, are able to participate in expert systems, thereby helping to build public trust in the blood system. As Powers (2003) suggests, in modern risk management systems, stakeholders play a key role in managing public reputation, or as he terms it, "reputational assurance". By drawing stakeholders' interests into the organization, and incorporating them into decision-making, he argues that organizations are able to tap into a form of legitimacy that provides support for organizational decisions. Barnes (1999) raises a similar idea in her research on the role of users in community care services decisionmaking. She demonstrates how mental health consumers and disabled people were conceptualized as a form of accountability and enhanced legitimacy in relation to policy decisions (Barnes, 1999). However, both Barnes (1999) and Power (2003) argue that the ability to legitimize decisions is not uniform, but influenced by the type of stakeholder who participates in the organizations.

This last point underscores a conceptual contribution I will make to Giddens' concept of access points. While Giddens speaks of the lay public in a general sense, his analysis does not distinguish between types of publics. Yet, as I will show, certain types of publics provide more value (re: trust and legitimacy) for governments, policy makers and the blood systems. For example, as noted by Hergon et al (2005) and O'Neill (2003),

consumer stakeholders who represent the hemophilia public play a more influential role than other stakeholders do in blood safety decisions because of their past experiences as victims of tainted blood. For this reason, a more nuanced examination of stakeholder participation is required to understand the various conceptualizations of stakeholders, illuminate how these shape their roles, and their influence on the blood system.

At the same time, the tenuous nature of building public trust may result in undesirable consequences such as distrust or lack of public participation and support. Giddens (1990) warns that, while access points may help to foster trust, they also represent *places of tension* between lay individuals and expert systems potentially resulting in distrust, cynicism and a lack of participation or disengagement from the system. Godbout (1998) expresses a similar warning when he argues that the points of contact between the state and individuals can have "perverse consequences if the actions are not in line with the beliefs and relationships people hold dear" (p. 61). A similar caution is echoed by Power, (2003) who argues "not all stakeholders recognized by such systems are equally important from a risk management point of view, in the sense of being equally capable of directly damaging reputation" (p. 156). This is a salient point to consider. As I will discuss in *Chapter 6*, while stakeholders and policy makers over safety decisions that are seen to have the ability to negatively influence trust of the public.

The work of Giddens contributes valuable insights about the articulation of risk and trust in modern society. However, this perspective has been criticized for its lack of recognition of the moral aspects of risk practices, as well as for failing to acknowledge how these aspects shape participatory processes and contribute to new forms of responsibility for policy makers and stakeholders (Rousell, 2003; Smith and Fiddler,

2008). As I will discuss in the next section, these moral aspects of the management of blood risks in Western blood systems that require exploration. To do this, I will draw upon Foucault's work on governmentality, as well as recent writings from this perspective on the stakeholder society. I will also incorporate perspectives from Douglas' work on risk and culture.

### **Governmentality and the Stakeholder Society**

In recent years, Western democratic governments, organizations and businesses have implemented processes to bring stakeholders into decision-making structures (Power, 2003; Abelson, Gauvin, MacKinnon and Watling, 2004). Increasingly, such processes are seen as important ways to build consensus for decisions that affect populations. This is particularly the case in relation to decisions about risks that have the potential to impact citizens, or in the case of corporations, decisions that may impact their shareholders. Additionally, these processes provide protection from legal liability by enabling policy makers or boards to demonstrate that all relevant groups and individuals have had a say in decisions that may affect them. This has been the case in the Canadian blood system where bringing the public, particularly consumers of blood, into decision-making structures has provided a way to bring in their perspectives and gained their support while also reducing the potential for liability of decisions that may be the wrong ones (O'Neill, 2003; Wilson et al., 2004). In that sense, we can examine these processes as an apparatus of governmental control that ensures that the interests of the state are met, while at the same time reducing the potential for negative public fallout about the decisions that the state makes on risk management.

The work of Foucault on *governmentality* helps better understand the role these processers play in risk governance. Over the past decade, Foucault's work has had tremendous influence on sociologists and health researchers who have examined the strategies, practices and institutions that have developed around risk (Contandriopoulos, 2004; Joyce, 2001; Petersen, 2998; Petersen & Lupton, 1996). Therefore, while Foucault did not deal directly with the topic of risk, his theory of governmentality is considered relevant to a sociological analysis of risk. Hence, it has been drawn upon to analyze risk as a cultural, political and social concept, intersecting with contexts of regulation and responsibility (Hunt; 2003, Lupton, 1999; Peterson, 2003). Below, I will discuss how Foucault's notion of governmentality provides an important framework with which to analyze how stakeholder participation has been articulated in relation to risk practices and the interests of government policy makers. It helps to reveal some of the moral or value perspectives that shape public participation processes and influence stakeholders' roles in decisions regarding risks to the blood system.

### A Governmentality Perspective on Governing

Foucault (1988) conceptualizes *governmentality* as the art of government, describing it as the "reason of state" (p.153) in reference to its nature and rationality. In government, Foucault (1988) sees an activity that not only shapes the conduct of people directly and coercively, but also constitutes them in such ways that they can be voluntarily governed in a way that meets the needs and interests of the state.

In this way, the theory of governmentality highlights the everyday relations of power, which extend beyond the state to include micro-institutional relations of power that order societies and transform human beings into subjects to be governed by others and by themselves. By this, Foucault meant that governance was not just an external practice that targeted populations from outside, but also a practice that motivated individuals to govern their own behaviour, ensuring that they assume measures of personal responsibility for their actions in a manner consistent with government policy interests and state regulation. According to Foucault (1993), "governing people is not a way to force people to do what the governor wants; it is always a versatile equilibrium, with complementarity and conflicts between techniques which assure coercion and processes through which the self is constructed or modified by himself" (p. 203-204).

Foucault's governmentality approach has important implications for understanding civil society and civic practices. Hardt (1998) argues that Foucault's assertion of power existing everywhere denies "the analytic separation of political society and civil society" (p. 28). From a governmentality approach, civil society operates as a fundamental site for the exercise of power. As Foucault (1991) argues, "it is the population itself on which government will act, either directly through large-scale campaigns, or indirectly through techniques that will make possible, without the full awareness of the people, the direction of the population in a manner consistent with their needs" (p. 100). Indeed, from a Foucauldian perspective, political power and rationalities do not simply exist in particular institutions such as the police and army. Rather, they are mediated through all institutions of civil society, even though they may seem "as if they have nothing in common with political power, and as if they are independent of it, while they are not" (Chomsky & Foucault 1997, p. 130).

### **Public Participation as a Strategy of Government**

For governmentality scholars, the notion of community and participatory strategies serve as salient examples of how the interests and rationalities of government are translated into practical interventions. In particular, Rose (1996) argues, "community has become a new specialization of government, [what he calls] government by community" (p. 332). In particular, he highlights the notion of *active citizenship* or *community involvement* in which "new modes of neighborhood participation, local empowerment and engagement of residents in decisions over their own lives will, it is thought, reactivate self-motivation, self-responsibility and self-reliance" (Rose, 1996, p. 335). Building on these insights, Marinetto (2003) agrees that community engagement is a form of government. He argues, "government has played an integral part in the burgeoning of active citizenship" (Marinetto, 2003, p. 117) by implementing policies that support and encourage active citizenry. Drawing on examples in the literature and his own analysis of the British Labour Party's community engagement processes, he shows how community has become a "new specialization of government" (Marinetto, 2003, p. 109), reactivating self-responsibility and self-help and providing a new way for government to ensure the prioritization of their interests. However, he cautions that too often governmentality scholars downplay the role of government in such strategies. Instead, Marinetto (2003), argues that active citizenship and community involvement demonstrate "that central government is not an impotent force in wider social matters", which is further evidenced by the lack of a "substantive transfer of power" (p. 117).

These works suggest that it is critical to pay attention to whether participatory processes represent a shift in power, or simply function to maintain the interests of government and decision-makers. Thus, when examining the role of stakeholders in the

Canadian blood system, we must pay attention to whether their involvement is merely a form of tokenized accountability for government, policy makers and CBS management, or an exercise in power that shapes blood safety policy decisions.

Foucault's conceptions of self-governance and power have been used as a framework to understand important changes to the field of health, including governance, policy and practice issues. One area that has drawn upon the governmentality perspective, and that is particularly relevant to this research, is the notion of the *stakeholder society* (Petersen, 2003; Macintyre, 1999). Petersen (2003) argues that, increasingly in health care, we are confronted with the notion of the *stakeholder* or *consumer* who has come to replace the notion of the *passive* or *inactive* patient or citizen. This notion comes with "new obligations and a new set of relationships with experts and agencies of the state in which all citizens and consumers have a responsibility to contribute and participate in managing risks to health" (Petersen, 2003, p. 194). In the stakeholder society, there is a mutual obligation between government and citizens, one in which citizens have an obligation to provide a contribution in order to have a say in policy processes (Macintyre, 1999).

Sociologists have drawn upon Foucault's work to explain participatory processes and the influential roles of stakeholders in relation to issues of power and legitimacy. A salient example can be found in the research by Gustaffson and Driver (2005) that examines the roles of parents in program setting for children in the U.K.'s "Sure Start Programs." The authors argue that a Foucauldian approach provides a way to view stakeholder involvement, not just as a "predictable part of governance in modern Western democracies where subjects need to be recruited to exercise power over themselves" (Gustaffson and Driver, 2005, p. 529). Rather, user involvement in policy discussions can exist as an alternative form of power for users to "contest, resist and re-interpret"

(Gustaffson & Driver, 2005, p. 541) policy and program decisions. Joyce (2001) puts a similar idea forward in his analysis of priority setting in the National Health Service of the U.K. Joyce (2001) argues that consumer stakeholders are useful to policy makers as they bring in the perspectives of users, helping to legitimate policy decisions. For this reason, consumer stakeholders are also able to influence priority setting in a way consistent with their own interests.

### **Risk as a Strategy of Government**

As this study is concerned with understanding the role and impact of participatory processes on decisions about blood risks, it is necessary to discuss how Foucault's work on governmentality has informed the risk literature. According to many sociologists and policy researchers, a Foucauldian perspective provides valuable insight into the ways in which discourses, strategies, practices and institutions around risk serve to bring it into being and construct it as a phenomenon requiring intervention (Hunt, 2003; Lupton, 1999). From this perspective, risk is understood as a governmental strategy by which populations are managed and monitored in a way that adheres to the interests and needs of the state (Lupton, 1999).

Central to this strategy are tools of the state, such as expert knowledges, or what Foucault calls *risk techniques* that provide the "guidelines and advice by which populations are surveyed, compared against norms, trained to conform with these norms, and rendered productive" (Lupton, 1999, p. 87). These risk techniques are valuable for governance arrangements, allowing governments to manage risks at the population level. In this way, certain groups can be identified as *high risk*, thereby requiring broad interventions based on specific knowledge and expertise. Within the blood system, an example is the creation of deferral criteria to remove potentially dangerous donors from infecting the blood supply

with pathogens such as HIV, HCV, vCJD and West Nile virus. Recipients of blood and blood products are also conceptualized in relation to risk. On the one hand, they are *at risk* with respect to any problems that arise in the blood system as they rely on blood products. On the other hand, they are seen as an *accountability risk* for the system, because of their role in legitimizing risk decisions and helping policy makers appear accountable to build trust.

Changes in the identification and management of risk are aligned with changes in political rationalities, thereby resulting in risk being conceptualized and dealt with in diverse ways that have strong links to ideas about the regulation of the individual by others, as well as how they should "deport themselves in relation to the state" (Lupton, 1999, p. 102). As Foucault (1991) reminds us, practices of governing are not simply top down directives. Practices of governing also include the external governing of public action through governmental policies and protocols for health, the adoption of a precautionary risk management approach and the practices of self-governance. These all serve to inculcate individuals to accept personal responsibility. Thus, risks create new levels of responsibility for individuals and groups who are expected to engage in practices that will at least reduce the impact of risks as in the case of health prevention practices such as weight loss, prenatal screening and genetics.

# **Governmentality and the Blood System**

This study draws upon the governmentality perspective to investigate how participatory processes have been integrated in the risk governance structures of the Canadian blood system. While participatory measures are seen as an important tool for incorporating stakeholders concerns about blood safety, the governmentality perspective reminds us to see them also as mechanisms that reflect the interests of the state. A

governmentality perspective draws attention to the importance of accounting for the political technologies that are used by regulatory agencies and CBS to manage risk. This study considers the management of risk as both a political and scientific process. The intent is to examine how government regulatory agencies, CBS and the various stakeholders negotiate their activities and interests to make decisions about risk and safety.

The discussion of the stakeholder society and the sociological research on participatory processes highlights a general weakness within the governmentality perspective to pay adequate attention to the "messy actualities of social relations" (O'Malley et al., 1997, p. 509), including counter-discourses and forms of resistance. Governmentality theorists have neglected to consider the nature of "strategies and practices initiated from below as themselves constitutive, rather than being merely resistant or adaptive" (Petersen, 2003, p. 197). For this reason, Petersen (2003) argues that we must study how stakeholders "use, manipulate and transform the contexts in which they find themselves" (p. 198). It is too simplistic to see stakeholders "as coerced objects or ideological dupes" (Garland, 1997, p. 183). Rather, contemporary strategies of governance enable "new avenues for action and new claims to citizenship rights based upon concepts such as consumer empowerment and participation" (Petersen, 2003, p. 198). Petersen (2003) remarks, that consumer groups have gained so much influence in the recent past that they should be considered "horizontal networks of governing" (p. 194).

Paying attention to the ways stakeholders are able to "rule from below" seems particularly important given the role that consumer stakeholders play in blood system decision-making through formal and informal involvement. In the coming chapters, I focus on the involvement of stakeholders in the Canadian blood system. I pay particular attention to blood consumers, namely the hemophilia community, whose members were most

affected by the contamination of the blood supply in the 1980s, and to the manner in which they are able to prioritize and advance their interests within the blood system.

Overall, the governmentality perspective offers an important framework to understand the interrelatedness of the state and society, and alerts us about the practices by which governments assert power and promote their interests. It highlights the way in which state interests are mediated through the institutions and organizations of civil society, such as participatory processes in which individuals participate in their own governance (Petersen, 2003). In this way, the governmentality approach directs one's analysis to consider the practices and institutions that serve to construct and manage risk. By doing so, it provides an important framework to examine the practices and mechanisms used to manage risk and public accountability in the Canadian blood system, as well as the consequences of such actions on the ability to ensure a sufficient, safe and sustainable supply of blood. It offers a vantage point from which to examine the articulation of risk practices at the regulatory level as well as within CBS. Further, it provides important insights about the macro-social sources of embeddedness. It thus alerts us to the way in which institutions and organizations of the blood system are anchored in broader political arrangements and "cultural systems of meaning" (Dacin et al., 1999, p. 320). As the blood supply is subsumed within the Canadian health system and is considered a *public good*, government can be seen as having an important role to play in ensuring that this good is not only safe, which is their primary role, but also available to all citizens and managed in a way that ensures public trust and confidence. This implies a more complex role for government and points to the need to examine how the state's interests are reflected in regulatory and organizational policies that guide participatory processes in the Canadian blood system.

At the same time, as discussed above, we also need to examine participatory processes as mechanisms that provide stakeholders, specifically consumer stakeholders, with a way to push forward their agendas and interests. While the governmentality perspective provides an important frame to view participatory processes, there is a need to further conceptualize these practices in relation to socio-cultural factors, as well as moral aspects of risk decisions and issues of accountability and responsibility. This multifaceted view will help to explain how the notion of stakeholder is conceptualized in relation to risk and precaution, and used to advance certain interests and forms of accountability.

### **Risk, Culture and Moral Responsibility**

In recent years, risk scholars have advanced ideas regarding the governing of modern society through cultural interpretation, particularly those regarding the identification and management of risk (Douglas; 1992; Ericson and Doyle, 2003; Garland, 2003; Lupton, 1999). This body of research has served to challenge the idea that risk practices are simply objective, individual, and utilitarian. Thus, in contrast to some of the risk literature, this body of work has produced a range of empirical evidence to demonstrate how socio-cultural assumptions influence the understandings of risk and risk decisions.

Much of this literature draws upon Mary Douglas' (1990, 1992) socio-cultural analyses of risk. A central aspect of her work on risk has been an explanation of how and why certain dangers are identified as risks while others are not, and the way in which these serve to maintain and support boundaries and categorizations (Douglas, 1985, 1966). Douglas claims that the content of beliefs about purity, danger and taboo in any given culture are essentially arbitrary, yet become culturally fixed as *pollution rules*, thereby

serving to organize and reinforce social relations according to hierarchies of power. For Douglas, pollution rules work in two ways. First, pollution ideas work instrumentally, to uphold social rules and the moral order. Second, pollution ideas work as symbols, or "analogies for expressing a general view of the social order" (Douglas, 1966, p. 14). In this way, pollution rules are an extension of the processes of classification because they "impose order on experience" (Douglas, 1966, p. 17) and generate social pressure to conform to the shared values and categories of the social world. Pollution beliefs operate as rhetorical devices within the ongoing cultural debate over the shape and direction of the social order. Yet, pollution beliefs do more than simply enforce conformity. They also protect the implicit assumptions behind shared social experiences, and in so doing, serve to reproduce the social world.

Douglas makes a direct connection between pollution beliefs and a cultural system of shared values. She advances the idea that different cultures denote certain activities as taboo, not because of objective harm that may arise from carrying out these activities, but as a way of maintaining and reinforcing the moral, political, religious or social order that binds members of that culture (Douglas, 1966). From this perspective, each type of society has its own ethical system, which consists of pollution and purity rules to identify risk (Douglas 1985). These rules are often relatively arbitrary, emerging from specific political, cultural, social, and historic contexts and reflecting deeper anxieties, fears and moral codes. These rules of pollution and purity used to identify risk also serve to "contain disorder, to support and bolster social ties, to create unity and experience in particular cultural settings" (Douglas, 1990, p. 3). Thus, different individuals and different communities might judge a risk more or less seriously because they value the consequences differently—they value differentially what is being harmed, who is doing the

harm, and who is responsible in any other way. In this way, the identification, and management of risk is inherently moral and reveals much about our psychological, cultural, social and institutional affiliations, values and norms.

Douglas' attention to the cultural, social, historical, and political influences on the rules of pollution and purity in the recognition and definition of risks is particularly salient for studying the practices used to manage risks in the blood system. Following the contamination of blood supply systems across the Western world, different countries have responded to similar risks in ways that are culturally, socially, and politically distinct. One example is found in the management of HIV, specifically the different approaches to the deferral of men who have sex with men. As we will see in *Chapter* 7, in Canada, men who have sex with men, even once since 1977, are permanently deferred from donating blood (CBS, 2009). Yet, in other countries such as New Zealand and South Africa, men who have sex with men are no longer permanently deferred. Moreover, in some countries "high risk sexual behaviour now includes heterosexual practices (Kondro, 2001). This suggests that risk constructions and risk reduction practices, particularly those related to sexuality, are socially, culturally and politically distinct. These reflect deeper anxieties and moral codes and thus, do not rely exclusively on scientific expertise and knowledge.

The work of Douglas has been particularly valuable in discussions of risk, and responsibility. As Ericson and Doyle (2003) note, the work of Douglas is critical in demonstrating that "risk is part of a political vocabulary of moral responsibility and accountability" (p. 4). For Douglas (1990), "risk is not only the probability of an event but also the probable magnitude of its outcome and everything depends on the value that is set on the outcome. The evaluation is a political, aesthetic and moral matter" (Douglas, 1990, p. 10). In this way, risk is used as a way to force accountability and moral responsibility for

action to "legitimize policy or to discredit it, to protect individuals from predatory institutions or to protect institutions from predatory individuals" (Douglas, 1990, p. 5).

In recent years, sociologists and other academic scholars have drawn upon the work of Douglas in conceptualizing precautionary decision-making as a form of moral responsibility and accountability. For example, Roussel (2003) focused on the criminal proceedings in France in the wake of the tainted blood scandal in that country. She argues that the contamination of the French blood supply changed the way risk management experts (as representatives of the state) and those responsible for safeguarding the blood supply, were held accountable for their failures to manage risk (Roussel, 2003). Thus, whereas previously politicians and blood system administrators could claim that some circumstances were beyond their control, they were now called upon to use prudence and precaution to manage both known and anticipated risks to the blood supply.

According to Roussel (2003), the new level of accountability and responsibility created for governments and blood operators made the adoption of the precautionary principle as a risk management strategy inevitable. The precautionary principle increased accountability by extending the definition of risk "to take into account what one can only imagine, suspect, presume or fear" (Ewald, 2002, p. 286). This sweeping definition certified, "publicly [that] there is no prejudicial event for which the political actor should be held responsible" (Roussel, 2003, p. 129). Under those circumstances, scientific uncertainty cannot be used as an excuse; rather it suggests a need for precaution (Roussel, 2003). In this way, the precautionary principle also protects the political actor from liability because "scientific uncertainties have henceforth to be translated into public health policies or other systematic measures to show that all the precautions have been taken to be close to zero risk" (Roussel, 2003, p. 128).

In Canada, the precautionary principle was adopted by the blood system in the wake of the tainted blood scandal and the Krever Inquiry. In laying out the principles that were to guide the new blood system, Krever (1997) paid specific attention to precautionary decision-making stating:

Preventative action should be taken when there is evidence that a potentially disease-causing agent is or may be blood borne, even when there is no evidence that recipients have been affected. The more severe the potential effect, the lower the threshold should be for taking action." (p. 1049)

As I will show in my analysis, precautionary decision-making demonstrates responsibility and accountability in the aftermath of the tainted blood scandal. It is a way in which the institutional system seeks to right a past wrong. This suggests that ideas about precautionary decisions are influenced by the social and political contexts in which they occur, supporting Hunt's (2003) assertion that "precautionary decisions are culturally loaded" (p. 116). It also supports the decision to use Douglas' framework to examine risks and precaution in the blood system.

As participatory processes have been implemented in the Canadian blood system as a way to re-establish trust and accountability in the aftermath of the tainted blood scandal, any analysis of stakeholder participation must take into consideration their social, cultural and historical contexts. As Hergon et al. (2005) demonstrate, in France consumers play an important role in prioritizing certain risks by drawing upon their past experiences as victims of tainted blood. I will show that the situation is very similar in Canada. The history of the tainted blood scandal lingers in the minds of Canadians, particularly people with hemophilia. This historical memory influences not only who participates in

participatory processes, but also how stakeholders and policy makers conceptualize risks and precaution.

Douglas' work points to a need to deconstruct state discourses and practices surrounding risk, as well as consider how risks become problematized in the first place and how they relate to larger historical, cultural, political and social practices. These discourses and practices are responses to multiple demands – cultural, social and economic – in the broader society. For this reason, it is too simplistic to examine the state as occupying a space from which it dictates the parameters of civic practices. Instead, those practices reflect the values, fears and cultural imaginings of government, social institutions, members of the public, stakeholder groups and expert groups. Just as the state is a product of multiple demands, so too are the risks. It is important to recognize that the definition and management of risks emerge from the specific socio-cultural, political and historical contexts in which they are located. Douglas' framework provides a valuable tool for understanding how participatory processes and stakeholders draw upon cultural, social and historical representations of risk to prioritize their interests and promote particular ideas of responsibility and accountability.

### **Summary and Conclusions**

This study concerns the involvement of stakeholders in the formal decision-making structures of the Canadian blood system. It uses Giddens (1990) conceptualization of risk and trust to understand how certain aspects of participatory processes are involved in relation to the risk management practices that were implemented following past contaminations. The collapse of public trust and confidence has meant that re-establishing public trust in blood safety has become a key goal of both government and the CBS, and is

an important determinant of regulatory practices (Ezekiel, 2006; Wilson et al., 2004). As Giddens (1990) reminds us, a key mechanism for re-establishing trust is through access points, through which members of the public, experts, and policy makers interact to make decisions about risks. Drawing upon Giddens, I will demonstrate how participatory processes serve as access points that policy makers and the public use to re-build trust in the aftermath of the tainted blood scandal. I will use the work of Douglas and the concepts of governmentality and the stakeholder society to provide a more nuanced and deeper understanding of how participatory processes function as sources of legitimacy for policy makers and stakeholders. The overall goal of this work is to show how risk related social processes are shaped by cultural, social and historical factors.

The concept of governmentality also guides the investigation of the governance of risk in the blood system. Important to this is the concept of the stakeholder society (Macintyre, 1999; Petersen, 2003), which will be used to examine the role and impact of the various stakeholders on the blood system. It will also be used to trace how the interests of the state and policy makers are reflected in participatory processes. The concept of the stakeholder society allows one to see stakeholders "not as coerced objects or ideological dupes, but as agents whose subjectivity is formed through active engagement with the [powers] that govern them and through which they govern themselves" (Petersen, 2003, p. 192). I will demonstrate how stakeholder participation functions as a mechanism of legitimacy and trust for governments, but also as an alternative form of power and influence for those so included, particularly consumer stakeholders.

I will also pay attention to the social, historical and cultural context in which participatory processes exist and function, using Douglas' framework of risk. For Douglas, risks are a product of multiple demands and are reflective of the historical, cultural,

political and social contexts. Douglas' attention to cultural, social, historical, and political influences on ideas about risks is particularly salient for studying how the Canadian blood system has responded to risks. It helps to provide an understanding of responsibility and accountability in relation to risks and, more recently, precaution. Finally, Douglas' framework also helps to advance our understanding of the roles of consumers in the formation of ideas about risks and the mechanisms used to manage them. The ability of consumer stakeholders to be involved in participatory processes as a way to legitimize blood safety policies and advance the interests of both government and their own communities rests on their ability to utilize historical and cultural representations of risk, danger and precaution.

In the next chapter, I will provide an overview of the methods I used to collect and analyze my data, as well as situate myself in the context of this study

## **Chapter Four:**

### Methodology and Context: The How, The What and The Who

In this chapter, I present the research methods that inform the present study. I provide a detailed description of the data collection procedures, the selection of the participants and an overview of the challenges encountered in accessing interviewees. Further, I describe the research problems I encountered when gathering data from stakeholders.

#### **The How: Research Methods**

To understand how the various stakeholders in the Canadian blood system negotiate their interests and make decisions about risk and safety, as well as provide a set of theoretical insights that illuminate participatory and the organizational processes involved in risk governance, I chose a qualitative research design. My reason for this choice was that a qualitative approach allows one to capture how stakeholders' views on how the blood system should operate and information on the processes that are involved in organizational practice and decision-making. Such intricate social processes as are involved in those aspects of the blood system are generally far more difficult to access through quantitative means. This is evidenced by the fact that, to date, much of the research that examines the management of risks to blood systems has relied on qualitative methods (e.g. Hergon et al., 2005; O'Neill, 2003; Ponte, 2006; Wilson et al., 2004, 2007). For example, in studying decisions made by those responsible for the French blood system, Hergon et al. (2005) relied on a qualitative approach similar to one used in this study, drawing on interview and meeting minutes data to investigate the role of consumer stakeholders in prioritizing some risks above others. Similarly, Ponte (2006) utilizes a qualitative methodology for her study comparing how the US and UK regulatory bodies identify and frame blood risks. She argues that a qualitative approach is well suited to understanding the "organization and culture of institutions and the people who occupy them" (Ponte, 2006, p. 342).

My qualitative research design involved a combination of in-depth interviews with key informants in the blood system, and an analysis of documents. As noted by Kvale (1996), interviews allow a researcher to "explore participants' worldviews, the meaning they ascribe to the work they do, and how they see their activities in relation to the actions and wishes of others" (p. 28). Additionally, documents can be used to "corroborate or contradict" (Dobrow et al., 2006, p. 1813) interview data, but also allows an analysis of organizational ideologies or histories that influence practice and policy. Therefore, this design allows me to focus on the interaction and context in which decisions and negotiations occur, providing for a rich description of the research issues.

### **Interview Participants: Description of Sampling Frame**

I selected interview participants from two main organizations within the Canadian Blood System, namely the Expert Advisory Committee on Blood Regulation (EAC-BR) and Canadian Blood Services (CBS). These two groups were chosen because they play key roles in the Canadian blood system and have made formal efforts to include members of the public and consumers. I selected interview participants from these organizations using

a criterion based sampling technique. The use of purposive sampling was important as I wished to identify, from within these organizations, those individuals likely most knowledgeable about the blood system who were currently participating in decision-making at either the regulatory or organizational level. Using this strategy, I selected key stakeholders on the EAC-BR and in CBS using the following criteria:

1) Chairperson(s) for each group.

2) Member(s) that represent governmental expertise or management.

3) Member(s) that represent organizational (CBS) expertise or management.

4) Consumer stakeholders, particularly representatives of the Canadian Hemophilia Society, but also other blood consumer organization representatives such as those representing thalassemia patients.

5) Stakeholder member(s) that represent other health/user organizations in Canada.

This diversity of participants was critical to capture the different perspective and interests of the key stakeholders in the blood system and the ways these perspectives are shaped by issues of blood safety.

This type of sampling strategy has been used in previous research on multiple stakeholders, health policy recommendations and decision-making. For example, Dobrow et al. (2006) used such a sampling approach when studying how different expert groups made up of various stakeholders developed policy recommendations for cancer screening. This strategy allowed them to compare stakeholders' perceptions about health issues and to examine the influence of their input on policy decisions. Similarly, Waitzkin et al. (2005) selected various stakeholders to investigate how they understand and construct key health issues and health services related to global trade, and illuminate the factors that impacted such constructions.

To access interview participants, I first sent an introductory letter to the secretariat of the EAC-BR, CBS management, the Chairs of the Board of Directors and the Chairs of the NLC (see Appendix A). As each group has a formal public mandate, their contact information was found on their respective websites. In the letter, I described the objective of this study as seeking to gain a better understanding of the processes through which stakeholders have been integrated into blood-system decision-making, particularly in relation to issues of blood safety and the implications of stakeholder inclusion on these decisions. I also described the amount of time each interview would take (30-45 minutes), the process of informed consent, contact information for the research team (office and email addresses and telephone numbers), and outlined the measures used to ensure confidentiality and anonymity.

Table 4.1 summarizes the numbers of interviewees from the EAC-BR and CBS who agreed to participate in the study.
# Table 4.1 – Total Number of Interviews with Canadian Blood Services and Expert Advisory Committee-Blood Regulation

Organization	Number of Interviews
Expert Advisory Committee on Blood Regulation	N = 6
Lay members	3
Expert members	3
Canadian Blood Services	N = 20
Management	4
Board of Directors	5
National Liaison Committee	11
	Total $N = 26$

# Expert Advisory Committee on Blood Regulation (EAC-BR)

The EAC-BR functions at the regulatory level of the Canadian Blood System, providing "timely advice on federal responsibilities within the national blood system related to blood, blood components, and blood products, and associated issues" (Expert Advisory Committee on Blood Regulation, 2006, para. 1). The EAC-BR is one of the advisory committees established by the Health Products and Food Branch (HPFB) of Health Canada. It is managed by the Office of Consumer and Public Involvement (OCAPI) and is guided by the overall policies of Health Canada (see Figure 4.1 for organizational chart). The membership of this committee is made up of both expert and lay members who represent a range of expertise; including medicine, basic and applied sciences, ethics and the public. Members on the Committee provide "health professional and related expertise and advice pertaining to risk/benefit assessments conducted by others within Health Canada, in order to assist the Biologics and Genetic Therapies Directorate with making appropriate risk management decisions" (Expert Advisory Committee on Blood Regulation, 2006, para. 2). While committee members provide advice, the ultimate responsibility for decision-making lies with the Biologics and Genetic Therapies Directorate. Members from the EAC-BR were selected for this study because of the role they play in providing advice about existing and emerging risks to the Canadian blood system. Figure 4.1 situates the EAC-BR within the overall regulatory system for Canada's health care system. Figure 4.1 - Health Canada Organizational Chart (Adapted from: http://www.hc-

sc.gc.ca/ahc-asc/branch-dirgen/index-eng.php)



Interviews with members of the EAC-BR were relatively easy to set up. Following their protocol for contact, I sent an introduction letter to the person responsible for overseeing the EAC-BR through the Office of Consumer and Public Involvement (OCAPI). After waiting a few weeks, I received an email that said that the group had asked me to contact them individually by email. Out of the ten members who were invited to participate in the study, six agreed to be interviewed (see table 4.1).

# Canadian Blood Services

CBS was created following the Krever Inquiry to deliver blood services in Canada, with the exception of Québec. The mandate of CBS is to "manage a safe, secure, accessible supply of blood and blood products for all Canadians (excluding the Province of Quebec)" (Canadian Blood Services, 1998, para. 1). I was primarily interested in interviewing management (Chief Executive Officer and the Chief Operating Officer), the employees responsible for establishing and maintaining the organization's participatory mechanisms, members of the Board of Directors, and stakeholders participating on the National Liaison Committee (NLC). I made this decision because individuals in those positions regularly interact with stakeholders and play a role in decisions about blood safety and organizational policy. Below, I provide a brief overview of each group.

# 1. CBS Management and Staff:

Members of the management team are key informants because they make decisions about blood safety, blood donation, public participation and communication with the public and the Board of Directors. These interviews would provide important insights into how management viewed participatory processes in the context of the organization and the role they saw stakeholders play in organizational decisions. This allowed me to compare the views of management with those of members on the Board of Directors and the National Liaison Committee.

In addition to management, I interviewed employees of CBS responsible for stakeholder participation in the organizational structure on their understanding of the mechanisms through which stakeholders are included in organizational decision-making, on the rationale for their inclusion and the organizational perspective on the outcome of this participation.

# 2. The Board of Directors of CBS:

The CBS Board of Directors consists of a chair, consumer representatives, regional representatives, as well as medical, scientific, technical, business and public health representatives. The Board is responsible for the "overall direction of the Canadian Blood Services' affairs" including: the appointment and dismissal of the Chief Executive Officer, ensuring that the operations of CBS are in line with the business plan, regulatory standards and statutory requirements (CBS, 2008, para. 1).

Members of the Board are important key informants because they play a crucial role in shaping policy direction for CBS and in establishing and maintaining participatory mechanisms for CBS. Such members were able to illuminate how the organization perceives participation measures and the roles of stakeholders, as well as how stakeholders participate in Board decision-making. In particular, the Board established a Public Participation Task Force in 2000 to review participatory processes and make changes to the inclusion of stakeholders in organizational decision-making.

# 3. National Liaison Committee (NLC)

The NLC is a particularly salient body within which I recruited interview participants. It is an advisory committee that reports to the Canadian Blood Services Board of Directors and consists of a membership that includes "one delegate from each of the Regional Liaison Committees; representatives from national organizations such as consumer groups, patient/recipient groups, health care professionals, and hospitals; national partners or sponsors of Canadian Blood Services (those organizations that plan or promote donor clinics on behalf of Canadian Blood Services); two Consumer Representatives on the Canadian Blood Services Board of Directors; and other appropriate individuals suggested by Committee members" (CBS, 2005b, para. 4).

The NLC is mandated to provide input on the blood system and/or on issues coming before the Board of Directors, ensure that special interests are brought to the attention of the Board and promote communication between Canadian Blood Services and pertinent external organizations. The NLC includes consumer stakeholders, health professional stakeholders, and stakeholders representing volunteer/health organizations/donors. Interviews with these members allowed me to examine how different stakeholders conceptualize risks and issues of blood safety, as well as compare what roles and influence their participation has on decisions made by CBS.

There were varying levels of difficulty in accessing potential CBS interview participants, with contact being much easier with some groups of participants than others. For example, shortly after sending in my introduction letters to CBS, management said they were interested in participating in the study and set up a full day of interviews with several senior staff members in Ottawa. In addition, I was invited to a two-day meeting in Ottawa with CBS management, members of the Board, and the entire NLC. This was one of the yearly in-person NLC meetings for discussing organizational policies, regulatory changes and any other pertinent issues. This meeting provided me the opportunity to explain my research to potential participants and to address issues of confidentiality and consent. In the end, I interviewed eleven members of the NLC, out of a total of seventeen. This ensured a broad selection of representatives from consumer/user groups, general health organizations and members of the regional liaison committees (see table 4.1).

In contrast, setting up interviews with the CBS Board of Directors was much more difficult to organize because of a lack of formal procedure for contacting members to inquire about their willingness to participate in research. The only way to access Board members was through CBS management, which jeopardized confidentiality to some

degree. In the end, I sent the introductory letter directly to the Chair of the Board who passed it on to all of the members. Those willing to be interviewed were instructed to contact me directly. This strategy was not particularly effective and I was able to interview only five Board members out of nine (see table 4.1).

#### **Interview Protocol**

Originally, I had intended to do all of my interviews in person, but that task became overwhelmingly difficult due to the amount of travel it would require and the busy schedules of many of the participants. For this reason, I began to do some of the interviews by telephone, with the consent, and in many cases, the preference of the participants. This enabled me to do more interviews than I would have been able to do, had I needed to fly all over the country, as the interviewees spanned from Newfoundland to British Columbia.

The interviews were open-ended but semi-structured (see Appendix B). I used an interview guide to ensure that all relevant issues were systematically addressed, ensuring more comprehensive coverage and helping to keep interactions focused. The questions on the guide were informed by the gaps in the blood donation and regulation literature, the theoretical insights of Foucault, Giddens and Douglas, as well as themes or patterns that have emerged in my initial review of critical documents. These included questions from the following three topic areas:

# 1) Participatory processes in the blood system

Questions in this category centered on understanding how, and why, participatory processes are integrated into the Canadian blood system, as well as on who is included in these processes. I asked questions regarding how the respondent viewed public participation, whom they considered a stakeholder and what groups/populations they

understood to be represented in the blood system. These questions provided a way to understand the conceptualization of the stakeholder, including how stakeholders are defined, what contributes to these definitions about stakeholders and how these definitions influence who is considered a stakeholder.

# 2) Roles of Stakeholders

Questions in this category focused on how interview participants saw the role of stakeholders in the Canadian blood system, particularly in the groups with which they were involved. I asked about what value or contribution they felt stakeholders in general, and they themselves, brought to the work of their group and, more generally, to the overall blood system. I paid particular attention to whether interview participants conceptualized different roles and values for certain types of stakeholders, or whether they felt that there were few differences. Particular attention was paid to issues of trust and blood safety as these are common themes in the literature.

# 3) Impact of Stakeholder participation on the blood system

Questions in this category focused on understanding how the various participants in the blood system viewed the impact of stakeholder participation on the development of blood policy and risk management practices, as well as on public trust (i.e. benefits and challenges). In this category, I also focused on understanding how participants defined and conceptualized issues of risk and blood safety. In doing so, I was trying to find out what were the shared and divergent ideas about risk and blood safety held by those involved in the EAC-BR and CBS, as well as understanding what influences these ideas. As participatory processes bring stakeholders' ideas and perceptions about risk into decision-making and have been said to influence policy, it is important to know whether there are

differing views about issues of blood safety between those participating in the blood system, and why these exist.

The interviews helped me to understand how stakeholders have been integrated into the governance structures of the blood system. In particular, the interviews provided insights into the roles that participatory processes play and what interests are served by such measures. In this way, the interviews provided a way of identifying the articulations between government, CBS and stakeholders. It allowed a better understanding of how blood risks are constructed, managed and negotiated among members, as well as how this influences risk management decisions. In addition, the interviews provided insights into whether there were differences in how issues of risk and safety are understood by the various participants, including the regulator, representatives of CBS management and Board, as well as consumer stakeholders. It also provided an opportunity to better understand why these differences exist.

The interview guide was slightly modified over time to focus attention on areas of particular importance that emerged from earlier interviews and to exclude questions that proved to be unproductive in obtaining data relevant to the goals of the research. For example, in an early version of the interview guide, I asked participants about voluntary donation, but realized that it had little relevance to the study at hand. Later, I instead asked more generally about blood safety policies. In general, interviews were approximately 45 minutes in duration, with some of the interviews going over one hour. With the informed consent of participants, I recorded interviews and took field notes. After each interview, I transcribed the recordings.

#### **Document Collection**

Documents were also sought out before, during and after interviews. These documents provided an important data source in terms of the substantive content as well as the "deeper meanings" (Ritchie and Lewis, 2003, p. 35) within documents. This type of analysis is particularly useful for historical examinations, comparisons of accounts between members of different groups, and, when observation techniques are not possible or are limited (Ritchie and Lewis, 2003). Document analysis served to provide background data that was used to corroborate, contradict or provide clarity to the interview data. I conducted a background document search on each group's website to identify a range of relevant documents (for full list of documents, see Appendix C). In particular, I looked for any materials that focused on how groups conceptualize risks. Such information was sought in position papers, risk assessments and organizational policies, including the MSM policy and other deferral policies. I also looked for organizational documents (such as annual reports) to provide an understanding of how the organization sees its role in the blood system.

In addition to documents from the two main two bodies (EAC-BR and the CBS), I also examined documents from Health Canada, the Canadian Hemophilia Society and the media. These documents allowed me to understand the broader context in which the EAC-BR and CBS operate. This understanding was particularly important because the EAC-BR is an expert committee of Health Canada and therefore guided by policies and strategies put in place by the Federal Government. For this reason, I looked at materials discussing why expert committees within Health Canada include public or lay members, how these committees are conceptualized in policy and what kind of outcomes are linked to these participatory measures. Similarly, it was important to include the Canadian Hemophilia

Society, a group from which many of the consumer stakeholders come. It is mentioned by name in many blood system documents like the Krever Inquiry and documents from CBS. This study, therefore, utilizes these documents as a way of understanding the background frameworks that govern how these organizations conceptualize their role in the blood system and reflect critical issues of blood safety and trust. Finally, while I do not extensively examine media reports on the Canadian blood system, I analyzed certain news stories that illustrate cultural understandings of this system.

# Documents:

- Policy statements related to risk, blood safety and public participation
- Annual Reports, audits or performance reports
- Meeting Minutes and agendas
- Interim reports
- Working drafts
- Other correspondence (public presentations, media stories, etc.) Specifically, for this study, documentation came from:
- Governmental documents from the EAC-BR including meeting minutes, consensus conference reports, the Office of Consumer and Public Involvement (OCAPI) and Health Canada
- 2. The Krever Report (3 Volumes)
- 3. Consumer organization documents, in particular documents from the Canadian Hemophilia Society (CHS) such as the yearly report cards on the blood system.
- Media documents, particularly those related to public perceptions of HIV and other blood risks.

The internet facilitated access to all forms of documentation. Each group that is a focus of this research has a public mandate and thus each has a website that is publicly accessible. For example, each group's website (Canadian Blood Services, Office of Consumer and Public Involvement, Exert Advisory Committee-Blood Regulation, Canadian Hemophilia Society) has publicly accessible archives that include policy papers, meeting minutes, and other relevant documents. As a way to validate the usefulness of documents, during interviews I asked participants what documents I should look at to understand their group better. Additionally, the relevance of documents became clearer after I had interviewed participants and dominant themes were apparent. These themes were used to guide further document searches and textual analyses. For example, consumers representing the CHS conceptualized their role in the blood system in relation to blood safety. Therefore, in reviewing their website, I paid particular attention to documents that illustrated how they conceptualized their role such as the "Report Card" that they produce every year grading each aspect of the blood system.

Finally, while the majority of the documents examined for this study were gathered through online sources, there were some documents received during my interviews. For example, many of the members of the CBS Board of Directors referred to the report of the *Public Participation Task Force* when speaking about the inclusion of stakeholders within the organization. In doing so, many of them suggested it was a key piece of information for review.

In general, documents served to provide an understanding of how ideas of risk and safety are articulated by each of the participant bodies, as well as the differences between different groups participating variously at the regulatory level, as experts, management and Board of Directors of CBS, and the various stakeholders. In addition, these types of data

provided an important mechanism for examining the formal and informal inter-linkages between the responsibilities and practices of the regulator, CBS and stakeholders in the governance structures of the blood system. Finally, this data also helped to illuminate how these constructions are reflected in blood policy and guide practice.

# **Data Analysis**

For this project, I drew upon an integrated analysis laid out by Bradley et al. (2006) that utilizes both a deductive approach to analysis adopted from the work of Miles and Huberman (1994), as well as the inductive approach to analysis espoused by grounded theorists Glaser (1992) and Glaser and Strauss (1967). Data analysis was an iterative process involving the following steps for a systematic approach: (a) reading for understanding, (b) development of coding structure, (c) categorizing data, (d) connecting categories, (e) conceptual mapping and (f) producing an account (Bradley et al. 2007).

Analysis of the data relied upon on a constant comparative approach. This involves comparing each piece of data with all the other data, both similar and different, to develop conceptualizations to explain the relations among them (Morse & Field, 1995; Thorne, 2000). It allows a researcher to compare different experiences within or between individuals to determine how they are different or similar and thereby develop an understanding of why this is so. For example, I examined the experiences of the various participants within the groups (CBS and EAC-BR), to see whether there were differences in how individual members of each group conceptualized participatory processes, particularly in relation to issues of trust and blood safety. In addition, it was important to compare groups to see if there were differences in how those participating at the regulatory level and those at the level of the blood operator conceptualize the participation of

stakeholders in risk decision-making. Documents were analyzed both before and after interviews, with coding occurring in the same manner as interviews. Below I will review each of these steps and provide examples of the analysis process.

# 1) Reading for understanding

The first step of analysis was to review all of the data without doing any coding. This helps to immerse oneself in the data and identify codes that may be relevant to the analysis and that can be used in the coding structure. As I am using textual and interview data, an initial read through of all the material helped to identify places in which policy may differ from interview explanations of stakeholders' roles and participation.

# 2) Development of coding structure

Prior to coding the data, I developed a general coding structure. The use of a coding structure, or what Miles and Huberman (1994) call a "start list" (p. 22), is to help integrate concepts that are already known or discussed in the literature. In the case of the blood system, one of these would be the role of public participation in relation to trust. A recurring theme in the blood literature focuses on the perceived role of stakeholders in helping blood systems to re-establish trust; therefore, in the initial coding it makes methodological and conceptual sense to acknowledge the importance of this concept in relation to public participation from the outset of one's analysis. However, as Bradley et al. (2007) warn, "care must be taken to avoid forcing data into these categories because a code exists for them" (p. 1763). Rather, a start list with pre-determined codes allows "new inquiries to benefit from and build on previous insights in the field" (Bradley et al., 2007, 1763).

I organized the initial coding structure according to three broad dimensions: (a) reasons for stakeholder participation in the blood system, (b) conceptualization of

stakeholders and their roles and (c) impact of stakeholder participation on the blood system. The first dimension (i.e. reasons for stakeholder participation) includes data segments related to how and why participatory processes have been integrated into the Canadian blood system. The second dimension (i.e. conceptualizing stakeholders) includes data segments related to how stakeholders are defined, and the roles associated with the various stakeholders. Because consumers form a distinct group of stakeholders in the blood system, I had already established a code for them. Similarly, as trust has been widely discussed in research on blood systems, particularly in discussions of public participation, one of the codes in this section pertained to the roles of stakeholders in relation to trust. The final category (i.e. impact of stakeholder participation) includes data segments related to policy implications, as well as to how participants defined and conceptualized issues of risk and blood safety.

The initial coding structure also contained codes for the settings (EAC-BR and CBS) as well as the participants within each setting. Participants from CBS were coded by management, members of the Board and NLC. In addition, I created codes to identify the various stakeholders participating on the Board of Directors and for the NLC, I coded for consumer stakeholders, health professional stakeholders, and stakeholders representing other health charities or donors. For the EAC-BR, I coded participants as either an expert member or a lay member. Coding by participant and setting allowed me to compare the differences and similarities among participants in different settings, as well as among the various participants in the same setting.

# 3) Applying the coding structure: categorizing the data

I categorized the data utilizing the initial coding structure. During this process, many of the initial broad codes were refined and organized into sub-categories that better reflected salient aspects of participant experiences or views. In particular, I divided the definition of stakeholder into three sub-categories: (a) member of the general public/lay individuals, (b) consumers and (c) health professionals/experts. This enabled me to organize the views and perspectives of interview participants and relevant documents. Similarly, in discussing the roles of stakeholders in relation to trust, I created sub-categories that reflected how participants spoke about the issue of trust. This allowed a comparison of how participants on the EAC-BR and those involved through CBS spoke about the role of stakeholders in relation to trust.

# *4) Connecting categories*

I examined coded categories and sub-categories for explanations that participants had about events, views, practices, or decisions regarding stakeholder participation in the Canadian blood system. These connections between categories and sub-categories helped to detect patterns across and within the bodies under study, allowing me to distinguish between the various participants and compare their perspectives on stakeholders and their roles. Making these connections enabled a better understanding of how the processes of public participation operate and the impact of these processes on the blood system. That process helped me to generate theoretical insights about the phenomena under study.

Findings derived from the interview data were compared to those that emerged from the analysis of documentary data (see Appendix C). Analyzing interview and document data allowed for cross-validation between the categories and served to highlight any inconsistencies between how participatory processes are conceptualized and framed in policy versus how they play out in practice. This analysis provided an understanding of how participatory processes function in practice and the implications that they may have on policy.

# 5) Conceptual mapping

The next step in the analysis was to conceptually map the links between the categories as well as between the categories and theory, so as to better understand how stakeholder participation functions in the Canadian Blood system. For example, in explaining the role of consumer stakeholders in building trust and legitimizing the work of CBS, I drew upon Giddens' (1990) notion of access points between expert systems and the public in order to explain the contingent nature of expert knowledge in the blood system. It is through these access points that consumers are able to exert power and influence blood safety policy. I also drew upon the work of Douglas and the concepts of governmentality and the stakeholder society so as to provide a more nuanced and deeper understanding of how participatory processes function as sources of legitimacy for policy makers and stakeholders. This also identified the ways in which risk related social processes are shaped by cultural, social and historical factors.

The final step was to produce an account of the findings. This dissertation reports on the findings of this study and provides insights into the manner in which stakeholders have been integrated into the Canadian blood system, as well as the impact of their participation on that system. In addition to the empirical analysis of stakeholder participation, this study situates these findings within larger debates about public participation and the role of consumers in policy decisions.

# **Summary and Conclusion**

In this chapter, I have discussed the research methods employed for this study. I have also highlighted some of the challenges that arose in accessing participants in the Canadian blood system. I have also outlined why a qualitative design was best suited for

this research. In the next chapter, I explore public participation at the regulatory level, specifically the role of lay representatives on the EAC-BR. More specifically, I describe how stakeholders and their roles are conceptualized in relation to the work of the EAC-BR, as well as in the broader context of the blood system.

# **Chapter Five:**

# Public Participation in Regulatory Risk Governance: Representatives of Governmental Responsibility for Blood Safety

Increasingly, public participation is seen as an effective way for governments to demonstrate accountability, restore public trust and build support for policy decisions, particularly those surrounding risks to public health (Gustafsson and Driver, 2005; Rothstein, 2007; Tomlin, 2004). In addition to participatory processes, there has been a push to enhance the use of scientific evidence in the development of risk management policy as a way to demonstrate accountability for policy decisions (Allio, Ballantine and Meads, 2005; Wilson et al., 2007). Nowhere is this truer than in relation to the management of known or potential risks to blood systems (Hergon et al., 2005; O'Neill, 2003; Ponte, 2006; Wilson et al., 2003; Wilson et al., 2007).

In Canada, public accountability for blood system decision-making came to the forefront following the tainted blood scandal and the resulting Krever Inquiry (Wilson et al., 2003). In response to these events, new practices of risk management and new relationships between governments, blood agencies and stakeholders have been established to demonstrate accountability and re-build trust in the safety of the blood system. A central aspect of these new practices, within both the regulator and blood operator has been the integration of public participation in blood safety decision-making. At the same time, governments and policy makers have implemented the precautionary principle to address scientific uncertainty related to blood risks (Wilson et al., 2007).

In this chapter, I examine participatory processes at the regulatory level of the blood system with a focus on the role of lay representation on the Expert Advisory Committee for Blood Regulation (EAC-BR). Drawing upon interview data from six members of the EAC-BR (out of a possible nine), including three expert members and three lay members, as well as regulatory, organizational and Committee documents, I investigate the role of lay members, and the impact they have on the work of the Committee. For this purpose, I draw upon Giddens' (1990) notion of access points, which are mechanisms or encounters that connect the public with expert systems. As I will show, lay membership is conceptualized as a way to demonstrate accountability and transparency for blood safety decisions. By connecting members of the lay public with expert bodies, lay membership creates access points that serve to mitigate public, or stakeholder, concerns about expert knowledge, thereby helping to rebuild public trust.

The inclusion of lay members is situated in the context of a recent history of contamination, a public inquiry, legal trials and new responsibilities for blood safety. I argue that these are culturally, socially and politically significant events that continue to redefine the identification and management of risks, as well as how trust is understood. Risk management now centers mainly on issues of contamination and relies on the scientific application of the precautionary principle. These events have also shaped the nature and conceptualization of lay membership on the EAC-BR.

It is crucial to understand that, from a regulatory perspective, the Canadian blood system does not operate independently from government. Decisions concerning the management of blood risks are made by Health Canada through its Biologic and Genetic Therapies Directorate. Health Canada categorizes blood (and blood products) as pharmaceutical products and is accountable for their safety (Health Canada, 2008). The

EAC-BR reports to Health Canada and does exactly what its name suggests – it offers advice to Health Canada, which makes the decisions that ensure the safety of the blood system. Health Canada makes recommendations on the safety of the blood system at two levels (Health Canada, 2008):

- 1. Within system safety which pertains to all the procedures involved in collecting and processing, including testing it for pathogens and transfusion procedures.
- Outside system safety which pertains to the exclusion of pathogens from the system, this is done through deferrals and screening of donors. It is through this process that the precautionary principle comes in to play and where the regulator is mandated to anticipate and eliminate potential (also known as theoretical) risks of contamination.

The blood operators (CBS and HQ) have to implement federal regulations and have a marginal degree of discretion when developing specific risk management practices, as they are only allowed to exceed the regulations (Wilson et al, 2007). As a regulator, Health Canada has received a direct mandate from government – to do everything possible to prevent Canadians from ever being transfused with contaminated blood. In that regard, this mandate has been largely successfully implemented – Canadians have one of the safest blood systems in the Western world (Wilson, 2007). There are several reasons for this state of affairs, the main one being accountability. The Krever Inquiry is one of the few Royal Commissions that had an impact in making government (in this case Health Canada) accountable for its failure to properly assume its mandate in regulating the Red Cross. That mistake cost the lives of many Canadians and cost taxpayers a lot of money in compensation and legal fees. It is a mistake that no one wants repeated.

It is in this context that lay participation in blood safety decisions is broadly conceptualized as a way to build trust. In practice, however, there are certain publics and types of knowledge that are seen as more valuable within these access points to the blood regulator. Given the scientific nature of the work required by the regulator, members of the general or lay public are excluded because they lack the necessary expertise to effectively participate. Instead, as I will demonstrate, lay participation on the EAC-BR is fundamentally about something other than public representation. It functions as way to legitimate the public's acceptance of scientific decision-making and adherence to the precautionary principle.

This chapter is organized into four parts. The first section provides an overview of the changes that have taken place in the blood system at the regulatory level following the tainted blood scandal and the Krever Inquiry. In particular, I examine how Krever's recommendations aimed at addressing scientific uncertainty have been integrated into policy and practice within the blood regulator. Following this, I examine how issues of risk and the responsibilities for managing them have changed, highlighting the role of the precautionary principle in current risk governance arrangements. In doing so, I illustrate how precaution functions as a demonstration of regulatory responsibility for blood safety. In the third section, I examine Krever's recommendations regarding lay participation, highlighting how members of the public have been included in regulatory bodies, specifically the EAC-BR. From here, I move into the fourth and final section, focusing on exploring how the role of lay members on the EAC-BR is conceptualized in relation to the work of the committee. Here I demonstrate how these roles are shaped by contextual and structural factors, particularly the regulator's responsibility for blood safety and the use of the precautionary principle. These factors influence who is able to participate as a lay

member and what roles they can play within the committee. In this section I also discuss the role of blood consumers in relation to the EAC-BR and more generally in relation to scientific and precautionary decision-making at the regulatory level.

# Situating the EAC-BR in the Regulatory Environment: Tainted Blood and the Krever Inquiry

The contamination of the blood supply and the Krever Inquiry had a profound impact on the regulation of blood and blood products in Canada. As I have discussed the tainted blood scandal and Krever Inquiry in detail in *Chapter 1*, I will focus instead on the aspects of Krever's recommendations that center on blood regulation and risk management.

The contamination of the blood supply was an event that typified several aspects of the risk society (Beck, 1996; Giddens, 1991). Unlike pre-modernity, in which risks were considered supernatural and thus beyond the control of humans, in late modernity many risks are generated by humans and are perceived by the broader public as representing a failure of science and technology. Additionally, rather than being confined to specific locals, risks in late modern society are often global in nature and thus have widespread effects (Beck, 1996; Giddens, 1991). For example, while HIV and HCV are biologic in nature, the ability of these viruses to produce such widespread and harmful outcomes results from human intervention (i.e. contaminated transfusion) or rather a lack of it (i.e. delays in testing). Thus, the past failure to adequately respond to risks in the blood system has lead to a declining trust and a loss of legitimacy for governments, policy makers and experts. As I will show, this loss of trust was a key concern that the Krever Inquiry addressed by recommending the creation of what Giddens has identified as access points

for the lay participation in expert bodies. His report also recommended the use of the precautionary principle in risk decision-making.

# **Creating a New Regulatory Environment**

The Krever Inquiry produced a set of fifty recommendations on how the new blood system in Canada should be run. One set of recommendations, numbers 29-45, pertained to the operation of the blood regulator. These outlined changes to how risks should be identified and managed, and specified new responsibilities for decisions related to blood safety. In these recommendations, Justice Krever highlighted the need for greater accountability for blood safety decisions, focusing on the importance of precautionary, independent, well-informed and reflexive decision-making on the part of the regulator (Krever, 1997).

Justice Krever's recommendation to use precaution for managing risks, and addressing scientific uncertainty inherent to this task, is of particular relevance to this study. The precautionary principle rests on the idea of preventative anticipation whereby measures may be taken in advance of scientific proof of evidence if further delays are judged as potentially costly to society and individuals (Ewald, 2002). During the Inquiry, Justice Krever (1997) criticized the blood authorities for delaying blood safety measures because of the lack of "definitive evidence of risk" (p. 1066) and felt that a national disaster could have been prevented by adhering to the dictum that "action to reduce risk should not await scientific certainty" (p. 1066). Precautionary decision-making is the focus of Recommendation 30, which underlines the need for a "policy of active, not passive regulation of the national blood supply system" (Krever, 1997, p. 1066).

In response to the recommendations, the federal government strengthened its regulatory role in relation to the blood system. Thus, while blood has been considered a

"drug" in Canada since 1988 and subjected to regulations under the Food and Drug Act, there has been a significant restructuring of regulatory responsibilities and activities following the events of the 1980s and 1990s (Wilson et al., 2004). Under the current structure, the blood operators (i.e. CBS and Héma Québec) are responsible for collecting, testing, manufacturing, distributing, purchasing and supplying blood products to all provinces. The provincial/territorial governments are responsible for funding the blood system and the federal government is responsible for regulating the safety of blood. In this chapter, I am primarily concerned with the latter set of responsibilities.

The federal government, through Health Canada, regulates blood safety through the identification of potentially dangerous pathogens and the populations in which such pathogens are evident. In order to identify these potential risks, Health Canada consults with external groups, namely the EAC-BR. Established in 1996 in response to Krever's calls for an expert committee, the EAC-BR provides advice to the Biologics and Genetic Therapies Directorate of Health Canada on "federal responsibilities within the national blood system related to blood, blood components, and blood products, and associated issues" (Health Canada, 2006 para. 2). Once it receives advice from the EAC-BR, Health Canada issues a directive to both Héma Québec and the Canadian Blood Services. The blood operators must meet the minimum risk management directive but can also exceed this directive within reason (Wilson, et al., 2004).

The creation of the EAC-BR illustrates what Giddens (1990) calls a *disembedding mechanism*, or what he refers to as the *abstract capacities* (p. 27) of the risk society. Disembedding mechanisms are "systems of technical accomplishment or professional expertise that organize large areas of the material and social environment in which we live today" (Giddens, 1990, p. 27). Like other technological activities in modernity, the expert

management of risk has become standardized and cuts across local contexts, displacing local forms of knowledge. However, according to Giddens (1990), the contradictory nature of expert knowledges, and past failure to respond to uncertain risks in the blood system has lead to a declining trust in scientific expertise.

As I will show in the upcoming section, the precautionary principle is a key feature of the new regulatory environment surrounding blood and guides the identification and management of risk within the blood system, including the work of the EAC-BR. No longer can scientific uncertainty be justified as a reason to delay taking actions to protect the public health. For this reason, Giddens' (1990) discussion of expert knowledge and reflexivity is particularly relevant for this study. While Giddens does not explicitly discuss the use of precaution in risk management, I argue that the implementation of this principle can be examined from a risk society perspective because it deals with issues of uncertainty and public trust. In addressing scientific uncertainty, the precautionary principle also plays a role in increasing the public's trust in expert systems of risk management. As Giddens (1990) notes, because of the complexity of managing modern risks, there is a need to address uncertainty surrounding science and expertise in such a manner as to make them acceptable to the general public. In the case of the blood system, this means that measures need to be implemented to address scientific uncertainty.

# Redefining Risk and Responsibility in the Canadian Blood System

In this section, I investigate the factors that have redefined risk and responsibility at the regulatory level of the Canadian blood system following the tainted blood scandal and the Krever Inquiry. I argue that the redefinition of risks lead to a redefinition of responsibility for managing those risks and has shaped the practices used to manage risks. As Douglas (1990) notes, "risk is part of a political vocabulary of moral responsibility and accountability" (p. 10). Or, as Foucault (1998) notes, changes in the identification and management of risk are aligned with changes in "political rationalities" (p. 153). By this, Foucault (1991) refers to forms of knowledge that contribute to new domains of regulation and intervention. This results in risk being conceptualized and dealt with in ways that adhere to the interests and needs of the state, with strong ideas about the regulation of the individual by others, as well as how they should "deport themselves in relation to the state" (Foucault, 1988, p.153).

# **Conceptualizing Risks and Responsibilities**

The tainted blood scandal and Krever Inquiry have redefined how risks are interpreted and identified in the Canadian blood system as well as who is responsible for their management. As Wilson et al. (2007) note, those events continue to influence current governance policies and understandings of how the public views blood safety. This influence is evident in regulatory documents. For example, in the meeting minutes of the *Public Advisory Committee of the Health Products and Food Branch,* there is an acknowledgement that "...the blood scandal is still present in the public mind" (Health Products and Food Branch, 2005a, Blood Donor Deferral, para. 1).

In responding to the tainted blood scandal, the blood regulator has put in place several mechanisms to identify and manage contamination risks. As Wilson et al. (2007) note, while most countries adapted their risk management approaches, "Canada`s experience was unique because of the extent of structural reform to the blood system...creating a new blood system" (p. 1387). A key aspect of these changes is a "clarification of how evidence should be used to formulate policy with respect to blood safety" (Wilson, 2007, p. 1387). In particular, there was an acknowledgement of scientific

uncertainty and the need for a precautionary approach to managing uncertain risks. Ewald argues that the "principle of precaution rounds out the agenda of the risk society" (2002, p. 295) and represents a form of "reflexive modernization." Precaution forces policy makers and regulators to make decisions about risks, not from a position of certainty, but from one of "doubt, suspicion, premonition, foreboding, challenge, mistrust, fear, and anxiety" (Ewald, 2002, p. 295). There is to some extent a "risk beyond risk, of which we do not have, nor cannot have, the knowledge or the measure" (Ewald, 2002, p. 294).

In recent years, Western blood systems, including Canada's have used the precautionary principle to address what are known as theoretical risks. These are risks that lack scientific certainty of transmission but can theoretically be transmitted through blood and blood products. Two examples of theoretical risks that have been addressed by precautionary policies are variant Creutzfeldt-Jakob disease (vCJD) and West Nile virus. In the case of vCJD, Wilson et al. (2007) suggest that, despite the lack of scientific certainty around transmission, policies were implemented to protect the blood system from contamination. One such policy was the deferral of blood donors from the United Kingdom, which had sustained a significant outbreak of vCJD in its livestock.

Those strict measures were implemented under the banner of the precautionary principle and reflect the continuing influence of the tainted blood scandal and the Krever Inquiry. As the example above illustrates, the notion of a "risk beyond risk" (Ewald, 2002, p. 294) is a key feature of precautionary risk decision-making in the Canadian blood system, which creates a "disrupted relationship with science" (Sanson-Hermitte, 1996 quoted in Ewald, 2002, p. 289). Therefore, unlike the past, risk regulators are now "less interested in the confidence science provides than in the suspicions and doubts it can

arouse both about what we know and what we do not know" (Sanson-Hermitte, 1996 quoted in Ewald, 2002, p. 289).

# Precaution as a Representation of Responsibility

The above comments suggest that the implementation of the precautionary principle is symptomatic of a redefinition of responsibility in the management of blood risks. As Giddens (1991) writes:

Risk is always related to security and safety. It is also always connected to responsibility. It isn't surprising therefore that as we move towards a world dominated by manufactured rather than external uncertainty, there is a renewed discussion of the nature of responsibility. (p.7)

Similarly, Ewald (2002) argues that precaution functions as a "principle of responsibility" (p. 299). No longer is it sufficient to consider risk normal and something that can be compensated. Instead, precaution translates into prevention and anticipation; the need to prevent certain risks from being taken. The consequences of this include a responsibility for regulating uncertainty and the creation of "precautionary legislation" (Ewald, 2002, p. 299).

Roussel's (2003) study of the French tainted blood scandal addresses this relationship between precaution and responsibility. Roussel (2003) argues that the contamination of the French blood supply increased the level of accountability of risk management experts and representatives of the state responsible for safeguarding the blood supply. Whereas previously, experts and blood system administrators could claim that some risks were beyond their control, they were now called upon to use prudence and precaution to manage known as well as anticipated risks to the blood supply. Roussel (2003) argues that in the post contamination context, "visibility mechanisms" including

expert bodies that provide scientific advice, became part of "a new politics of visible precaution" (p. 140) whereby policy makers and experts publicized the precautionary measures they implemented to demonstrate how responsible they were to the public. Roussel (2003) cites the well-publicized destruction of 50,000 animals thought to be at risk of foot and mouth disease as an example of such public displays of risk management.

Individuals responsible for identifying and managing risks in the Canadian blood system are acutely aware of the burden of responsibility placed on them by "precautionary legislation" (Ewald, 2002, p. 299). In discussing the terms of reference for the EAC-BR, a representative from Health Canada (2004) comments, "As the regulator, we are legally liable to make decisions on the basis of safety" (Discussion, para. 4). Wilson et al. (2007) echoes this point when stating that:

Canadian officials are eminently aware of the public health consequences of the transfusion transmission of hepatitis C and HIV. They also cannot help but be aware of the legal consequences...the current incentive structure does little to protect against liability. (p. 182)

An important factor that accounts for the influence of the precautionary principle in the blood system is that Health Canada is subject to litigation if it fails to adequately protect the Canadian public against the risks associated with the products it regulates, including blood and blood products (Health Products and Food Branch, 2005). To contrast, the US Food and Drug Administration (FDA), which plays a similar regulatory role in blood safety, is protected against legislative actions such as lawsuits and injury-related claims.

The "politics of visible precaution" (Rousell, 2003, p. 140) have resulted in the implementation of stringent deferral policies that are always well publicized in the media as well as on the two blood operators' respective websites. For example, in 2006, CBS and

HQ quickly reacted to the potential threat posed by *Simian Foamy Virus* (SFV) by screening and permanently deferring donors "that report having ever taken care of or handled monkeys or their body fluids on a regular basis in their job, regardless of the type of monkey or type of exposure" (Health Canada, 2009, para. 5). Although this risk is small, the preventative actions of the blood operators were well publicized in nation-wide news reports and on their websites (Thorne, 2006). Those actions were similar to the ones taken by the blood operators when they implemented a strict deferral policy for vCJD and when they decided to maintain a lifetime donor deferral of men who have sex with men (MSM) even though other Western countries have changed this policy.

# **Precaution Trumps Sufficiency and Cost**

Adherence to the precautionary principle is prioritized over concerns with cost and sufficiency. In a discussion over the terms of reference for the EAC-BR, a representative from Health Canada stated that, "As the regulator, we are legally liable to make decisions on the basis of safety; therefore, invited guests who represent regulated bodies should not be asked to comment on costs associated with Health Canada regulation or policy" (Health Canada, 2004, Discussion, para. 4). Yet, some researchers have noted the negative impact of the precautionary principle on costs. In particular, Wilson and Hebert (2003) report that over a three-year period, expenditures in the blood system increased by fifty percent. Moreover, cost-effectiveness ratios of precautionary safety measures far exceed what is considered acceptable for improving the health of Canadians (Wilson et al., 2007). A generally acceptable cost effectiveness ratio is between \$50,000 and \$100,000 per quality adjusted life years (QALY). By contrast, nucleic acid amplification testing to detect the presence of HCV in the blood supply has a ratio of \$4 million/QALY (Wilson et al., 2007, p. 182).

All participants on the EAC-BR acknowledged that the issue of cost was a concern but considered it to be outside of the committee's mandate. As one expert member explains:

This is a very important question, and it is one the committee has had many discussions about over the years. I would say that it is not something that the committee addresses. Now we do not lose sight of it, but when the issue has actually been raised during discussion that has not been what the bureau wants. The bureau sees it as their role to do cost-benefit analysis and while that may be part of the information they share with us, as part of the background information, is not something we take into consideration. You know that a lot of costly stuff is done in the blood system, and I think many of us question this, but since the Krever report there has not been any room to argue that things are too costly. If there is any potential benefit even incremental from it, we tend to say yes to it.

(Interview #2 – Expert member)

Another expert member voiced a similar opinion:

But I think the provinces are starting to put some pressure on restraining some of the costs. It is still such a political minefield. So I think we can look at how we pay \$6 million a year to prevent not a single infection in the blood system, which you may keep doing again and again and again, but it is probably not going to change. I think part of it is being so close to the tainted blood scandal and a spin off from this is that I do think the public has perhaps not fully come on board with respect to the safety of the blood system. I think they're much better than they were, but I think there's still a lack of confidence.

(Interview #1 – Expert member)

Unlike other sectors of the health system, the blood system is not subjected to the same level of scrutiny and accountability in regards to the costs associated with its operations. This suggests that government is unwilling to consider cost containment measures for the blood system because this could undermine the strict implementation of the precautionary principle and undermine the public trust in the blood system. The comments below support this point:

You know, there is a philosophical discussion around cost; you know, is this worth \$1 million? Is one life worth \$1 million? But this decision is also an emotional discussion around cost. You know, if you are that person that might be infected with something... maybe you have a really, really remote chance you are about one person out of a million, it is still a very big deal to you and we have a responsibility to protect the Canadian public.

# (Interview #3 – Expert member)

I think this is about cultural values and in Canada we want, more than other systems, to have a very safe supply of blood – for the population to be safe. I really do think, that even more than other countries, we are willing to be ahead of others in terms of safety.

#### (Interview #6 – Lay member)

What is small and what is significantly small is up for debate, and it depends on who you are and what your position is. My standpoint for this is that no risk is acceptable. So when this is your position cost consideration falls by the wayside. (Interview #4 – Lay member)

It is also important to note that the lack of concern around issues of cost may also be due to the fact that the federal government legislates blood safety, but the provinces must pay for the blood system out of their budgets.

At the regulatory level, the priority of precaution over the issue of a sufficient supply of blood is evident in meeting minutes and organizational documents. For instance, in the report from the Consensus Conference on HIV and Hepatitis, a representative from Health Canada states, "Although security of supply is an important issue, Health Canada considers blood safety to be the highest priority" (Chiavetta et al., 2003, p. 16). This is also reflected in meeting minutes of the Public Advisory Committee of the Health Products and Food Branch of Health Canada. Their February 18-19, 2005 meeting minutes includes the following entry, "The Canadian public wants to have zero-risk blood products. The Committee believes it is better to discourage a few donors than to collect dangerous blood" (Health Products and Food Branch, 2005a, Blood Donor Deferral, para. 1).

The above comments indicate a prioritization of the precautionary principle in risk management over issues of sufficiency and cost. Members of the EAC-BR see their responsibility also as being the protection of the blood supply against contamination rather than ensuring sufficiency and financial efficacy. This finding supports Ewald's (2002) contention that "precaution is an attitude of protection" (p. 298). The prioritization of the precautionary principle in the Canadian blood system is also explained by the influence of blood consumers, particularly representatives of the hemophilia population. Because of their past history as victims of tainted blood, consumers have come to view contamination as the primary threat to the blood supply and expect those who are managing it to do everything possible to eliminate that risk.

I close this discussion by returning to the idea that the responsibility for managing blood risks in Canada was redefined following the tainted blood scandal and the Krever Inquiry. As Giddens (1990) notes, the complexity of modern risks requires addressing the uncertainty inherent to their scientific management. While the risk society scholarship does not explicitly discuss the use of precaution in addressing scientific uncertainty, I argue that the implementation of this principle can be examined from a risk society perspective because it deals with issues of uncertainty and public trust. In the blood system, a key consequence of the redefinition of risks has been the application of the precautionary principle to address scientific uncertainty and theoretical risks such as vCJD. In line with Ewald (2002), I argued that precaution functions as a "principle of responsibility" (p. 299) that holds governments and policy makers responsible for anticipating and preventing potential risks.

As Giddens (1990) suggests, because of the complexity of managing modern risks, there is a need to address uncertainty surrounding science and expertise in a manner acceptable to the general public. In the case of the blood system, this means that measures need to be implemented to bridge risk management experts (and their precautionary approaches to risk) with interested publics. As I will examine in the next section, Giddens' notion of access points is particularly useful in understanding the nature of these measures in the Canadian blood system and the role they play in building trust and legitimating risk policy decisions.

# Establishing Lay Participation in Regulatory Blood Decision-Making

In this section, I discuss how lay participation in the EAC-BR is conceptualized and shaped in relation to the tainted blood scandal, Krever's recommendations and the resulting redefinitions of risk and responsibility.

Krever's recommendations and the resulting regulatory structures that were put in place exemplify the concept of the stakeholder society (Macintyre, 1999; Petersen, 2003). Petersen (2003), drawing upon the work of Macintyre (1999), argues that in contemporary health care, the notion of the stakeholder or consumer has replaced the notion of the passive or inactive patient or citizen. In the stakeholder society, there is a mutual obligation between government and citizens, one in which citizens have a say in policy processes (Macintyre, 1999). In this way, the notion of the stakeholder society compliments the concept of risk society by drawing attention to the existence of active publics that have come to play important roles in contemporary risk decision-making.

# The Role of Access Points to Expert Risk Management Bodies

In addition to regulatory changes to the technical aspects of risk management, Krever also recommended the implementation of measures to involve the public in the blood system. Thus, Recommendation 33 centers on the appointment of an advisory committee (which became the EAC-BR) to assist in the assessment and management of risk. As Justice Krever (1997) states:

The membership of the committee should include persons from the different fields of interest and expertise that relate to the protection of the safety of the blood supply, such as representatives from relevant medical, scientific, and public health professions, ethicists, manufacturers, *and consumer groups*. (p. 1066)
In addition to the inclusion of consumers, Justice Krever also spoke about the need to make the blood regulator accountable to the Canadian public. In Recommendation 34, Krever (1997) states that decision-making must be "open and accessible to the public, [if public] confidence in the federal Department of Health" (p. 1067) is to be re-established.

These recommendations illustrate key ideas from the literature on risk society (Beck, 1992; Giddens, 1990). As discussed in *Chapter* 2, mechanisms that foster public trust allow institutions and governments to more effectively achieve their goals in managing risk in the population (Giddens, 1990). They are also effective in helping government and policy makers deal with legitimacy crises when risk management procedures fail to prevent threats to the health of a population (Giddens, 1990). More specifically, if the public trusts government and policy makers to do the very best they can to manage risk, then it is also more likely to excuse government and policy makers for the occasional lapses of safety.

For Giddens, access points that connect the public and experts/policy makers are important mechanisms for building trust. He argues that, while society has become increasingly dependent on abstract systems of technical expertise, the scientific uncertainty associated with managing modern risks also creates the potential for undermining the validity of expert knowledge in the eyes of the public (Giddens, 1990). The contradictory nature of expert knowledge and past failures to adequately respond to risks, such as in the case of the tainted blood scandal, are examples that illustrate the fallibility of these technical systems of risk management and their dire consequences in terms of the loss of public trust. Governments have responded to this issue by establishing mechanisms that connect the public with risk management experts. Thus, these access points provide a way

for individuals to "directly confront those responsible for the development and/or implementation of abstract systems of expertise" (Ali, 1997, p. 485).

In the case of the Canadian blood system, several access points were created in response to Krever's recommendations for public accountability and public participation. The first such access point was the National Blood Safety Council (NBSC), which was created in 1997 under the leadership of the then federal Minister of Health, the Honorable Alan Rock (Norris, 2008). The mandate of the NBSC was to "provide advice to the Minister of Health on public health, ethical, public policy and other aspects of blood safety in Canada, including issues pertaining to blood regulation and surveillance" (CBS, 1998b, para. 10). The Council did this by identifying any "flaws or gaps" in how risks were identified and managed at the regulatory and organizational (blood operator) levels, as well as providing a "forum for communication among all stakeholders involved in the blood system" (CBS, 1998b, para. 10), including users and the public.

In July 2003 the federal government announced that it was dissolving the NBSC and consolidating it under the name, membership and mandate of the EAC-BR (Norris, 2008). While the dissolution of the NBSC reduced transparency on the part of government, I will argue that the government made this decision because it felt there was no longer a need for such public oversight of risk management practices in the in the blood system. In all probability they felt that way because of the implementation of the precautionary principle in guiding all risk management decisions made within the system. In other words, I suggest that the use of the precautionary principle provided the government with the necessary legitimacy to claim that it was doing everything possible to manage risk in the blood system, and thus public oversight was no longer required to the same degree.

With the dissolution of the NBSC, the EAC-BR became the only body at the regulatory level to include lay members who represented the public. The roles and responsibilities of the EAC-BR, as well as the criteria for member inclusion are laid out in its terms of reference. Those terms state that, "The Committee may have both Core and Ad Hoc members selected for their medical/scientific expertise or knowledge pertinent to the mandate of the Committee. The Committee will also have two members who represent the community at large, [who account for] lay representation" (Health Canada, 2006, Membership, para. 1). In addition, the terms of references lay out the criteria for the selection of those members:

The membership of the Committee as a whole will reflect an appropriate blend of gender, regional, ethnic and language representation, covering several areas of expertise, including medicine, basic and applied sciences and issues of ethics such as a lay person representing the public. (Health Canada, 2006, Membership, para.2)

The integration of lay members, or access points, into the risk governance structures of the Canadian blood system can be understood as an aspect of the stakeholder society. Under the model of the stakeholder society, individuals participate and take action if they want a say in policymaking. In the next section, I discuss how lay participation in the EAC-BR is conceptualized in relation to the redefinition of responsibility in blood risk management following the tainted blood scandal and Krever Inquiry, and the way in which these changes shape participatory processes. In doing so, I will also demonstrate that several structural and contextual factors influence how this access point actually functions in practice. In particular, drawing upon the model provided by the stakeholder society perspective, I draw attention to the different publics that exist and to their varying roles in policy decision-making.

#### Lay Membership on the EAC-BR: Redefining Public Participation

As I have shown, in Canada and other Western countries, one important change in the blood system has been the integration of the public into regulatory decision-making as a way to demonstrate accountability and re-establish trust. In this section, I examine the role of lay members on the EAC-BR, highlighting the manner in which the blood regulator conceptualizes this role, and how this role is assumed in practice on the committee. I argue that this is important as the re-definition of responsibility in the blood system influences who is selected to serve as lay member and what role they play on the committee.

In line with Marinetto (2003) and O'Malley et al. (1997), I focus on the role of the state when attempting to understand public participatory processes in the blood system. They argue there is a need to emphasize government and the role of the state when attempting to understand how participatory processes operate, particularly in relation to the governance of risk. I pay particular attention to how the various institutions in the blood system are anchored in broader political arrangements and "cultural systems of meaning" (Dacen et al, 1999, p. 320) that each represents their own interests. This is important, as these arrangements and interests shape the roles of lay members on the EAC-BR. The works of Douglas (1966; 1992) on risk and Foucault's (1991) notion of governmentality provide important frameworks with which to analyze how participatory processes have been articulated in relation to risk practices and the interests of government and policy makers. Those frameworks help highlight the moral influences that shape participatory processes and the role of lay members in blood safety decisions.

I will argue that these participatory policies serve the interests of government more than those of the public, with the exception of those blood consumers who are primarily

concerned with issues of contamination. Those concerns are well-addressed by the current precautionary approach to risk management

# Lay Members: Representing History and Trust through Responsibility

Giddens (1990) argues "the conditions of modernity all depend upon trust vested in abstract capacities, such as expert systems" (p. 26). However, as he warns, the contradictory nature of expert knowledge and past failure to respond to uncertain risks has resulted in a declining trust in scientific expertise and in the mechanisms of risk management. Therefore, strategies to foster public trust, such as access points, are needed to enable the state to promote co-operation and achieve its goal of governance (Giddens, 1990). One such access point is the inclusion of lay members on committees that regulate risk. The EAC-BR is an example of one such attempt to include lay members as a way to build trust and support for blood safety decisions.

This function is reflected in the interviews with various members of the EAC-BR who saw lay membership as a way to provide the EAC-BR with a non-expert perspective on their work as a way to build trust. One expert member commented that:

I think that it shows the public is represented and it demonstrates transparency. I think it makes people feel more secure and I think that is a good thing because it builds trust. I think this is particularly important in the blood system because of what happened in the past.

#### (Interview #3 – Expert member)

Another lay member voiced a similar opinion:

I think what follows from stakeholders is that we really build respect and I think we build respect for the professionals at the table. We build a mutual respect; I think we build respect for Health Canada, and for the government and of many of the decisions that are being made. And I think what comes back is trust. And I think a trust in the ability of the regulator to do what they need to do. So I think that is really, really key, especially for the blood system because so many mistakes were made in the past.

(Interview #5 – Lay member)

Lay representation is described in a similar manner in a Health Protection and Food Branch policy document on public participation. In describing the rationale for public participation, this document recommends "including a range of perspectives in the decision-making process enhances the quality, credibility, and accountability of the decisions the Health Products and Food Branch makes about a regulated product, and encourages public trust and support in its decision making" (Health Products and Food Branch, 2005b, p. 2).

Lay members also represent a collective memory for the past failures of the blood system. As one lay member said, "You know after the tainted blood scandal, you simply cannot leave out the stakeholders – it is just not right and I do not think the Canadian public would stand for it" (Interview #4 – Lay member). An expert member further commented, "I think it makes the group seem more public – you know, after the tainted blood scandal, the public did not trust the blood system" (Interview #3 – Expert member). A lay member echoed this comment, saying:

I think it is really important in this blood system, particularly after the public inquiry, that we have different viewpoints at the table. You know, that was one of the problems in the past blood system is that they were not including the public and listening to the public when they were making decisions, and I think that is absolutely critical. It is the only way to build trust.

(Interview #6 – Lay member)

Yet, a few members of the EAC-BR expressed reservations about the usefulness of lay representation in maintaining public trust, largely because of the relative anonymity of this committee. When an expert member was asked about whether they felt the involvement of lay representatives on the EAC-BR generated trust, he responded:

I would hope so, because it shows openness to the public. Now, I am not sure how many people in the public know about this work, but those that do...I think trust the system more.

(Interview #1 – Expert member)

One lay member responded to the same question saying:

Well, maybe not the general public because they would not know about us, but I would say, you know health stakeholders in every health groups know we are there and I think they trust that we are bringing their issues to the table.

(Interview #4 – Lay member)

Another lay member commented:

Well, I am not sure...I do not know how our inclusion is communicated to the general public. First of all the role of this particular committee...I do not how widely known, it is to the general public, or if it is known or at all. So the inclusion of lay representatives, if the public doesn't know anything about it...I'm not sure what kind of impact would have a building trust, unless it was more widely disseminated about what this group is in what they do. I mean, I can ask everyone my neighborhood, if they knew this group did and none of them would know.

(Interview #6 – Lay member)

An expert member made similar comments:

*Respondent*: I think the value in having these different perspectives is to make sure that Health Canada is not just thinking inside the box. I do think it shows that Health Canada is being accountable you know...this is important for government. It builds trust, which is also important since so much of it was lost after the tainted blood scandal.

*Interviewer*: How do you think having these different perspectives builds trust? *Respondent*: Well, I do not know. I guess, you know...it shows that Health Canada is being open when making their decisions.

*Interviewer*: Is knowledge of this committee well known to the public? Do you have any open meetings or publicize any information about the work? Respondent: Well, no, not really. Not that I know of. I guess it's not that open.

(Interview #3 – Expert member)

As these participants point out, one reason for this lack of public profile is that the EAC-BR was not established to be an open committee whose work is publicly accessible. Instead, it was given the mandate to provide expert advice on potential blood risks to the regulator, not the general public. Furthermore, while the EAC-BR does have a website that is available to the public with access to meeting minutes, the committee does not publish public reports, nor are the meeting minutes kept up to date. There are also no formal procedures to ensure that lay members on the EAC-BR report back to the broader public. When I asked blood consumers from the Canadian Blood Services whether they knew of any public involvement at the regulatory level, only one respondent, a consumer representing the Canadian Hemophilia Society (CHS), knew that the EAC-BR had lay participation, as there was a representative from the CHS on the committee. Despite their

in-depth engagement with the blood system, the majority of blood consumers did not know about lay participation at the regulatory level.

Given the above finding, we must then ask ourselves why members of the EAC-BR feel that lay participation on the committee contributes to building public trust even though they have so little contact with the public? I suggest that one answer is that they view trust being generated not by public contact, but rather by their ability to make sound scientific recommendations to Health Canada on the basis of the precautionary principle. More specifically, as I will show, members of the EAC-BR felt that their unswerving dedication to the science of risk management was the best guarantor of trust rather than public visibility. Thus, by adhering to a precautionary approach to risks, the regulator has been able to avoid potential adverse events, such as other contaminations, which could negatively impact trust.

Within this context, lay members on the EAC-BR were included to address prior issues of accountability under the Red Cross where experts made decisions that did not always prioritize safety but rather sought to balance out several aspects, including ensuring the sufficiency of the blood supply and protecting the reputation of donor communities. The tainted blood scandal shifted the responsibility of the regulator toward an agenda of complete safety, thereby transforming the role of lay membership to one of insuring that the EAC-BR operated according the dictates of the precautionary principle (Wilson, 2007). Members of the EAC-BR saw their role and the role of lay members not so much in terms of representing the public, but more to serve as witnesses of competent scientific management of risk. This is illustrated in the words of an expert member on the EAC-BR:

What I would say is that we are still living with the experience of HIV and Hepatitis B and C in our blood supply. But I would say that is a situation where the

risk assessment was done at the time of HIV and the lessons were learned from HIV, and we had to do things differently if we were going to have a safe blood system. So I see it as a positive thing that we are being more precautious.

(Interview #2 – Expert member)

The perspective on trust and public participation can be traced back to the redefined responsibility of government vis-à-vis the management of threats to blood safety. It is reflected in Giddens' (1990) assertion that "trust offers a reliability in the face of contingent outcomes" thereby serving to "minimize concerns about possible risk" (p. 33). Similarly, Straten (2002) argues that public trust is not simply trust placed in the regulatory system itself, but that trust is also vested in a "group or person in a societal institution or system, reflecting a general assumption regarding whether a system or institution can be trusted to act in the best interests of the broader public" (p. 229).

This view on trust and public participation is illustrated by the following comment from a lay member on the EAC-BR:

Honestly, I do not even know if they should be concerned about trust. You know this committee is here to make sure the system is safe and to look at the science. That is it. That is their responsibility. Anyway...they are not going to get the public's trust if the blood is not safe so they are kind of the same thing.

(Interview #5 – Lay member)

Another lay member reiterated this:

Well, I think that by ensuring the system is safe, or as safe as it can be, the public trusts it more. Because of what happened in the past, it is impossible to re-establish trust unless the government does their job and keeps the system safe.

(Interview #4- Lay member)

A similar idea was expressed by the following expert member:

We are here to provide advice on risks, we look at the science, the scientists discuss the evidence and we provide advice. All of this is done to make sure the system is safe. That is where trust will come from.

#### (Interview #3 – Expert member)

Hansen et al. (2003) note that while research on risk often emphasizes the importance of trust, there is little information on how trust is conceptualized by those who are involved in regulating risk. Similarly, in their analysis of public participation measures in the development of public policies around genetics in the U.S., Ard and Natowicz (2001) argue that it is important to examine how the public is conceptualized in regulatory circles, particularly in relation to the governance of risk. These are important questions that were addressed in the above examination of lay participation. As is evident in the comments of EAC-BR members, trust building is seen primarily as a function of responsible risk management and as an assurance of blood safety. In essence, this reflects Giddens' (1990) notion of trust as something bound up in "abstract capacities" or "expert systems." It is a form of faith or confidence that "such systems generally work as they are supposed to" (Giddens, 1990, p. 29). Thus, one could assume that as long as there are no adverse events, such as the contaminations that occurred in the 1980s and 1990s, public trust will not be at risk.

Lay members on the EAC-BR did not have a mandate to discuss the work of the committee in the public sphere. Rather, their inclusion was sought to address prior issues of accountability and transparency. Under the Red Cross, experts made decisions that did not always prioritize safety but rather sought to balance out several aspects, including

ensuring the sufficiency of the blood supply and protecting the reputation of donor communities.

The next section addresses how the EAC-BR's reliance on scientific expertise influences who can be involved and the roles lay members play on the committee.

# **Providing Public Perspectives on Scientific Decision-Making**

At the same time that the federal government increased stakeholder participation as a way to include public perspectives in regulatory decisions concerning blood, it also mandated a precautionary approach to risk management that relied on a strict scientific appraisal of threats to the blood supply (Ponte, 2006; Wilson et al., 2007). Yet, little attention has been paid to how scientific expertise influences public participation in risk management. In general, members of the EAC-BR conceptualized lay participation along traditional terms as the process of representing broad public interests on the committee. Further examination, presented in this section, reveals that the committee's advisory role and its reliance scientific expertise, even in conditions of precaution, influences the participation of lay members, shaping the type of stakeholder that is able to participate.

In the interviews, both lay and expert members of the EAC-BR described the role of lay members in terms of their ability to represent the public and provide the perspective of the non-expert on safety. Two lay members explained their roles this way:

We are there to provide the perspective of the public. Our role is to really bring the views and perceptions of the public to the decision-making table about risks and what the government should be doing to ensure safety and also how the public will react to information or changes.

(Interview # 5 – Lay member)

I would also bring in the public's perception of what those risks are. One of the big issues we would provide to them is how to address the public with respect to the risk posed by their blood and blood products given potential emerging pathogens.

(Interview #4 – Lay member)

Similarly, an expert member commented, "They really represent the public and those who have or do require blood and blood products...the consumer populations" (Interview #1 – Expert member). However, this member was the only one who spoke about the representation of blood consumers on the EAC-BR. No one else spoke about the need for consumer representation on the EAC-BR. This is in contrast to what occurs within the CBS (to be discussed in *Chapter 6*), where blood consumers are strongly represented due to their experience as victims of tainted blood.

At the same time, expert members on the EAC-BR also viewed themselves as representing the public perspective on the committee. As one expert member put it, "I suppose they bring in the perspective of the public, but that is also what I would do. While I am on the committee as a scientist, I am also a member of the public and think about how the public might look at these risks" (Interview #3 – Expert member). This was reiterated by another expert member who said: "We would all, sort of have some elements of public perception that we would bring forth to the work of this committee" (Interview #2 – Expert member). Another expert member similarly commented, "I also really feel like I speak for the public and thinking about the public in terms of how they would feel about some of the sisues" (Interview #1 – Expert member).

While both lay and expert members spoke of representing the public, they also distinguished the knowledge they each brought to the committee. In discussing how they were different from expert members, one lay member explained, "Well, I mean we do not

have the scientific expertise so we approach things differently" (Interview #5 - Lay member). One expert member expressed a similar idea:

I think it has quite a bit of value because, as I mentioned before, anybody is a potential recipient of blood products, and I think that questions about their use and how to address the cost issues in the risk issues makes it important to have these different viewpoints. I think, you know, this is both from the perspective of those who have received blood and blood products, or represent people who were direct blood users, or people who understand the social implications of testing in donor exclusion and how best to address public concerns.

# (Interview #1 – Expert member)

Although expert members recognized that lay members did not have the same scientific expertise, they nonetheless felt their inclusion provided a "reality check" that complemented the scientific recommendations of the committee. For example, one expert member, in responding to a question about what lay members bring to the EAC-BR said, "I think the lay reps provide a checkpoint so to speak. I mean, there are a lot of others, but I think having them there provides us a checkpoint" (Interview #3 – Expert member). Another member added that, "They provide a reality check on some of the discussions that happen at the scientific level" (Interview #1 – Expert member). He went on to say, "We've had major divides between the scientists, and in that situation there's no question that the input of the lay people with regard to what appears as sensible, is always useful for breaking those divides" (Interview #1 – Expert member).

Interestingly, while lay members were seen as representing the non-expert perspectives of the public, none could be considered as typical members of the lay or general public. All of the lay members held university degrees; one of the lay members had

a Masters degree and a second lay member was a physician who specialized in hematology. Therefore, while lay members were seen to provide a non-expert perspective, this did not mean that they did not understand science and scientific evidence. As the quotes below illustrate, members of the EAC-BR must have an understanding of science to be able to participate, even in matters that are precautionary. As one of the lay member states:

We focus on safety and looking at the science to see what it says that will help ensure safety. However, we also know that we have to pay attention to what the science cannot tell us. So then we are precautionary.

An expert member responded similarly when asked what informs the advice the committee provides Health Canada:

Science is the first thing – obviously. We look at the science to see what it says around risks and then precaution...the system is guided by the use of the precautionary principle. We have to think past evidence to what is possible. What *could* happen?

# (Interview #1 – Expert member)

(Interview # 4 - Lay member)

As we will see in the next section, in discussing who could be included as a lay representative, many participants agreed that, while member of the lay or general public are stakeholders in the blood system, it would be unlikely that they would be considered for inclusion in the EAC-BR. As I commented earlier, there is no formal process for choosing lay members and the terms of reference for the EAC-BR do not mention specific criteria for participation. With the exception of the lay member who represents the CHS

who was actively recruited, none of the other lay members could identify a specific reason why they were approached to serve on the committee.

# Expert Knowledge and the Challenge of Lay Participation

The need to understand expert knowledge shapes who can participate on the EAC-BR and the roles they are able to play in the work of the committee. It is here that the work of Foucault on governmentality, particularly his discussion about expert knowledges, provides a valuable frame to understand the impact of expertise on participatory processes. For Foucault, expert knowledges are a central aspect of regulatory power and provide governments with the necessary techniques to ensure that risks are dealt with in a way that coheres with the interests of the state (Foucault, 1991; Lupton, 1999). Thus, in the case of the EAC-BR, expert knowledge about science is central to the committee's function as advisor to the blood regulator, i.e. Health Canada. However, the requirement of scientific literacy and the technical nature of the work created barriers to participation on the EAC-BR.

When asked if they thought it would be possible for a member of the general, lay public to participate on this committee, both lay and experts members of the committee felt this would be unlikely given the need for all members to be able to read and understand scientific data:

The way it is set up right now I do not think so, because the data and the way that the scientific information is presented are very technical. Generally it is presented by way of clinical studies, clinical trials and statistics. For somebody without any background it would be very difficult to get up to speed on the amount of learning required. I think it would get in the way of their ability to actually provide advice and contribute meaningfully. So I do not think it would be fair to them. I do not

think it would be fair to the committee. And, I do not think it would be fair to the stakeholders that we are representing.

### (Interview #4 – Lay member)

I think it is daunting for someone who does not understand anything around science writing, about medicine, or anything about disease processes to be involved. Although it does not seem to be one of the criterions for inclusion, I cannot see how you would be involved without having that background.

# (Interview #5 – Lay member)

You know, it would be highly variable. The documents we look at our very technical and very high-level, so I would think you would need somebody who has a fairly high level of educational background and or interest in the area. You know, they keep saying you have to write documents for the grade six level, but we could not function as a committee if that was necessary to do. It would be an interesting challenge to see how you could incorporate people at that level into the committee. But whether it would alternately be worthwhile, or have any benefit would be the question you have to ask and answer first.

# (Interview #1 – Expert member)

I think when we are talking about the general public that is a lot more difficult. I am not sure if the general public would either, a) want to be involved, or b) would even know how to be involved. So I think that is a really challenging issue for the Committee.

#### (Interview #2 – Expert member)

Similarly, Wilson et al. (2007) suggests that the lack of public involvement in the blood system is a consequence of the complexity of risk management assessments. They argued "the technical nature of many blood safety initiatives makes them somewhat inaccessible to the general public" (Wilson, 2007, p. 182).

The importance of being scientifically literate was further evidenced by the fact that none of the committee materials were written in *lay language*. The following discussion with an expert member further supports this point:

*Interviewer*: Are the materials for the lay representatives provided in lay language or is there a chance for discussion so people can clarify any issues they may have? *Respondent*: The lay members get exactly the same information presented in the same way that the other members do. Any of us, if we have questions or need clarification, can get that done at the committee level.

*Interviewer*: Do you think this has an impact on the ability of lay members to participate?

*Respondent*: No. As I said, these are not just people off the street. They are also experts in their own way and they understand the science behind what we are doing. If they were regular people, then maybe it would. But...again, it would just be too hard, the science is very complex.

(Interview #1 – Expert member)

Another lay member similarly commented:

The scientists and the docs carry this committee. I do not think the issue of public perception really plays an impact at all. They try to base it on the best science

available. So I have not seen a lot of public perception in this committee. From my perspective, the role of this committee is all about science.

(Interview #6 – Lay member)

The comments above highlight the hybrid status of lay members on the EAC-BR. While they are acknowledged as representing the lay public, they are not themselves representative of the average individual. Rather, these participatory processes constitute another level of expertise that may not necessarily represent the interests of the wider public, which could be concerned not just by blood contamination but also by the issues of cost containment and blood sufficiency. As Wilson et al. (2007) has suggested, the propensity by regulators to implement expensive risk management procedures like leukoreduction to address remote risks is an example of what happens when expert science is no longer under public scrutiny. These researchers speculate that such expensive risk management measures might have not been implemented had members of the general public been involved, because those members would have given more consideration to issues of cost effectiveness (Wilson et al., 2007). However, there is little data to suggest this is the case. As we saw earlier in the chapter when discussing the redefinition of risk and responsibility, there is a continued perception that the Canadian public continues to be afraid of potential contaminations and prefers to prioritize issues of blood safety over the concerns of sufficiency and cost. As one expert member explains:

This is a very important question, and it is one the committee has had many discussions about over the years. I would say that it is not something that the committee addresses. Now we do not lose sight of it, but when the issue has actually been raised during discussion that has not been what the bureau wants. The bureau sees it as their role to do cost-benefit analysis and while that may be part of

the information they share with us, as part of the background information, is not something we take into consideration. You know that a lot of costly stuff is done in the blood system, and I think many of us question this, but since the Krever report there has not been any room to argue that things are too costly. If there is any potential benefit even incremental from it. We tend to say yes to it.

(Interview #2 – Expert member)

Another expert member voiced a similar opinion:

But I think the provinces are starting to put some pressure on restraining some of the costs. But it is still such a political minefield. So I think we can look at how we pay \$6 million a year to prevent not a single infection in the blood system, which you may keep doing again and again and again, but it is probably not going to change. I think part of it is being so close to the tainted blood scandal and a spin off from this is that I do think the public has perhaps not fully come on board with respect to the safety of the blood system. I think they are much better than they were, but I think there is still a lack of confidence.

# (Interview #1 – Expert member)

This underscores the challenges that arise when technical systems of risk management are mandated to interact with the "public" in an effort to secure broad support for the expert management of risk. When Giddens spoke of "access points," he did not address how difficult it would be for lay individuals to interact with experts without being experts themselves. However, it is not just members of the lay public that may have a difficult time participating. While lay members all have a certain level of scientific literacy, the technical nature of the work also created barriers to their participation. This is evidenced in the comments of one of the lay members:

I find it a little heavy. I have a little bit of an advantage because I spent 15 years doing medical education, and being a medical writer. Some of the chemical stuff gets a little heavy and anyway, quite frankly, a lot of the discussion on this committee is very scientific and very clinical and nature. So basically I am just there listening and participating as much as I can, which is not much.

(Interview #6 – Lay member)

The following comment by another lay member further illustrates the dominance of a scientific culture on the committee and its impact on lay participation. As one lay member noted:

I know that my comments and the things I bring forward are just as important as the views of the scientists bring forward. From my perspective there is real respect and belief in the value of the public into this process. [But] science is the first thing – obviously. We look at the scientific evidence and see what it says about different pathogens that could get into the blood system.

(Interview #5 – Lay member)

The challenge of participating on the committee due to technical nature of the work was also raised by an expert member on the Committee:

Some of the people who were physicians on the front line, and researchers on the front line, they get it better, but it is not so easy for somebody who is outside of Health Canada or outside of the blood services to jump in. This one in particular is hard because it is so science oriented.

(Interview # 3 – Expert member)

One of the lay members even questioned the value of having lay representatives on the committee:

I really think fundamentally that this committee should question the value of having lay representatives on the committees. I guess, I mean, if it is mandated then fine, you have got to have it. But you know...if they are going beyond their capacity then I think there needs to be a more in-depth look at what they could provide and why they are there; if you have them on there just because they are a token lay representative.

#### (Interview #6 – Lay member)

I have highlighted in this section how the government's redefined responsibility for blood safety in the wake of the tainted blood scandal and the reliance on scientific evidence influenced the nature of public participation in the regulation of blood risk. This issue was raised by Hagendijk (2004) who, in a study of public participation in regulatory decisions in the European Union, remarked that:

...Two voices are struggling to be heard. The dominant voice is the inclusive voice, assuring the reader that citizens' concerns should be taken seriously, and ought not to be treated in a condescending way. In contrast with this, however, a second, more "scientistic" voice argues that the public can only contribute properly if it is adequately educated and instructed. (p. 46)

In this vein, I have drawn attention to the challenges associated with the inclusion of lay members on the EAC-BR, and showed that due to the technical nature of the work of the committee, only certain publics are able to participate as lay members. In particular, lay members need to have an understanding of science and scientific evidence to be able to effectively participate in the work of the Committee. As I demonstrated, the responsibility

of the regulator is to ensure that the blood supply is safe from contamination. To that end, the materials the EAC-BR has to review are scientific in nature and require a high level of scientific literacy if the Committee is able to fulfill their mandate and provide Health Canada with recommendations that enhance blood safety. I argued that the integration of participatory processes into regulatory blood safety decision-making is more a reflection of governmental interests than a desire to include public views on risk in regulatory decision-making. As we saw in the comments of one of the EAC-BR lay members, "I don't think the issue of public perception really plays an impact at all. They try to base it on the best science available. So I have not seen a lot of public perception in this committee. From my perspective, the role of this committee is all about science" (Interview #6 – Lay member). As Foucault (1991) reminds us, practices of governing are not simply top down directives. Thus, in this context they may also include the governing of public action through governmental mechanisms such as public participation.

In the next section, I will briefly discuss the role of consumers, specifically hemophilia consumers, in relation to the EAC-BR. A review of their participation is important as Krever singled out this population in his recommendations for the blood system. Moreover, unlike any other groups, they have been integrated in regulatory discussions regarding blood safety and included on the EAC-BR.

# The Role of Blood Consumers on the EAC-BR

Some of the blood literature has highlighted the unique and influential role of blood consumers, particularly those representing the hemophilia population, in regulatory decisions about blood risks (Hergon et al., 2005; O'Neill, 2003; Ponte, 2006). For example, when studying the role non-scientific factors played in the identification and regulation of vCJD in the US and the UK, Ponte (2006) found that hemophilia consumers

were able to sway regulatory practices toward the prioritization of the precautionary principle in the management of the blood supply by invoking the experiences of their community with HIV and HCV. Hergon et al. (2005) observed this type of activism on the part of the hemophilia community in the French blood system. Like their counterpart in other blood systems, they were effective in advancing precautionary measures by reminding expert members of the impact of past blood contaminations on their communities.

In Canada, Justice Krever made specific reference to the inclusion of blood consumers at the regulatory level, particularly those individuals most affected by the tainted blood supply (1997). For Krever, the inclusion of these individuals was important for restoring public trust in the blood system as they had been most affected by the past failures of risk management. The influential role of blood consumers has also been noted in some of the Canadian research (Wilson et al., 2004; Wilson et al. 2007). For example, Wilson et al. (2004) highlight the active participation of "high volume blood users" (p. 185) in the Canadian blood system, particularly in relation to blood safety. They argue "the participation of these groups, and the absence of the general public, creates pressure for the blood system to introduce measures that protect the blood supply" (Wilson et al., 2004, p. 185).

Despite the above noted influence of blood consumers, members of the EAC-BR did not seem aware that one of their members was a representative of the Canadian Hemophilia Society (CHS), nor could they identify any liaison between the CHS and the EAC-BR. When asked whether consumer groups such as the CHS were participating on the EAC-BR, one expert member said, "No. I have not been privy to the involvement of any of those groups. Now, I do think one of the members of our group is associated with

the Canadian Hemophilia Society, but do not really know that for sure" (Interview #2 – Expert member). Lay members were equally unsure about the involvement of the committee with the CHS. One lay member said, "You know I am not really sure. I do not really know who the other lay representatives are on the committee" (Interview #6 – Lay member). A review of meeting minutes and interview data did not reveal that the CHS or other blood consumers had any connection to the EAC-BR. Those groups did not make any presentations to the EAC-BR, and the sole lay member from the CHS on the EAC-BR participated in the same manner as other lay members.

One caveat to this generalization is necessary. Since EAC-BR minutes are protected, it is not possible to verify whether individual members raised any discussions on issues of concern to consumers. Nor is it possible to verify if there were any interactions with consumer organizations. However, if there had been discussions or contact, one would expect that someone on the EAC-BR would have acknowledged this during the interviews. The only exception occurred in 2004 when Health Canada requested the CHS to send a representative to serve on the EAC-BR when its membership expanded from one lay member to three members (Health Canada, 2004).

This is not to suggest that consumers do not monitor the work of the EAC-BR. For example, the CHS published four online public report cards of the Canadian blood system, beginning in 1999 (CHS, 2007). In these report cards, the CHS graded the performance of CBS, HQ, Health Canada, and the provinces. Each group was graded on issues such as safety, supply/sufficiency, transparency/accountability and compensation. In the 2003-2004 CHS "Report Card on the Canadian Blood System," the CHS criticized the EAC-BR for not being publicly accessible because significant portions of its agenda and minutes were protected from public view (CHS, 2005). They commented on the "highly secretive

manner" (CHS, 2005, p. 5) of the EAC-BR and called upon Health Canada to make the EAC-BR truly responsive by opening it to the public like the United States Food and Drug Administration's Blood Products Advisory Committee. Similar criticisms were made again in 2007 by the CHS in their Report Card (CHS, 2007).

I argue that the closed nature of the EAC-BR is a consequence of its role as an expert advisor to Health Canada on issues related to blood safety. All meeting agenda items are decided upon by Health Canada. Guests must have permission to present. Therefore, it is difficult for members of the CHS or other consumer groups to attend or participate in matters pertaining to the EAC-BR. Furthermore, there are no public meetings and no public forums. While the meeting minutes are made public, they are years behind in schedule and, even then, much of the discussion is held in camera and thus not publicly available.

Interestingly, despite this apparent lack of openness, none of the blood consumers I interviewed seemed concerned about the lack of consumer involvement on the EAC-BR. Only one consumer I interviewed knew that one of the lay members was a representative of the CHS. Even then, that consumer raised doubt about the usefulness of involving consumers in EAC-BR:

Now the reason I say I do not want consumers on this committee [the EAC-BR] is that I want the regulator to be coldhearted and scientific. The work of this committee should be guided by science and scientific principles only. That is it.

(Interview # 13- NLC consumer)

This comment begs us to explain why consumers feel little need to be involved on the EAC-BR and in the regulatory environment. One possible reason is that both the regulator and blood consumers have come to accept that the scientific practices of EAC-

BR provide sufficient guarantees for the safety of the blood supply. In other words, an ongoing and well-entrenched policy of strict adherence to the precautionary principle has made it unnecessary for blood consumers to monitor the work of the regulator and, more specifically, the EAC-BR. Since the new risk governance arrangements, one being the implementation of the precautionary principle, there has been no contaminations of the blood supply. As I will explain in *Chapter 6*, under the new regulatory regime, both blood consumers and the regulator have come to prioritize issues of contamination and the role of the precautionary principle when making decisions about blood safety.

# **Summary and Conclusions**

In this chapter I have investigated how participatory processes have been integrated at the regulatory level of the blood system by examining the role of lay members on the EAC-BR. Lay membership was initially conceptualized as a way to demonstrate accountability and transparency for blood safety decisions in the wake of the Krever Inquiry. This was seen as an important step in rebuilding public trust in the Canadian blood system. This participatory process was in response to the devastating impact of the contamination of the blood supply, a public inquiry and subsequent legal trials. Those events redefined the identification and management of risks in the Canadian blood system, as well as how issues of trust and accountability are framed. Changes in risk management practices altered the role of lay membership at the regulatory level. In particular, these practices necessitated a requisite level of scientific expertise that implicitly restricted membership on the EAC-BR to those individuals possessing scientific literacy. In practice, exclusive adherence to the precautionary principle also reduced the role of those members to one of overseeing and legitimating the scientific decisions made by expert members on

the EAC-BR. Other legitimate public issues, such as concerns about the costs of risk management measures, their impact on the blood supply, or on the communities of individuals deferred as a result of those measures, were simply not considered to be part of the mandate of lay members on the EAC-BR. This finding raises questions about the usefulness and effectiveness of lay representation on the EAC-BR. Despite the rhetoric, and Giddens' (1990, 1991) ideas regarding public participation and trust, it seems that in practice lay members on the EAC-BR do little more than give symbolic nods to the risk management decisions made by expert members.

As Rothstein (2007) observes, studying "deviations between intention and practice" (p. 585) enable us to identify the implications of participatory processes on policy. One of the tensions I highlighted centered on the conceptualization of lay participation and public trust. Using Giddens' notion of access points, I framed lay participation as a way to build trust in expert decisions regarding risks. However, as I have shown, there is little to suggest that lay membership on the EAC-BR ensures transparency and builds trust at the moment. This is even acknowledged by members of the EAC-BR who expressed reservations about the ability of the committee to build public trust in the blood system.

Instead, I suggested that the exercise of building trust has shifted toward expert knowledge, safety and the scientific management of risks. Public trust is now seen as a function of a technocratic approach to risk management that prioritizes scientific evidence and expertise in avoiding contamination events. It has become the responsibility of the regulator and a consequence of the precautionary principle. Thus, using the Foucauldian notion of governmentality, we can frame participatory processes (in this case the inclusion of lay members on the EAC-BR) as an extension of governmental responsibility. While these processes bring the public into risk governance structures, they do so at the expense

of being anchored into broader political arrangements that serve the needs and governance interests of the state. As Marinetto (2003) notes, government has played a central role in supporting the notion of the "active citizen" (p. 116). This notion serves as a demonstration of the inter-relationship between civil society and the political realm, which is strongly linked to the way society and it institutions are governed by politics. Therefore, government cannot be seen as an "impotent force" (Marinetto, 2003, p. 116) in such matters.

These findings also highlight a gap in Giddens' conceptualization of access points. I have argued that the scientific nature of risk decisions in the EAC-BR serves to exclude members of the general public as they lack the expert knowledge required to effectively participate. Thus, while there is a conception of legitimacy attached to public involvement, in practice certain publics and types of knowledge are more valuable than others in the management of blood risk. In his discussion of access points, Giddens does not distinguish between the types of publics that are included in participatory processes, nor does he comment on how other factors, in this case governmental responsibility, might impact who is able to take advantage of those access points.

Finally, in order to better understand how participatory processes operate, I drew upon the notion of the stakeholder society as a way to complement Giddens' notion of access points. In particular, the notion of stakeholder society draws attention to the different publics that exist and their varying roles in contemporary health care decisions. This will be more relevant to *Chapter 6* when I discuss the role of lay members (also known as stakeholders) in CBS. As we will see, CBS needs to have the trust of the public to recruit donors and ensure a sufficient supply of blood. This requirement creates different roles and opportunities for lay members. In particular, I will examine the unique and

influential role that hemophilia consumers play in implementing blood safety regulations and the impact this has on the participation of other stakeholders in CBS.

# **Chapter Six:**

# Consumer Stakeholder Participation in Canadian Blood Services: Issues of Trust, Moral Capital and Reputational Risk

The contamination of Canada's blood supply and Krever Inquiry resulted in the removal of the Red Cross, an organization that had run the blood system since 1947, and the establishment of two new blood operators: Canadian Blood Services (CBS) for English Canada and Héma Québec (HQ) for Québec (Wilson et al., 2007). As with the regulator, safety and accountability became key issues for the new blood operators as a way to restore public trust in the blood system (Ezekiel, 2006; Wilson et al., 2007). The issue of trust is particularly important to the blood operators as the Canadian blood system relies on voluntary donors to ensure a sufficient supply of blood and blood products (Ezekiel, 2006; Krever, 1997). As discussed in *Chapter 5*, responsibility for sufficiency falls under the purview of the blood operators, not the regulator. Central to rebuilding trust in the blood system is the integration of participatory processes in the governance structures of the blood operators. For the purpose of rebuilding trust, a series of participatory processes were established at the national, provincial and regional level to facilitate the participation of a variety of stakeholders, including blood consumers, and health professionals.

In this chapter, I examine the role of stakeholders, paying particular attention to the role of consumer stakeholders in CBS. The notion of stakeholder is complex and multi-faceted. A traditional definition can be found in the work of Freeman (1984), who defined

stakeholders as "groups or individuals who can significantly affect or be affected by an organization's activities" (p. 46). The term *consumer stakeholder* refers to an individual who is a user of a product or service, or an individual living with disease or who represents the interests of people living with disease (Allsop et al., 2004). In the context of the blood system, the term *consumer* refers to those individuals who represent patients living with rare blood and bleeding disorders, such as hemophilia (Hergon et al. 2005; Wilson et al. 2001). For clarity, I will distinguish between two types of stakeholders in this chapter:

- Non-consumer stakeholders (referred to herein as simply "stakeholders"): this includes donors, health professionals and representatives from health organizations.
- 2. Consumer stakeholders: this includes current high volume blood users, such as those individuals representing thalassemia and other rare blood and bleeding disorders. This group also includes past users, such as hemophilia patients, many of whom were infected with tainted blood. They are now past users because the product they currently use is not made from human blood.

The involvement of stakeholders in the blood system resulted from the new risk governance arrangements that were put in place after the Krever Inquiry. Those arrangements required CBS to take into account the views of stakeholders in establishing their risk management practices. The following comments from CBS management articulate the relationship between stakeholders and the blood operator:

We cannot define the acceptability of risk alone. The only way we can define acceptable risk is in a societal fashion. So all the stakeholders to the system ought to have a view as to what is an acceptable risk and what they are prepared to bear. Whether they are the recipients, whether they are the funders, whether they are the

regulators, whether they are the operators, whatever they may be. The definition of the acceptance of a reasonable level of risk has to be a mutually agreed upon concept. This is the only way to build trust and without trust we have more risk.

(Interview #1 - Management)

Ultimately, blood has a huge impact on public health. So, clearly there is a linkage to all of this. So, the other fundamental part of it for me is all of this public involvement we have had actually contributes directly to the decision-making. Because I do not think we ever set ourselves up to be the only experts in terms of the blood system. We have a lot of knowledge, and we have a lot of expertise within Canadian Blood Services, yet there are an awful lot of others who also have knowledge and have more knowledge than we do. So they are there with us when we are talking about blood safety.

#### (Interview #2 – Management)

This chapter draws upon interview data from 20 respondents within CBS, including four CBS managers and staff, five members of the Board of Directors (including the two consumer members) and eleven members of the National Liaison Committee (NLC) (five of them consumers). I also draw upon an analysis of relevant organizational documents and policies. This chapter is organized into three sections. I begin by discussing the mechanisms through which consumer stakeholders are integrated in the blood system in the wake of the tainted blood scandal. Then, I report on the influence of consumer stakeholders from the perspective of members of the NLC and articulate how they draw upon their experiences as victims of tainted blood to strengthen their power base within the blood system. In doing so, they advance their own interests while also providing CBS with effective legitimization of its handling of the blood supply in the eyes of the public. In the

final section, I examine how CBS staff, management and Board of Directors viewed the role of consumer stakeholders in helping the organization protect its reputation and fulfill its responsibilities.

The findings report on the integration of stakeholders within the NLC and their roles in legitimating the risk management practices of CBS. I argue that for these participatory processes to work efficiently as trust mechanisms, they must involve consumer stakeholders from an identifiable blood consumer population, namely the hemophilia community. As victims of tainted blood, many of whom are living with HIV, these participating consumer stakeholders possess "moral capital" (Kane, 2001, p. 10). This is a "resource" that can be used to legitimate positions, organizations or individuals or for "mobilizing support and for disarming opposition" (Kane, 2001, p. 11). Within the context of CBS, the moral capital of consumers is used to bestow legitimacy on the risk management practices of CBS, thereby helping the blood operator maintain its reputation as a trustworthy overseer of the blood supply. The moral capital derived by consumer stakeholders because of their experiences as victims of tainted blood translates into a form of power enabling consumer stakeholders to ensure that their concerns are addressed in organizational policies related to blood safety. This addresses what Garland (1997) and Stenson (1998) identify as a neglected aspect of the governmentality research: stakeholder power.

Previous research has highlighted the contributions that consumer stakeholders have made in the context of health care institutions (e.g. Allsop et al., 2004; Brown, 1999; Crawford, 2002). For example, in their research on the roles of parents in program setting for children in the U.K.'s "Sure Start Programs," Gustafsson and Driver (2005) argue that consumer involvement exists as an alternative form of power to "contest, resist and re-

interpret" (p. 541) policy and program decisions. In analyzing consumer involvement in the National Health Service of the U.K., Joyce (2001) similarly observes that consumer stakeholders are useful to policy makers because they can help legitimate controversial policy decisions or decisions that have the potential to be misunderstood by the public. Petersen (2003) also argues that stakeholders have the potential to "use, manipulate, and transform the contexts in which they find themselves" pointing to contemporary strategies of governance that enable "new avenues for action and new claims to citizenship rights based upon concepts such as consumer, empowerment and participation" (p. 198). He further remarks that consumer groups have gained enough influence in various organizations in the recent past that they should be considered "horizontal networks of governing" (2003, p. 194).

Prior research has examined the roles of stakeholders in blood systems in a fairly limited way. In particular, Hergon et al. (2005), O'Neill (2007), Ponte (2006), and Wilson et al. (2004) have reported that consumer stakeholders play an influential role in the management of blood risk, but their research has been primarily descriptive and collectively, offers minimal insight into the mechanisms by which blood consumers exert their influence on risk decision-making. While consumer stakeholders are integrated into the blood system, it remains unclear as to how their influence is perceived by other players in the blood system.

# Canadian Blood Services: Tainted Blood, Justice Krever and the Making of a New Blood Operator

The Krever Inquiry reviewed all aspects of the blood system to determine the factors that led to the tainted blood scandal and provide recommendations that would

ensure such contaminations never happened again. Justice Krever outlined several problems with the Canadian Red Cross Society (Red Cross), which he felt contributed to the contamination of the blood supply. He found that a key problem was the presence of ineffective governance structures within the Red Cross that relied too heavily on the input of volunteers and who lacked the necessary expertise to understand the scientific nature of potential risks to the blood supply (Krever, 1997). Partly because of this, the Red Cross allowed concerns unrelated to safety to overshadow their decision making, which delayed the implementation of precautionary measures to safeguard the blood system. Krever argued that the Red Cross rejected the public health philosophy of the precautionary principle that "action to reduce risk should not await scientific certainty" (1997, p. 989). This contributed to the Red Cross underestimating the risk of HIV contamination and delayed the implementation of risk management decisions that would have reduced the number of people infected with HIV.

One explanation put forth by Justice Krever to explain why the Red Cross delayed the introduction of precautionary measures was that the organization was concerned about being seen as discriminating against donors on the basis of their sexual orientation. He singled out this concern as a primary factor in delaying the implementation of screening for at-risk groups and communities, surrogate testing and measures to trace and inform donors who had been potentially infected with contaminated blood (Krever, 1997). As Krever (1997) stated:

The Red Cross was particularly sensitive to them [allegations of discrimination] because two of the principles of the international Red Cross to which the Canadian Red Cross adhered were impartiality and neutrality, both of which implied that there should be no discrimination against individuals. Partly because of this sensitivity, the
Red Cross did not adequately educate the public about the groups at high risk of contracting AIDS. (p. 996)

To address this issue, Krever made twenty-five recommendations in four areas of operation: organizational principles, funding, management and operation, and donors and recipients relations. Underlining these recommendations was the notion that the new blood operator should be given the capacity to implement safety measures without needing government approval and for its Board of Directors to be independent from government (Krever, 1997). Justice Krever (1997) also specified that committees should be established in a restructured blood system to "facilitate the work of the national blood service" (p. 1054). In particular, he suggested the creation of a "safety committee," a "technical and scientific committee," and a "liaison committee" (1997, p. 1055). As part of this restructuring, Krever focused on the issue of accountability by recommending that stakeholders be integrated into these governance committees.

### **Overview of Canadian Blood Services' Mandate**

In February 1998, CBS was incorporated and by September of that year, it became the blood supplier for Canada with the exception of Québec, where HQ fulfills that role (Wilson et al., 2004). The responsibilities and mandate of CBS are outlined in the Memorandum of Understanding (MOU) that was signed between the Federal, Provincial and Territorial Ministers of Health. In the MOU, the Ministers laid out four governing principles of the new blood system:

- 1. The safety of the blood supply is paramount
- 2. A fully integrated approach is essential
- 3. Accountabilities must be clear
- 4. Decision making must be transparent (CBS, 2002)

The mandate of CBS is to "manage a safe, secure, accessible supply of blood and blood products for all Canadians (excluding the Province of Québec)" (CBS, 2002, p. 15). Its core functions are recruitment, collection, manufacturing, testing, and distribution of blood and blood products, with the related functions of research and development, education, utilization management and diagnostic services (CBS, 2002). CBS, as with HQ, is required to address any risks associated with the performance of those functions in a precautionary manner (Krever, 1997). Under its governance structures, both blood operators must implement blood safety directives issued by Health Canada. The blood operators can exceed these directives by implementing blood safety policies that are more stringent, but they cannot implement measures that bring any added risk (Wilson et al., 2004).

# **Stakeholder Participation in Canadian Blood Services**

The mandate for a new blood operator also involved the integration of stakeholders into the blood system's risk governance structures. Krever's recommendations and the subsequent involvement of stakeholders in this regard, exemplify the concept of the stakeholder society (Macintyre, 1999; Petersen, 2003). In the stakeholder society, there is a mutual obligation between government and citizens, one in which citizens have a say in policy processes (Macintyre, 1999, p. 114). Additionally, there are distinctions between the types of stakeholders and the roles they play. Petersen (2003), drawing upon the notion of the stakeholder society, argues that in contemporary health care, the notion of the "stakeholder" or "consumer" has replaced the notion of the "passive" or "inactive" patient or citizen. As I will show, these distinctions are important to address as they are aligned with different conceptualizations and different roles. A number of Justice Krever's recommendations for the blood operator centered on the need to rebuild public trust and confidence by increasing the transparency and accountability of blood safety decision making. He recommended the implementation of measures that allowed the public better access to information about blood safety decisions of the blood operator. More specifically, Krever stated that (1997):

The current lack of confidence in the blood supply system affects donors of blood, consumers of blood components and blood products, and the public at large. This lack of confidence results, in no small measure, from the absence of public participation in the decision-making process that, until now, has characterized the system. Members of the public are entitled to know the risks and uncertainties. Actions that are taken to minimize the risks must be communicated to the public,

including the reasons for choosing one action or measure over another. (p. 1051) In Recommendation 12, Krever (1997) makes specific reference to the inclusion of "consumers of blood components and blood products as well as blood donors" (p. 1054) in the workings of the new blood operator. Similarly, in Recommendation 14, he states that in order "to promote the principle of openness, all committees should have as members, representatives of consumer groups and the public and that minutes of meetings and background materials should be available to the public" (Krever, 1997, p. 1055).

In response to these recommendations, CBS created two primary access points through which to engage stakeholders. The first was the formal inclusion of two consumers on the twelve-person Board of Directors (Abecassis et al., 2009). The second access point was the creation of the *Consumer Advisory Committee* (CAC). This committee was created to bring to CBS the views of key consumers including hemophilia, cancer and transplant

patients, as well as members of the public who could be considered potential users but not on a regular or extensive basis (Leiss et al., 2000).

In 2000, CBS created a *Public Participation Task Force* (PPTF), to review these mechanisms and advise the Board about the effectiveness of public participation in CBS. Reporting back to the Board of Directors, the PPTF criticized the creation of the CAC as an initiative that "downgraded…what Krever had proposed" (Leiss et al., 2000, p. 11). In particular, the PPTF found that the CAC lacked influence and did not have sufficient access to the Board of Directors as it reported directly to the Chief Executive Officer. As a result, the CAC was dissolved in 2001 by CBS management and the Board.

# The National Liaison Committee (NLC)

To replace the CAC, CBS created the National Liaison Committee (NLC) in 2001, which reports directly to the Board of Directors. This change not only better aligned the NLC with Krever's recommendations, but also gave stakeholders direct access into CBS' policy and decision-making processes (Abecassis, 2009). The NLC has a mandate to report on the ideas, opinions and concerns of blood consumers from across Canada. As noted in its terms of reference, the "National Liaison Committee will ensure that Canadians contribute to decision making on issues affecting the blood system" (CBS, 2005b, p. 1). The functions of NLC members are to:

- Provide input on the blood system and/or on issues coming before the Board of Directors
- Ensure that special interests are brought to the attention of the Board
- Promote communication between Canadian Blood Services and pertinent external organizations

The membership structure of the NLC consisted of "not less than 10 people," including:

- One delegate from each of the Regional Liaison Committees\
- Representatives from national organizations such as consumer groups, patient/recipient groups, health care professionals, and hospitals
- National partners or sponsors of Canadian Blood Services (those organizations that plan or promote donor clinics on behalf of Canadian Blood Services)
- Two Consumer Representatives from the Canadian Blood Services Board of Directors (who co-chair the NLC)
- Other appropriate individuals suggested by Committee members

(CBS, 2005b, p. 2).

The NLC meets in person twice a year, with one meeting held with the entire Board. The key function of the NLC is to represent the public viewpoint regarding issues of risk and blood safety. In a recent report done on CBS, the NLC was described as a mechanism "to engage their stakeholders in a substantive dialogue about what the risks are, what constitutes acceptable levels of risk, and what measures would best reduce risk to acceptable levels" (Ezekiel, 2006, p. 4) so as to rebuild trust in CBS. As visible in the above description, there is a diversity of stakeholders who serve on NLC. However, as I will discuss in the following section, consumer stakeholders play a different role in CBS than do other stakeholders.

### **Stakeholder Influence in CBS**

In this section, I outline the attributes of each type of stakeholder on the NLC and examine the implication of those attributes in terms of stakeholder influence on CBS with a particular focus on the influence of consumer stakeholder. In his work on the involvement role of stakeholders in corporate risk management, Power (2003) argues that different types of stakeholders have different influences on organizations and the outcomes they need to achieve. This is indeed the case in the blood system. Consumer stakeholders, particularly those representing the hemophilia population, are more effective for building trust and demonstrating legitimacy. Because of their moral capital derived past experiences as victim of tainted blood, hemophilia consumers provide CBS with legitimacy that other stakeholders participating in CBS do not. The ability to provide legitimacy is historically situated in reference to the tainted blood scandal and thus is a rare and unusual aspect of power. In articulating this influence, I will show how consumer stakeholders exert power and influence "from below" (Petersen, 2003, p. 198) by virtue of their association with identifiable consumer community groups.

# **Rebuilding Trust through Moral Capital: The Role of Consumer Stakeholders**

CBS management, Board members, and stakeholders themselves viewed stakeholder involvement, and especially consumer stakeholder involvement, as an effective way to rebuild trust and confidence in the blood operator. This is reflected in the following comments from two CBS managers and a member of the Board:

And the huge issue, the huge benefit is trust. Trust is a very big and very critical issue for this organization. This organization lost a lot of trust and now we are trying to regain it and it is only because these committees continue to function, and stakeholders and consumers have faith in the process. So it is the trust. I think that is the biggest benefit.

# (Interview #1 – Management)

We did not do this simply because Krever said that we should do it. We genuinely believe it is the right thing to do. Actually, we the system, and Canadians at large,

will benefit from it. What do I mean by that? I think by demonstrating that we are being transparent and accountable we will help build trust in the system and fundamentally trust is critical because it had collapsed previously.

(Interview #2 – Management)

You know, I think if we look back at what happened with the Red Cross...they sat in a boardroom, two or three of them, and made a decision about what they were going to do with people's lives, which is wrong, because those people were never included. So now to look at CBS that has the NLC, the Regional Liaison Committees and two consumers on the board. These are people whose lives are going to be affected by the blood and blood products that we provide. So they are right there saying "Yes, I agree," or "I want you to think about this issue..." this builds trust.

### (Interview #5 – Board)

The value of stakeholders is also acknowledged indirectly in CBS documents that reaffirm the value of public participation. For example, the 2004-2005 *Annual Report* states that, "the entrenchment of public involvement into its [CBS'] values is essential to ensuring a safe blood system and maintaining Canadians' trust" (CBS, 2006, p. 33). The CBS website also states, "We firmly believe that involving the public in our decision-making is essential to restoring Canadians' faith in the blood system" (CBS, 2010, para. 3).

Likewise, all of the stakeholders I interviewed from the NLC conceptualized the value of their participation in relation to increasing public trust in the blood operator. This is illustrated by the following comments:

We bring trust in the CBS and the decisions they make...that is probably the most important thing we bring. After the tainted blood scandal, people did not trust the system.

## (Interview #16 – NLC)

I think that by demonstrating that you are including a whole bunch of people that interact with the system, this builds trust. I think particularly by having the representation of user groups...that they participate and they are treated with respect, this builds trust. It shows people that CBS can be trusted.

(Interview #11 – NLC)

We do have a voice in making change. They can say we told them what to do that and they heard. So I think it really builds confidence, particularly in that group, and I am talking about the Hemophilia Society.

### (Interview #10 – NLC)

What the last two comments also suggest is that certain types of stakeholders, namely blood consumers, are seen as more valuable than others in relation to the aim of maintaining public trust in the blood system. This was expressed by consumer stakeholders as well as most non-consumer stakeholders representing health professionals and health organizations. The involvement of blood consumers as bearers of risk provides a particularly potent form of legitimacy for CBS. As a NLC stakeholder explains, "I think you would be hard pressed to describe the blood system in Canada without also speaking about the Canadian Hemophilia Society" (Interview #11 - NLC). Another quote from a member of the CBS management team reaffirms this point, "I distinguish a little bit in my mind between the bearers of risk, which is clearly the patient, their voice needs to be given a disproportionate position" (Interview #1 - Management).

Blood consumers who had been victimized by the tainted blood scandal derived their legitimacy as living links to the past failures of the blood system. Their involvement serves as a symbolic but also living testimony of past failures of the blood system. As two members of the board explains:

That is probably the best set of checks and balances we have on the board, because when you are interacting personally with people you know, and you know that some of them actually have health conditions resulting from tainted blood, your views of the decisions you make is quite different.

(Interview # 5– Board)

Well not to put too fine a point on it, but nobody else on our board has the perspective of a victim of HIV and hepatitis C that were gotten from the blood system. I mean really does one need to say more? Because no matter how much the rest of us empathize, we are not living that life, and we have not had that experience. To me, that would also be related to safety. And then as well, none of us have the experience of knowing that every week of our lives we depend on the blood system. It certainly keeps me on the straight and narrow and I think it keeps all of the board on the straight and narrow.

#### (Interview #8 -Board)

As we can see from the comments above, the hemophilia community was not simply granted ready access and influence within the blood system. This came about because of their past experiences as victims of tainted blood. As Bayer (1999) notes, social interest groups need to "differentiate themselves in order to survive" (p. 108). The tainted blood scandal did just that for hemophilia patients; it provided a shared experience and narrative that was used to mobilize patients so as to prevent another contamination tragedy.

The nature and extent of this tragedy served as an inspiration to advocate for safety within the blood system, but also clearly distinguished them from other blood users who were not as profoundly affected by the scandal, or from non-consumer stakeholders who had no such history. This point is reflected in the following two comments:

I think when you have people that are so impacted like they were before, like the hemophilia patients. I think when you involve these people it brings more confidence and trust in the system.

### (Interview #10 – NLC)

While many members of the NLC are not patients, they could at some point, conceive of themselves as being a patient, and we all know that they would want the safest blood possible. More importantly, I think that what really helped was for them to be sitting next to real existing patients to fully understand, and drive home that safety concern.

### (Interview #19 – NLC)

An important note here is that the hemophilia community derives its legitimacy as past bearers of blood risk rather than as current ones. At the moment, the majority of this population relies on synthetic blood products rather than on products derived from human blood (Canadian Hemophilia Society, 2009). Nonetheless, despite this caveat, the hemophilia stakeholders were perceived as valuable contributors, as suggested by the following comment:

We continue to see the Hemophilia Society as a very significant stakeholder. As individuals, their risks are exceedingly low and there are other canaries in the mine. There are other patients getting much greater exposure to human blood than hemophilia patients. However, the fact is that the Hemophilia Society is simply the

most outspoken and the group that has the greatest legitimacy. For whatever reason, that is the reality on their part. It is a very hard-earned reality.

(Interview #2 – Management)

This legitimacy is explained by the extent of the tainted blood tragedy and the greater degree to which the hemophilia community was affected. As noted in Chapter 2, over 1,100 transfused Canadians were infected with HIV, of whom 700 had hemophilia and other bleeding disorders and the remaining 400 were transfusion recipients (surgery, childbirth, etc.) (CHS, 2010). For example, by the end of 1982, 56% of hemophiliacs in Montreal were infected with HIV; by 1988, 74% of hemophiliacs were infected with HIV (Gilmore & Sommerville, 1999). In addition, 30,000 people were infected HCV, and many were infected with both viruses (Gilmore & Sommerville, 1999).

As I will discuss in the last section, this past history provides the hemophilia community with so much influence as a consumer stakeholder group, that their involvement in the blood system would be seen as a central aspect of risk governance.

# The Expertise of Consumer Stakeholders

In order to utilize access points in organizations to their advantage, consumer stakeholders require savvy and knowledge of internal organizational politics. The hemophilia stakeholders represent a community that has been very successful at mobilizing members who are well-educated and have in-depth knowledge of science, blood risk, and who are also versed in the art of public communication (Feldman and Bayer, 1999). As Bayer (1999) notes, in the aftermath of the tainted blood scandal hemophilia communities mobilized across North America, and transformed themselves "from a loosely linked group of patients whose health was paternalistically managed [into a] social interest group with an identity, an animus, and a strategy" (p. 295). The following comment from a member of

the CBS management team illustrates this point, "They also happen to be incredibly wellinformed. They have remained well-informed through the years of the tainted blood scandal, up until now" (Interview #3 – CBS staff). The next series of comments by CBS management, staff and a non-consumer NLC member also underlines how knowledgeable this community is, and the manner in which this plays out in terms of their advocacy efforts within the NLC:

Blood consumers are extremely knowledgeable, and the best example of this would be the Canadian Hemophilia Society. They are so aware of what is happening. They are aware in terms of reactions that their members are having to product. They are aware of new trends. They are very aware of security supply issues. They provide credible input.

### (Interview #2 – Management)

I think the Hemophilia Society just is one of those natural stakeholders. They have so much experience and resources. From my perspective, not everybody and not everybody's voice carries the same weight. I mean, you cannot have all of the stakeholders having the same influence.

### (Interview #4 – CBS staff)

I would say that some of them (hemophilia patients) are more knowledgeable. I mean, you know they are doctors and they are experts, and so you know, they probably say more and participate more. I think because of their experience, you know they are experts about the blood system.

# (Interview # 10 - NLC)

These comments indicate that hemophilia consumers have acquired influence in the blood system from their moral capital as past victims of contaminated blood, but also

because they are proactive and keep themselves up-to-date with new emergent risks to the blood supply. Their representatives are conversant in the language of science that is privileged by the blood operator, which has allowed them to become recognized as experts in their own right within the NLC and the blood operator. The expertise found in this stakeholder community has allowed it to make informed contributions in risk policy discussions and to be effective in promoting its own interests in the blood system. This informed activism has enabled blood consumers to successfully promote their concerns about the risk of blood contamination, often at the expense of other risk concerns held primarily by non-consumer stakeholders on the NLC.

# **Points of Tension and Reputational Risk**

Giddens (1990) suggested that while access points help to foster trust, they also represent places of tension where stakeholders wage battles against the organizations they seek to change. Godbout (1998) similarly warns that the points of contact between the state, policy makers and stakeholders can have negative consequences when the actions of policy makers do not adequately address the concerns of stakeholders. One such point of tension concerns the potentially negative impact that consumer stakeholders have on an organization's reputation. Power (2003) suggests that consumer stakeholders derive much of their power from their ability to enhance or undermine the reputation of the organizations they wish to influence.

The example of the hemophilia community illustrates concern with reputational risk as a point of tension between stakeholders and organizations. Of particular concern for CBS is the influence of the hemophilia community, which is tied to their history as victims of the tainted blood scandal and also to the continued public awareness of this historical tragedy. Because of this, the hemophilia community has a lot of influence as a consumer

stakeholder group because they are perceived as a potential liability by the blood operator due to their ability to negatively impact public opinion about the operator's risk management practices. The blood operator and other stakeholders on the NLC saw securing this community's ongoing support as a matter of great importance because disapproval could shatter public trust and have disastrous consequences for the blood supply. The comments below by two non-consumer stakeholders on the NLC illustrate the nature of this concern:

I think in particular if the Canadian Hemophilia Society was not happy with the decision then all Canadians would know. And I think that the Canadian Blood Services would have a very big issue on their hands. I think that, you know, knowing their history knowing what they went through, Canadians would listen to the Canadian Hemophilia Society. I think that it Canadians would think it was a big concern if the Hemophilia Society didn't trust the blood system.

#### (Interview #10 – NLC)

I think that patients have a very strong influence on the blood system at this point. I think that the hemophilia population is able to project into the public ideas about the blood systems' safety. That is powerful. So, I do not know what will have to happen for changes to occur.

#### (Interview # 12 - NLC)

One member of CBS staff even expressed the opinion that consumer stakeholders, particularly members of the hemophilia community, had become so influential that they could be considered a factor in the maintenance of a conservative approach to risk regulation in the blood system:

Because of Krever and because of all the attention that was around the blood I do not think we could make a significant change in the system, particularly if we were not confident that the stakeholders who had the most direct involvement, consumers, the ones we are closest to, if they had a different opinion or were opposed. It just never would happen. We would not be able to make the change happen. Now, they can be neutral and that can happen, but we would never be successful in making change if the minute we made the change they would be as saying, this is the wrong decision, and here is why. We would be toast.

(Interview #4 – CBS staff)

One strategy of influence used by the hemophilia community is a report card, which is a tool devised by the Canadian Hemophilia Society (CHS) to grade CBS and HQ, as well as the regulator, Health Canada, and also provincial governments, particularly in relation to safety issues. One member of CBS management described the use of this report card as being a tool that allows the hemophilia stakeholders to tap into their extensive social networks outside of the blood system and use those networks as a source of influence:

We know they are very effective advocates. They have effective networks; you know they have the report card. So we are thinking what are we going to get on the report card because of this decision? You know, if we make a decision that is contrary to their perspective, how are they going to react? And what would that mean for public trust?

# (Interview # 2 – Management)

To date, the CHS has published report cards in 1999, 2002, 2003-2004 and 2005-2007. In the first report card, CBS was given a grade of C for blood safety, with HQ receiving a B, Health Canada a C and the provinces a C- (CHS, 2007). By 2005-2007, the

CBS and Héma Québec both received an A for safety, while the federal government received a B- and most provinces, with the exception of Québec, received an A (CHS, 2007).

This report card illustrates the manner in which consumer stakeholders learn to wage advocacy battles by being reflexive agents and learning to adapt and diffuse measures to control them by the organizations they seek to influence. In this case, the hemophilia community sought to supplement internal advocacy efforts by making these report cards widely available on websites and in the media. This strategy is effective because the report cards are distributed outside of the blood system and thus cannot be co-opted by CBS.

Such stakeholder reflexivity has historical roots in previous traumatic experiences with risk and risk governance. Giddens' (1990) notes that past failures by expert systems to address risks and protect the public have produced greater risk awareness among members of the public, as well as challenges to expert knowledge. He refers to this phenomenon as form of risk "reflexivity" (1991, p. 85), which results in a realization by non-expert publics that the scientific knowledges on which expert risk decisions rest is contested and contingent on human consensus rather than rationality. In the case of the hemophilia community, this reflexivity initially emerged out of their struggle with the terrible consequences of the tainted blood scandal and previously unsuccessful attempts to influence the Red Cross in implementing more proactive risk containment measures for HIV and HCV.

Power (2003) suggests that consumer stakeholders use reputational risk as a source of power, and exert influence by inserting themselves into the organizational processes in a way that suggests an organization is being responsive to the needs and concerns of its public. In that manner, organizations have increasingly drawn consumer stakeholders

deeper into their risk management practices, giving the appearance that decisions are being made and endorsed by the very people who would be most affected by the consequences of those decisions. The adage of keeping one's friends close and one's enemy even closer seems to apply here in explaining how consumer stakeholders have become increasingly embedded in the organizations they seek to influence. The example of the hemophilia community illustrates this aspect of the risk society and underlines the need to consider reflexivity as an important factor when studying the activities of stakeholders.

# **Points of Tension: Risk Priorities**

While tensions can exist between stakeholders and the organizations they seek to influence, there are also other points of tension that develop between stakeholders within the same organization. A common source of tension between stakeholders has to do with incompatibilities and divergence in the interests of the respective communities they represent. In the case of the NLC, the interviews revealed significant tensions between consumer and non-consumer stakeholders concerning issues of risk priority and risk management in the blood system. These divergences served as a case study to help better articulate risk governance practices in the blood system.

Risk governance practices address two types of risks in the blood systems. The first and most concerning risk has to do with the introduction of a pathogen into the blood supply, which then can be transfused into many other individuals. Failure to deal with contamination risk was the main factor that resulted in the tainted blood scandal when HIV first surfaced as a human disease and subsequently entered into the blood supply of many countries, including Canada.

The second risk, though not always explicitly defined as such, has to do with possible shortages of blood and blood products, which can have dire consequences for

individuals requiring a transfusion because of injury or illness. While this sufficiency risk is not regulated in the same manner as contamination risk, it is nonetheless an issue that blood operators must address as part of their mandates as health care institutions. There is also a relationship between the risks of sufficiency and contamination in the sense that regulating contamination risks by deferring an increasingly larger number of donors can lower the donation rate and the blood supply. Yet, not controlling contamination risks can lead to a loss of public trust in the safety of the blood system, which can also negatively affect supply. This situation is what happened in the aftermath of the tainted blood scandal, where Canada's blood supply drastically diminished as potential donors stayed away because of concerns about safety. A blood operator must therefore ensure the safety of the blood supply while also addressing the risk of having a depleted supply of blood.

The interviews revealed that consumer stakeholders from the hemophilia community and other groups reliant on blood and blood products (e.g., people with thalassemia and other rare blood and bleeding disorders) prioritized the risk of contamination above concerns with blood sufficiency. The following comments illustrate how these consumers conceptualized contamination risk as a more pressing concern than the issue of blood supply:

But when you put all these things together it is the best possible thing we can do if it is the safest thing we can do. And that is what we demand. The risk, if you look at the down side of this decision, is all towards the recipients. They bear the risk. There is no risk for the donor so this shows you that, you know, there is no balance. The risks to the blood supply are too great even though they are small.

(Interview #13 - NLC)

So for me and my group, blood shortages are a very real thing. But they are not as important as making sure the blood is safe. I mean, we can postpone things like surgeries but getting bad blood...there is nothing we can do if that happens.

(Interview #16 – NLC)

I know there is a lot of talk about sufficiency issues, but I really do not see that as such a big deal. I mean, generally, there is enough blood for what Canadians need. There may be some delays, but a small delay is better than contracting a disease from blood that could have been avoided had we been conscious enough about the risks and addressed them appropriately.

# (Interview #19 – NLC)

It is important to note here that consumers did acknowledge blood sufficiency as a valid concern, but prioritized it as a lesser concern when compared to the risk of contamination. However, two of the respondents were quite a bit more dismissive of the issue of blood sufficiency, as reflected in this comment:

Yeah, we also have to think about the amount of blood. How will this impact the supply so that we have enough? But, at the same time, we have never been sufficient and I do not think we ever will, so is it such a big deal? I mean, we import blood now.

### (Interview #14 – NLC)

The other consumer member went farther and challenged the validity of conceptualizing sufficiency as a risk:

Bullshit. It is a bullshit argument. Sufficiency is managed like everything else, we have added executives working for CBS, and they are trying to get people in. In

fact, there has not actually been a shortage of blood since CBS was formed. They have done away with shortages.

### (Interview #13 – NLC)

Consumer stakeholders spoke about the prioritizing of contamination risk in relation to the history of their respective communities' experience with blood contaminated by HIV and HCV. The following comments revealed a conceptualization of contamination risk as being historically grounded in past trauma rather than as informed by scientific notions of risk:

But what is significantly small and what is not significantly small is up for debate. It depends on who you are and what your position is. Since I am representing the hemophilia population and our community was so devastated by contaminations, my position is that we must, or CBS must, protect the blood supply from contamination risks.

#### (Interview #19 – NLC)

I reminded the Board (at the previous month's closed Board meeting), that CBS did not exist to provide jobs for staff, or for the sake of donors, or for some set of other broader public policy goals. I reminded them that CBS exists for the sole purpose of providing safe and effective treatment for patients. Obviously, my view was a little at variance with others who wish to keep all the stakeholders happy. As far as I am concerned, only one stakeholder is at risk of injury and death, and the system exists to serve and protect them.

# (Interview #9 -Board/Consumer)

The views of consumer stakeholders on risk contrasted with those of stakeholders representing health professionals and health organizations, including patient

representatives from non-blood consumer health organizations. They saw the issue of blood sufficiency as posing a much higher threat. While they acknowledged contamination as an important risk, they were also more vocal than consumer stakeholders about the need to better address the risk posed by blood shortages resulting from donor deferral and donor apathy. Several non-consumer stakeholders also commented that insufficient attention was devoted on the NLC and within CBS to the impact of measures to address contamination risk in the blood system. Several health care professionals spoke about their own experiences with having to cope with blood shortages in hospitals. One NLC health professional member said, "I think shortages are the biggest issue we have to face, yet they are not appropriately addressed, it is all about safety from contamination" (Interview #15 – NLC). Three other non-consumer NLC members reiterated this concern, two of which represent health professionals:

I guess if anything I am concerned about shortages and the issue of supply. I do not know that we have really addressed that issue. You know, we focus a lot on pathogens but not supply. Yeah, I think the new challenge is getting more blood.

#### (Interview #11 – NLC)

From my perspective, and I think I am not alone, I think that having an insufficient supply of blood should be treated more seriously. I just do not see this being taken as a real issue. I think contamination fears are given more priority than sufficiency and I do not really understand it. We face shortages daily and yet we will spend resources addressing risks that are really not risks at all. I mean, when the risk ratio is so low you have to ask yourself if this is a real risk.

(Interview #17 – NLC)

When problems arise you know, so all the transmissible disease testing and all of those safety features that we spend a fortune on are done, well, that means nothing if you get to the hospital level and lack the resources, which is where the safety issues will be.

# (Interview #12 – NLC)

The above comments illustrate how the various stakeholders on the NLC conceptualized risks differently depending on past experiences and vested interests in the blood system. For blood consumers, their exposure to contaminated blood in the 1980s and early 1990s continues to resonate, and informs their efforts in prioritizing contamination as the primary threat to the safety of the blood supply. This past history gave members of that community a sense of responsibility and a dedication to making sure such a catastrophe does not befall their community again. By contrast, non-consumer stakeholders, many of whom are from the health care community, deal primarily with blood shortages in hospitals and thus view the potential for a shortage of blood as a risk that is at least equivalent to the contamination risk. While these differences obviously did not result in open hostility between the two groups of stakeholders, they nonetheless constitute points of tension within the NLC.

In the next section, I will explore the implications of this prioritization of risk in terms of the types of policies that have been implemented by CBS to minimize the risk of contamination and the costs associated with the implementation of those policies.

# **Prioritizing Risk Containment above the Issue of Cost**

In commenting about the precautionary principle as an approach to risk management, Ewald (2002) warned that "precaution is an attitude of protection" that comes with its own "logic of responsibility" (p. 298). Ewald (2002) added that relying on the precautionary principle to manage risk can lead to a slippery slope where organizations sidestep issues of costs versus benefits in order to ensure absolute control over risks, including remote ones. As he notes, "with the irreversible, we rediscover the irreparable. Not everything is a matter of economics. Not everything can be assessed a money equivalent" (Ewald, 2002, p. 285).

This issue of cost containment was another point of tension between consumer and non-consumer stakeholders on the NLC that was mentioned in the interviews. Consumer stakeholders emphasized that the precautionary principle should remain the guiding principle in the governance of risk irrespective of the costs involved in implementing the associated risk management measures. Consumers reiterated that decisions to address contamination should only be founded on strong scientific evidence, and follow Justice Krever's recommendation of using the precautionary principle whenever risks could not be adequately ascertained by scientific means. Consumers saw the precautionary principle as upholding the spirit of Krever's recommendations and as a means of making sure that the threat of contamination would continue to be prioritized above any other concerns, including financial ones. One consumer commented, "They have to follow it, precaution, because that is what Krever said. So, precaution means safety" (Interview #6 – Board/Consumer). Another consumer member of the NLC echoed that comment, "Listen, if you change the policy because the science says you should, then that is fine. But the science has to be there. And if it is not then you cannot change anything" (Interview #14 – NLC). Another consumer on the NLC reaffirmed the importance of adhering to a precautionary approach:

You know, one of the things that comes in here is the precautionary principle. Krever talked about this, Judge Campbell talked about this after SARS ... the

consumers that I talked to, particularly those with rare blood and bleeding disorders...we do not want any risk to our lives.

### (Interview #13 – NLC)

The above comments show that the precautionary principle defined the views of consumer stakeholders in regard to the management of risk in the blood system, which trumped concerns over the costs involved in controlling contamination risk. The following comments from consumer stakeholders illustrate this point:

The cost issue generally comes from putting more eggs in one basket than in another. You know from my perspective, cost is an issue, but we cannot, we cannot water it down. All of us with rare blood and bleeding disorders, we are such a small number so how can you possibly justify reducing spending on safety?

### (Interview #14 – NLC)

Listen, I know it is expensive. But, again, what is too expensive? If people get infected with a virus through no fault of their own then the system is going to have to pay. That is expensive. The Krever inquiry and the trials and the compensation... those were expensive. So, I think it is expensive in the short term but in the long term it is cost effective. Plus, I think it is a moral responsibility of the blood system to ensure that it is as safe as possible. I really believe that. There is no way the Canadian public would stand for another infection. I do not think the system could ever recover from that. Then we would really have a blood sufficiency problem.

# (Interview #19 – NLC)

By contrast, health professionals and other non-consumer stakeholders on the NLC viewed the issue of the cost of implementing blood safety measures based on the precautionary principle as a more important concern. These stakeholders decried the

disproportionate amount of resources dedicated to address even the most remote risk of contamination, particularly in relation to the limited funding allocated to recruit blood donors and manage blood sufficiency. The following comments from non-consumer stakeholders on the NLC representing the health care sector reflect this alternate view on the issue of cost:

It was one guy from the CHS who wanted to test every unit of blood throughout the whole year to check for West Nile without thinking about the cost of it at all, which turned out to be like \$30 million. All I know is that it was higher than the national budget of my entire organization.

# (Interview #15 – NLC)

I think cost is a big issue. As a person that works in the health care field, we see cuts daily to our programs...there is not enough money for the work that needs to be done. I think most areas of health care are seeing this, but with blood it is different, there is very little tolerance to implement a restriction on funding because of the fear of contamination. I get it because of what happened, but at the same time, it can be very frustrating.

### (Interview #11- NLC)

Cost is key for me. I have to tell you, I look at what the blood system spends and I am astounded. As a person that works in health and faces cutbacks all the time, the idea that we would spend hundreds of millions of dollars to prevent something that is only *theoretical* is tough to swallow. I understand the need for precaution, but we have to start asking ourselves how much is too much? I think for some people, such as patients, they do not understand the cost pressures facing health systems. Again,

like I said before, it is about priorities. If you feel that blood free from all real and potential contaminations is the most important thing, then I guess cost is not a big deal. But, if you are trying to ensure that health systems have enough money to function, then cost is a big deal. I think Canadians would be stunned to know how much the blood system spends to prevent infections. It is staggering.

### (Interview #12 – NLC)

Several of the non-consumer stakeholders even felt that the powerful influence exerted by consumer stakeholders on the NLC overshadowed the concerns of other stakeholders about costs and sufficiency. When asked to explain why there was a disproportionate focus on contamination among blood consumers, non-consumer stakeholders ventured several opinions:

I think that at this point, the patient's voice has more say than mine does. They can continue to talk about the infections and that is scary for CBS, scary for government and scary for the public. No one wants to be reminded of all the people infected with HIV.

### (Interview #17 – NLC)

They are still very afraid about pathogens so they have really pushed for safety. You know, people with my disease as a group do not use a lot of blood and blood products. But on the whole, you know, someone is going to need a surgery, and maybe you would need two or three in a lifetime. But someone who is a regular user would need it all the time. You know...a group like the Hemophilia Society, while it is small, they used a much larger volume of blood than many other groups. So I can see where the concern for safety comes from, you know, maybe if I was one of them, a hemophiliac or a user of blood, I might also push for it. I hope not, but maybe I would.

#### (Interview #15 – NLC)

To the consumer groups no cost is too much if there is an increase in safety. Now, I am not sure if the consumer entirely understands how much more it is going to cost. I mean, the risks are so low already that we have to ask ourselves if it is worth it. When does it become too costly?

### (Interview #11 – NLC)

The above comments suggest that concerns about risk containment, quite literally at all cost, are rooted in the experiences of consumer stakeholders with tainted blood. This justifiable concern then translates into an advocacy focus that trumps the concerns of other stakeholders who do not have the same traumatic experiences.

Overall, the interviews reveal that the various stakeholders on the NLC do not speak with a unified voice about risk governance but rather represent communities with different and at times competing interests about risks and the manner in which to control them. How these competing interests play out on the NLC involves several factors beyond the scientific appraisal of risk, including past experiences with contamination and the moral capital that blood consumers posses as victims of the tainted blood scandal. These factors give blood consumers a power base from which to ensure that their concerns about contamination risks remain at the forefront of NLC discussions, above other concerns such blood sufficiency and the cost associated with implementing risk containment measures.

# **Consumer Inclusion as a Form of Risk Management**

Power (2003) argues that contemporary organizations see reputation as a form of capital that can be used to manage the "societal perceptions of the corporation" (p. 156). He further discusses how stakeholders can play a key role in managing threats to reputation risk by providing corporations with a form of reputational assurance. By acknowledging stakeholders' interests and incorporating them into decision-making, corporations acquire a form of legitimacy that enhances their reputation as responsive and responsible decision makers.

In this section, I examine the manner in which CBS staff, management and members of the Board of Directors viewed the role of consumer stakeholders in helping the blood operator protect its reputation as a trustworthy organization and fulfill its responsibilities. This section represents an effort to better articulate the relationship between reputation, the moral capital of consumer stakeholders, and the issue of blood sufficiency. The focus is on the manner by which consumer stakeholders are used by the blood operator to enhance public trust in its risk management practices. As Wilson et al. (2007) comment in their research on the handling of the vCJD threat by CBS, the stringent application of the precautionary principle in the blood system can be seen as serving two purposes. First, it obviously protects the blood supply against contaminations. As importantly, it also demonstrates in a very public way that CBS is always acting proactively and aggressively to control potential threats. In the latter case, the endorsement of consumer stakeholders serves to amplify this message, with the hope that it ensures continued rates of blood donation.

# Trust, Risk Management and Blood Sufficiency

The core responsibilities of the blood operator include donor recruitment, the collection, manufacturing, testing, and distribution of blood and blood products, and related functions such as research and development, education, utilization management and diagnostic services (CBS, 2002). CBS is thus responsible not only for ensuring the blood supply is free from contaminations, but that it is also sufficient in supply. As indicated in CBS' *2003-2004 Report to Canadians*, "The primary risk is, of course, the risk associated with the availability and safety of the blood supply" (p. 22). The centrality of this risk for CBS is evidenced by the fact that in each annual report, there are sections on blood safety that discuss the safety of blood and blood products, the technologies available to test known and emerging pathogens, and a section on "Security of Supply" that focuses on blood sufficiency.

Ensuring blood sufficiency creates complex challenges for CBS, particularly in terms of ramping up donor recruitment efforts to compensate for an ever-increasing pool of deferred donors as a result of managing contamination risks. The following comments from two members of CBS management and one Board member underline these challenges:

The security of supply is a critical dimension. To exaggerate the point, you could have the almost perfectly safe unit of blood...you could spend \$100 million testing it, but if you are only going to have one unit of blood on the shelf well your system is then unsafe..."

# (Interview #1 – Management)

Not having enough blood on the shelf is as important as managing something that theoretically might get into the system. Security of supply, versus safety balance has to be achieved. We like to ensure that both sides of that argument are presented but it is very difficult as actions taken for one impact the other.

### (Interview #2 – Management)

So we talk about risk and the cost associated with managing risks there really are multiple balancing acts that need to occur, because when we decide to test for one thing, it often means we cannot test for another thing or it reduces our flexibility to do testing.

# (Interview #5 – Board)

In the interviews, CBS management, staff and members of the Board of Directors spoke about the relationship between the issue of blood sufficiency and public trust. The following comments reflect this point:

And if there is no public trust, there is no blood system. Public trust leads to higher blood donations, which leads to a sufficient supply of product being on the shelves or enough for anybody whenever and wherever they need.

(Interview #2 – Management)

So, if you are not open and people do not trust you, they are not going to give you this raw product for nothing. It is why it is imperative to be as open and transparent as possible.

(Interview #5 - Board)

This issue of public trust was also prominently mentioned in several CBS documents. For example, a news release from CBS entitled "Building Trust One Day: Every Day" states that "the increase in trust has translated into record levels for recruitment" (CBS, 2006, para. 2).

The interviews also revealed that CBS management, staff and members of the Board of Directors conceptualized the issue of trust as being primarily a function of its risk management practices. By this, I mean that public trust, or more precisely the lack of public trust, was conceptualized as a risk. The following comments are quite typical:

I think, from CBS' point of view, we decided at the beginning that there was only one real way to regain the trust of the consumers and Canadians in general and that was that safety had to be the highest priority.

### (Interview #8 – Board)

I think, by demonstrating that we are being transparent and accountable...that blood safety is our priority, we will help build trust in the system and fundamentally trust is critical for us as an organization, particularly as we rely on the public to give blood.

### (Interview #2 – Management)

What these comments also illustrate is that competent risk management is insufficient by itself to build trust; another crucial ingredient is the public awareness of those practices and a belief that they are being applied in a scientific manner. Thus, one can argue here that the precautionary principle serves not only as a scientific strategy for managing risk, but also as a kind of branding that CBS uses to show the public that it is doing everything possible to ensure the safety of the blood supply. The following comments by a Board member and a manager illustrate this last point:

But, if there is any risk, even just a mathematical model of risk...even something that is considered small, we must address it. I think this is key to safety and to trust. Precaution will ensure that the CBS attends to all risks, regardless of how small.

Because of this, Canadians will trust us as an organization because they will see that we prioritize safety.

(Interview #9 – Board)

You know, you have to look at the science. But that will not swing on its own, because a variety of things that have to come together like precaution. But again we have to apply this precautionary principle and say, well can you balance all of these the risks, including reputational risk and trust?

### (Interview #2 – Management)

The above comments also suggest a deep concern within CBS about even the most remote risks because another contamination of the blood supply, even on a small scale, could have a terrible impact on the reputation of CBS and undermine its ability to ensure blood sufficiency. Thus, the use of the precautionary principle is not only a scientific strategy to protect the public against blood contamination risk; its application in the most stringent manner serves to protect the reputation of CBS as a trustworthy blood operator.

# **Consumer Stakeholders as Endorsers of CBS**

In this section, I outline the actions taken by CBS to increase public awareness of its risk management practices by seeking the endorsement of consumer stakeholders. Power (2003) proposes that "high profile disasters" of which the tainted blood scandal is an example, have motivated corporations to adopt risk management strategies that incorporate mechanisms of "corporate social responsibility" (p. 147) like stakeholder participation. Those strategies allow corporations to take into account social concerns and to clarify the role of an organization within society. He argues that this process of internalizing societal concerns about risk is an effective a way to demonstrate corporate responsibility, which he describes as a "window of responsiveness" (Power, 2003, p. 111).

Another useful concept for this discussion is the concept of trust. According to Giddens (1990), trust is a fundamental aspect of the functioning of social institutions and involves the public having confidence in the capacity of expert systems to operate as expected in relation to a given set of risk circumstances, and in accordance to the best available expert knowledge. One challenge that risk governance institutions face with their expert practices, is to translate them from their specific organizational contexts into the public arena in a manner as to instil public confidence. This is a challenge for CBS, which makes its decisions about risk measures in expert committees, but also needs to generate public trust about the safety of the blood supply.

One way to conceptualize this translation process is to consider risk management practices as important symbolic value that can be publicized on websites and through the media. Giddens' (1990) defines "symbolic tokens" as "media of interchange which can be passed around without regard to the specific characteristics of the individuals or groups that handle them at any particular juncture" (p. 22). In this study, the interviews revealed that what gave the risk management practices of the blood operator their symbolic value were endorsements by consumer stakeholders, particularly those were victimized by the tainted blood scandal like members of the hemophilia community. Such endorsements like the report cards put out by the Hemophilia Society are, in Giddens' (1990) words, "disembedded" (p. 21) from the context of the blood operator, and thus not likely to be seen by members of the public as tainted by the interests of this organization. These kinds of endorsements (as long as they are unambiguously positive) are more likely to be trusted by members of the public, which then may translate into confidence in the blood system. This level of trust is then assumed to translate into a greater willingness to donate blood, which in turn allows CBS to maintain blood sufficiency.

Blood consumers confer symbolic value to CBS' risk management practices because of their moral capital as past victims of the tainted blood scandal. This is particularly true for the hemophilia community, which is publically recognized as the group most affected by contaminated blood, and also as the community whose struggle and persistent advocacy has made the blood system safer for all Canadians. In that sense, the hemophilia stakeholders more than any another group deliver the legitimacy that CBS requires to demonstrate trustworthiness in the eyes of an ever concerned public. Through their historically derived status, the hemophilia community has positioned itself as the guarantors of trust for CBS; securing their ongoing support is a matter of great importance for the blood operator CBS, as disapproval would most certainly shatter public trust and have disastrous consequences for the blood supply.

The importance of consumer stakeholder endorsement in enhancing confidence of the public in CBS is evidenced by the following comments from members of CBS management and staff:

That kind of support goes a long way in building public trust. I mean, we can sit here and say, trust us, trust us, we are trustworthy. But, without those major stakeholders also saying this to the public on our behalf, it can be very difficult. So, to have a third-party endorsement from, say the Canadian Hemophilia Society...then the public says okay I guess I trust them.

(Interview #3 – CBS staff)

We have had to draw on those relationships or used those relationships to get our message out to the public about safety in the blood system. So we sent a PSA for immediate release, we talk about measures we have implemented to make the

system safer, and then we will use a quote by one of the major consumer groups to support it.

### (Interview # 4 - CBS staff)

Power (2003) argues "not all stakeholders recognized by such systems are equally important from a risk management point of view, in the sense of being equally capable of directly damaging reputation" (p. 156). This was quite evident in the interviews as several CBS staff and management identified the endorsement of consumer stakeholders, particularly those representing the hemophilia community, as being the most effective in enhancing trust in the blood system:

In the early years, the headlines in the major newspapers were an indicator of how Canadians felt. The front-page news would say no trust in the blood system. I mean all of the headlines and all of the negativity was laid out in the press. So now there is very little negative front-page news about the blood system. I think it is a good indicator of the trust that they will speak out as a third-party endorsement of what we are doing. So you know, let us see, you hear something in the news and often you will hear the Canadian Hemophilia Society coming out saying the blood system is safe, one of the safest in the world.

# (Interview # 4 – CBS staff)

Third-party endorsement is very important for us as an organization, particularly from consumers and those indirectly impacted and harmed by the blood supply in the past. Particularly when talking about safety, third-party endorsement, particularly the hemophilia society, is a really important part of the public believing that the system is safe.

(Interview #1 – Management)

This type of endorsement also involves activities on the part of consumer stakeholders to draw attention to the need to maintain the blood supply within their extensive networks. One NLC stakeholder mentioned about how he regularly posted messages about blood safety and impending blood shortages on his community's website:

About just a month ago I got an e-mail from the NLC saying that they were facing a blood shortage and they wanted us to reach out to our communities to bring in some donors. You know, so they wanted us to do things, so I posted a banner of blood donation on the website.

(Interview # 16 - NLC)

The last comment above illustrates the way consumer stakeholders enhance the reputation of CBS by extensive social networks in which they are respected and trusted. Through their historically derived symbolic capital, the hemophilia community has become the guarantors of trust for CBS; securing their ongoing support is a matter of survival for the blood operator CBS as disapproval would most certainly shatter public trust and have disastrous consequences for the blood supply. However, by doing so, blood consumers have come to be conceptualized by CBS as a risk if their interests are not adequately represented in all safety policies. In this way, I suggest that consumer participation functions as a mechanism of legitimacy and trust, and, in doing so, is central to risk governance arrangements.

# **Summary and Conclusions**

In this chapter, I have examined how stakeholders have been integrated into CBS and articulated how participatory processes operate in relation to trust and safety. I argued that these processes work as trust mechanisms because the stakeholders involved have
specific histories in relation to the tainted blood scandal. I have suggested that CBS gains legitimacy from associating itself with an identifiable consumer community. In particular, consumer stakeholders representing the hemophilia population legitimate blood safety decisions in ways that are not possible for other publics. As past victims of tainted blood, their involvement is seen as central to helping the blood operator maintain its reputation and public trust. In this context, trust is considered fragile and maintaining it is dependent on endorsements by consumer stakeholders, particularly those representing the hemophilia population and past victims of tainted blood.

Drawing upon the work of Power (2003), I have argued that because consumers play an important role in trust and organizational reputation, they also present a risk to organizations and thus their interests must be appropriately addressed. I suggested that the findings further elaborate Giddens' work on access points by illustrating how the process of engaging consumer stakeholders translates into a form of power for these stakeholders. As past victims of bad risk decision-making, hemophilia consumers have the moral capital that enables them to remind the public about the contingent nature of expert knowledge. In doing so, they can ensure that their priorities around risk, namely that of contamination and precaution, are prioritized within CBS.

This analysis has also articulated the concept of the stakeholder society and the mechanisms by which stakeholders are integrated into risk governance. This aspect of the study contributes to what Garland (1997) and Stenson (1998) identify as a neglected aspect of the governmentality research. I have shown how consumer stakeholders exert their influence from below and within the context of being able to draw upon their historical experiences to legitimize the work of CBS. This influence gives them leverage to advance

their own vested interests in the blood system, including a request that more emphasis be placed on precaution and science in the identification of contamination risks.

The integration of stakeholders into CBS has important implications for policy and organizational processes. One implication that is increasingly acknowledged in the literature is the issue of cost. As illustrated, Wilson et al. (2007) report that over a three-year period there has been a 50% increase in testing expenditures in the blood system. While it is difficult to trace such costs increases to the inclusion of consumers, as previously discussed, Wilson et al. (2004) have suggested that the inclusion of "high volume blood users" (p. 185) at the decision making level puts in an increased pressure on the CBS and Health Canada to implement blood safety measures regardless of cost. Another implication is that stakeholders on the NLC who represented health professionals and non-blood consumers felt that their voices were given less consideration in organizational decision-making.

While it may be tempting to feel that consumer stakeholders are too powerful in CBS, one must remember that such processes operate within a regulatory environment that is ultimately responsible and interested in issues of contamination and precaution. Therefore, while the findings suggest that consumer stakeholders are influential in promoting certain types of risks and responses to them, the CBS must adhere to regulations laid out by Health Canada, not those put forth by consumers. As previously noted, while CBS can recommend changes to donor screening, the final say on all issues related to blood safety lies with Health Canada as the regulator of the Canadian blood system.

In the next chapter I will examine the "men who have sex with men" blood donor deferral policy, which was implemented to protect the blood supply from Human Immunodeficiency Virus (HIV). This policy will serve as a case study to illustrate the

cultural, social and political influences on risk management, as well as how ideas about risks are contested across various groups of stakeholders.

# **Chapter Seven**

# Science, Precaution and Stakeholder Interests: An Examination of the Men Who Have Sex with Men Blood Donor Deferral Policy

HIV has been a major concern for blood systems and governments since its appearance and detection in the early 1980s. This virus led to the contaminations of most blood systems and the deaths of hundreds of thousands of people worldwide. To safeguard the system from HIV, as well as other risks, and rebuild public trust in blood safety, various risk management policies have been implemented. As with many countries, Canada's approach to blood safety rests on two major aspects: blood testing and donor screening to defer either temporarily or permanently potential blood donors who may present a risk to the blood system.

One of the most controversial of these risk management policies is the permanent deferral of men who have sex with men (MSM) from donating blood, henceforth referred to as the MSM policy. In recent years, with the introduction of new technologies to more effectively screen blood for viruses such as HIV, this controversy has increased. In response, many Western blood systems have begun to re-examine this policy to determine whether changes are required. In Canada, the Expert Advisory Committee for Blood Regulation (EAC-BR) and the Canadian Blood Services (CBS) have reviewed the MSM policy in recent years, bringing together scientific experts and stakeholders affected by the policy, including representatives from the gay, lesbian, bisexual and transgendered

(GLBT) community and representatives from the blood consumer community, such as the Canadian Hemophilia Society (CHS) and the thalassemia population. These examinations have not resulted in a change of policy; men who have sex with men even once since 1977 continue to be permanently deferred from donating blood in Canada.

The MSM blood donor deferral policy provides a valuable case study to illustrate how stakeholder participation functions in policy making, particularly in relation to issues of blood safety and public trust. This policy serves as a case study to illustrate the cultural, moral and political influences on risk management, as well as how ideas about risks are contested across various groups of stakeholders. Furthermore, the inclusion of a more broad range of stakeholders into the reviews of the MSM policy enables us to see how other interested stakeholders participate in blood safety decisions. This chapter is examines how stakeholder groups advocating against the MSM policy are integrated into MSM policy decisions, and compares the impact of their participation on policy decisions with that of consumer stakeholders who support the policy.

This chapter draws upon interview data from 6 members of the EAC-BR and 19 participants from the CBS, including 2 members of management, 2 staff, 15 members of the Board and the NLC. In addition to interview data, I reviewed relevant documents from Health Canada, CBS, as well as stakeholder advocates, including AIDS organizations and gay rights groups in Canada. The first part of this chapter provides a brief history of the identification of HIV and the implementation of the MSM deferral policy in Canada and internationally. Then, I examine how the two stakeholder groups – consumers and advocates – conceptualize the risks of MSM and view the policy. Next, I examine recent reviews of this policy at the regulatory level and within CBS, focusing on how the various stakeholders have been integrated into these processes, through an examination of their

roles and impact on this policy. I conclude with a discussion of the policy, social and governance implications of the MSM policy.

The MSM policy illustrates the complexities of stakeholder participation in policy making and the manner in which ideas about risk are contested across stakeholder groups. As well, it demonstrates how some ideas become prioritized in blood safety policy decisions. As Douglas (1992) suggests, ideas about risk emerge from specific political, cultural, social and historic contexts and reflect deeper anxieties, fears and moral codes. In this way, the identification and management of risk reveals much about psychological, cultural, social and institutional affiliations, values and norms. I argue that different historical experiences with this virus influence the positions of these two stakeholder groups about the MSM policy. Although the MSM policy is framed in relation to science and the precautionary principle, it also illustrates the moral, cultural and historical factors that influence the way risks are identified and managed.

Throughout this dissertation, I have focused on the issue of trust and shown how participatory processes or access points have been integrated into risk governance arrangements as a way to rebuild trust following the tainted blood scandal. However, these processes function differently at the regulatory versus organizational levels. As I will show, with the implementation of a precautionary approach to risk management, there is little need to integrate any external stakeholders into discussions about the MSM policy at the regulatory level as government can show that all measures have been taken to ensure blood safety. However, with CBS the situation is much different. The new risk governance arrangements established following the tainted blood scandal and Krever Inquiry have resulted in a complex situation whereby CBS must implement the recommendations of the regulator with regard to blood safety. Yet, because of the importance of accountability and

trust, they must also carry out extensive reviews with multiple stakeholders even though, given government policy, there is almost no chance the regulator will accept a change in policy.

# The Politics of Blood Safety: An Overview of the MSM Deferral Policy

In Chapter 2, I provided an in-depth review of the contamination of the Canadian blood supply with HIV. In this section, I focus specifically on the actions taken to protect the blood system against HIV, particularly the implementation of early screening procedures that led up to the creation of the MSM blood donor deferral policy. In doing so, I will survey the points of tension that arose during the creation of this policy and I will examine the different responses of Canadian and American officials and blood operators. As I will illustrate, from the inception of the MSM blood donor deferral, there have been disagreements between stakeholders from the GLBT community and blood consumers, as well as those responsible for the blood systems, on what constitutes risk.

# Identifying At Risk Populations: Key Players and Controversies

In the U.S. and Canada, AIDS emerged in 1982.<sup>2</sup> Early epidemiological evidence showed that there were certain populations that seemed to be most at risk for AIDS and thus needed to be excluded from donating blood. These included Haitians, homosexuals, intravenous drug users, the sexual partners of these populations, and individuals with signs and symptoms of AIDS (Krever, 1997; Gilmore & Sommerville, 1999).

In 1982, following a report on AIDS in hemophiliacs, including one infant that had received blood from a gay man, the Center for Disease Control in the U.S. advised blood collection agencies to screen out potential at risk donors, of which one group was gay men (Schiltz, 1987, p. 206). Initially these recommendations were rejected as American blood

<sup>&</sup>lt;sup>2</sup> As HIV was not discovered until 1985, the acronym AIDS was used (Krever, 1997: xxv)

banks did not want to appear to discriminate against gay men who had become a crucial source of blood (Bayer, 1999). In response to this lack of action, the Hemophilia Foundation in the U.S. demanded that blood banks ban blood donations from gay men. While the national Gay Task Force denounced the Hemophilia Foundation for such a demand, in early 1983 the U.S. blood banks began to implement measures to prevent those individuals considered to be at high risk for AIDS from donating blood including the MSM population (Krever, 1997). Most of these measures centered on educating the public, as well as these specific populations, to refrain from donating blood. For example, pamphlets were distributed describing the groups at high risk of contracting AIDS, the symptoms of AIDS, not to donate blood (Krever, 1997). Additionally, blood clinic staff began to directly question individuals to determine whether they belonged to a high risk group or had the signs and symptoms of AIDS, and if so, excluded them from donating blood (Krever, 1997).

In Canada in 1982, eight cases of AIDS were reported to the Health Protection Branch in Canada, and a published study of 34 Montreal haemophiliacs showed they had unexplained immune defects (Gilmore & Sommerville, 1999). Health Canada's Bureau of Biologics asked the Canadian Red Cross, which was responsible for the blood system, and the Canadian Hemophilia Society to monitor AIDS among their populations. In 1983, the Canadian Hemophilia Society recommended that the Red Cross take steps to reduce the risk of AIDS (Picard, 1998). That same year, the Red Cross publicly asked, "homosexual and bisexual men with multiple partners to abstain from giving blood, along with newly arrived Haitian immigrants and intravenous drug users" (Picard, 1998, p. 73). However, following this public appeal, some gay and Haitian organizations filed discrimination

complaints against the Red Cross; boycotted blood donor clinics and emphasized civil rights concerns. In response, the Red Cross withdrew questions to potential blood donors about high risk practices as well as questions about AIDS symptoms, leaving only one diagnostic question "Are you well" (Picard, 1998, p. 147)?

It has been noted that the Canadian approach to donor exclusion in the face of HIV was softer than that of the U.S. as it was strongly influenced by the Red Cross' "ideology of trust and altruism" (Gilmore & Sommerville, 1999, p. 134). Asking questions about being at risk for AIDS was conceptualized as being distrustful and had the potential to impact sufficiency as donors from these communities stopped giving blood. We will see later in the chapter that while the blood operator at the time, the Red Cross, bowed to the advocacy efforts of those deferred, this is no longer the case. As I will illustrate, the implementation of the precautionary principle as a way to demonstrate responsibility for blood safety means that civil rights concerns of gay and lesbian populations and issues of sufficiency are no longer a guiding force in blood safety decisions. Unlike the current governance structure, in which Health Canada plays a central and active role in regulating blood safety, in the 1980s there was little governmental accountability for blood safety. While Health Canada did regulate blood and blood products, it has been noted "the government did not feel compelled to regulate the Red Cross because of its reputation" (Gilmore & Sommerville, 1999, p. 131). Therefore, issues of blood sufficiency and ideology were able to take priority over what was considered uncertain and unproven risks.

In 1983, following the withdrawal of questions targeted at high risk populations, including MSM, the Canadian Red Cross created a pamphlet describing the groups at risk for AIDS. Donors were to read it and exclude themselves from donating if they were at

risk. Yet, even this pamphlet was not distributed until 1984 and when it was, there was little accountability to ensure that all blood clinics were handing it out (Krever, 1997).

In 1985, the first transfusion-associated case of HIV in Canada was officially reported. By that time, there were hundreds of Canadians, of whom many were hemophiliacs, which were infected with HIV (Krever, 1997). It was in the same year that the donor screening pamphlet was re-created by the Canadian Red Cross to include a description of risk groups including: active homosexuals or bisexual males, drug abusers who inject drugs, people who have been to areas during the last 5 years where AIDS is endemic and sexual partners of anyone from those groups (Krever, 1999). However, even this pamphlet did not tell donors who had given blood but were concerned about their donation, to speak with a nurse or representative in the clinic to remove their donation. The pamphlet also did not say anything about the symptoms of AIDS, nor did it describe what behaviours might put homosexual men at risk. This stood in contrast to the U.S. that had already started to define the risk for homosexual men as "any male who had sex with another male since 1977" (Krever, 1999, p. 276).

It was not until 1986 that the pamphlet given to potential donors in Canada was revised to include a description of those high-risk groups unable to donate blood "to define unequivocally the largest group at high risk of contracting AIDS as any male who has had sex with another male since 1977" (Krever, 1997, p. 292). While this pamphlet was part of a strategy to encourage self-exclusion from blood donation for the MSM population, it did not form the basis of an active donor screening at the time of donation. Men who have sex with men were not actively deferred from donating blood; rather they were responsible for self-deferral. This took place almost a year later than in the U.S. In 1989, the Donor Health Assessment Questionnaire became an official document, with the content regulated by Health Canada. At this time, the following statement was added, "The following activities put you at risk for AIDS: intravenous drug use, living in an area where AIDS is common, regular treatment with blood and clotting factors, men who have sex with men, and sex with any of the above" (Leiss et al, 2007, p. 4). Potential donors were asked if any of these activities pertained to them and if so, they were permanently deferred, meaning they could not give blood. It was not until 1997 that the more specific question - "Male donors: have you had sex with a man, even once, since 1977?" (Leiss et al., 2007, p. 4) was separated from the general list and asked on its own. It has remained the same ever since.

#### **Challenges to the MSM Policy**

The American Association of Blood Banks (AABB) was one of the first groups that began advocating for changes to the MSM policy of permanent deferral, issuing the following public statement, "Since 1997, the American Association of Blood Banks (AABB) has advocated that the deferral period for male to male sex be changed to 12 months" (AABB, 2006, para. 1). Along with American Blood Centers (ABC) and the American Red Cross (ARC), the AABB reiterated their support for a change for a one year deferral of MSM at the Food and Drug Administration (FDA) meeting on "Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT)" as captured in this press release:

AABB, ABC and ARC believe that the current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted and recommend that deferral criteria be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted

infections. Presenting blood donors judged to be at risk of exposure via heterosexual routes are deferred for one year.

(AABB, 2006, para. 3)

These organizations justified their request on the basis of four key points: the HIV window period has been reduced to 16 days, in asymptomatic individuals HIV infection develops within less than one year, seroconversion of health care workers exposed to HIV occurred in less than 6 months, and the advancements of testing, specifically Nucleic Acid Testing (NAT), which enables blood systems to detect small levels of the virus in blood much more quickly and accurately than in the past (AABB, 2006).

Despite calls to change this policy from blood banks, the Red Cross and gay and lesbian advocates, the U.S. Food and Drug Administration (FDA) has not supported a change to the MSM deferral. Men who have had sex with men even once since 1977 remain, to this day, permanently deferred from giving blood in the United States (FDA, 2009, para. 1).

In Canada, the introduction of new testing technologies and mechanisms to ensure blood safety was a key factor leading to several groups calling for a change in the MSM policy, including the Canadian Federation of Students (CFS), as well as gay rights organizations, such as Equality for Gays and Lesbians Everywhere (EGALE) and the Canadian AIDS Society (CAS). These groups boycotted blood donor clinics at various Canadian universities to protest the policy, which they felt was homophobic and discriminated against gay men (Millar, 2007). Up to this day, McGill, Concordia, Carleton and King's University College have permanently banned blood donor clinics from their campuses. York University and the University of Western Ontario, have spoken publicly

about wanting to see a change in this policy that they also feel is discriminatory (Ginsberg, 2008).

The MSM policy has led to lawsuits, the most current being the case of Kyle Freeman versus Canadian Blood Services. In 2002, Mr. Freeman sent an email to CBS stating that he disagreed with the MSM policy. At the same time, he admitted that, although he was a sexually active gay man he had continued to donate blood by providing false information during donor screening. In response, CBS filed a lawsuit against Kyle Freeman for knowingly giving blood even though he is gay (McKinnon, 2010). Mr. Freeman responded by counter-suing CBS arguing that the lifetime deferral of gav men as blood donors is not scientifically valid and violates his constitutional right to equal treatment regardless of sexual orientation (CHS, 2010). The trial ended in early 2010, with a decision given in September. The Court determined that Mr. Freeman is liable for his misrepresentations on his sexual history and ordered him to pay CBS \$10,000 for lying about his sexual history and endangering blood recipients. Judge Aitken, who presided over the matter, ruled that Mr. Freeman could not invoke the Charter of Rights and Freedoms equality provision to challenge the constitutionality of the questionnaire, as CBS is not a government agency and thus not covered by the Charter (Makin, 2010).

By contrast, the Canadian Hemophilia Society (CHS), which represents blood consumers from the hemophilia population, has continued to support the MSM policy. In the Freeman trial, the CHS received intervener status to "represent recipients of the blood system and to support maintenance of the current MSM donor deferral criteria" (CHS, 2009, para. 6). The CHS has also published position papers on the MSM policy and garnered media attention as a result of their interventions in this debate. Their success

illustrates how they have mobilized their moral capital as past victims of tainted blood so as to legitimize their role in the MSM debate.

#### **Stakeholder Positions on the MSM Policy**

Mary Douglas' (1985, 1996) work on risk speaks to how and why certain dangers are identified as risks while other are not, and the way in which these serve to maintain and support boundaries and categorizations. She describes how pollution beliefs become imbedded in cultural systems of shared values. Each society develops its own ethical system, which includes pollution and purity rules that are meant to identify and prevent risk (Douglas, 1985). These rules and the risks they identify are inherently moral in that they reveal much about the psychological, cultural, social and institutional norms of a given society. The work of Douglas is also valuable in studying the structures of power and responsibility that are associated with the development and implement of these rules. As Ericson and Doyle (2003) note, the work of Douglas is critical in demonstrating that "risk is part of a political vocabulary of moral responsibility and accountability" (p. 4).

Drawing from the theoretical insights of Douglas, in the following analysis I examine how the positions of various stakeholders in the MSM policy debate are rooted in contingent interpretations of scientific evidence that are historically situated and political in nature. More specifically, I compare arguments put forth by stakeholders who are opposed to the policy, to those of supporters of this policy with particular focus on blood consumers representing the hemophilia population.

#### **Contrasting Views on Discrimination and Rights**

One argument put forward by stakeholders opposed to the MSM policy is that the policy is discriminatory and based on homophobic characterizations of gay men. For

example, a Canadian Federation of Students (CFS) document titled "End the Ban," describes the MSM policy in the following terms, "The ban on blood donation from the MSM community is discriminatory, and based on out-dated science and broad and old-fashioned stereotypes of the queer population" (CFS, 2010, para. 2). The Canadian AIDS Society (CAS) (2007) made a similar argument in the following press release:

There is clearly a double standard that discriminates against homosexuals and men who have sex with men. Heterosexuals are not subject to the same treatment, since they are deferred for a mere six months after having sex with an unknown partner. This deferral period was reduced from a year to six months in 2005. The current policy is not equitable. A homosexual man in a monogamous relationship, for example, could be at lower risk for HIV transmission than would a heterosexual man or woman who has had multiple partners, yet there is a significant discrepancy between the deferral periods for homosexuals and heterosexuals. (para. 2)

A comment that a representative from a Québec AIDS organization, Mr. Roger Leclerc (Parliament, March 29, 2001), made during the Standing Committee on Health meeting in 2001 expresses a similar position:

Gays are rejected collectively as blood donors not because they are individuals with a potentially higher-risk conduct, but because they belong to the gay community. In this respect, the entire gay community and each of its members individually view this as discrimination that is difficult to justify given that circumstances have changed since this questionnaire was designed. (p. 1125)

For stakeholders opposed to the MSM policy, the policy impedes their right to give blood and participate in a valued form of citizenship. Mr. Freeman, who sued CBS for discrimination, stated that the policy made him feel "like a second class citizen"

(Stechyson, 2010: A8, para. 9). He went on to say that "he lied on the questionnaire to help those in need. It is the ultimate gift" (Stechyson, 2010, A8, para. 10). A comment from a representatives of the *Table de Concertation des Gais et Lesbiennes du Québec* echoes Mr. Freeman's concerns about the policy, "Giving blood is more than an act of generosity, it is a citizen's duty. Even if homosexuals are highly responsible, they cannot fulfill this duty" (Parliament, March 29, 2001, p. 1130). A similar theme can be found in the comment of a representative from the *Organismes Communautaires Québécois de Lutte Contre le Sida* (COCQ-SIDA) (Parliament, March 29, 2001):

The gay community that has a collective constitutional right...the right to be recognized as citizens in their own right. At present we urge people to donate blood by appealing to their humanitarian side. I am exaggerating, but if you give blood, you are a hero. By preventing me from giving blood, I am prevented from becoming a hero. Perhaps we should take a second look at the way we solicit blood donors in an effort to lighten up on all of this vainglory, this temporary glory that surrounds blood donors. If we were to do this, the debate would no doubt be a little bit less emotional. (p. 1125)

The moral values associated with voluntary blood donation, like altruism and good citizenship, have been well reported in the literature on donor motivation (Boe and Ponder, 1981; Gray, 1997; Lightman, 1981; Oswalt, 1977; Piliavin and Callero, 1982, 1987, 1990, 1991). However, Valentine (2005) states that the "imaginative construction of the altruistic, embodied citizen as blood donor seems also to risk a corollary of the bad or non-citizen that is the donor who is not altruistic and who endangers the public sphere through inappropriate occupation of it" (p. 126). She argues that decisions made to manage risk in the blood system serve, by excluding individuals with particular histories of risk behaviour,

to "re-inscribe the boundaries of civic belonging" (Valentine, 2005, p. 117) and lead to those individuals being denied, by extension, of their capacity to fully assume their identity as citizens. The comments from the above stakeholders are consistent with Valentine's argument about the denial of citizenship as a consequence of blood risk management.

Stakeholders supporting the MSM policy argue that these discriminatory practices are justified because they protect the safety of the blood system. A CHS (2007) position paper on MSM makes this point clearly:

By their very nature, blood donor screening and deferral criteria are discriminatory; however, they are reasonably justifiable where they provide increased protection to public health. While the risk of HIV transmission through the transfusion of blood and blood products has been reduced significantly, the transmission of blood-borne pathogens including HIV remains significant among men who have sex with another man. In the absence of perfect testing, donor screening, including the existing MSM deferral, remains an essential component of blood safety. (para. 25) The notion of *justified discrimination* was also a theme in our interviews with representatives from blood consumer communities:

As part of the mandate of the Hemophilia Society, just like any other publicly funded institution or not-for-profit, we do not discriminate in any way. However, when it comes to blood and blood products it is the opinion of the society [that] zero risk is the goal, or as close to zero risk as we can get. Therefore, it is appropriate in some cases, to "discriminate" against those that would cause risk.

# (Interview #6 – EAC-BR - Lay member)

You know, we're not just talking about HIV, we're talking about the other diseases such as HHV8, which is a sleeper, and it is out there, and for immune compromised

people it is a risk. Who knows what else is out there. We do not know. You know, hepatitis C was underground for 30 years before we discovered it. So what else is there? We get an average of one new disease per year and a lot of the blood-borne sexually transmitted diseases have been associated with men having sex with men. It is not particular behaviors, because lots of people have those particular behaviors, but you do not see the epidemiology in heterosexual people or in different races. So it is very specific in terms of a population. So, in my view, it is justifiable to exclude these populations.

#### (Interview #13 – NLC consumer)

Consumers on the NLC prioritized the risk of contamination above others, and legitimized their position in light of their experience as victims of tainted blood. This is illustrated in the comments below:

You know, so for the MSM population I think it is having somebody there who wants to donate because you know they want to be part of society. Well that is great. But that cannot over-ride patients' need for safe blood. It just cannot.

#### (Interview #16 – NLC consumer)

In my mind, it turns from being a health issue, which is how it should be seen, to a social issue. So it shows you that some people have been successful in making this a social issue rather than a health issue. You know it is being phrased around this issue of human rights, but that is not what it is. It is about our right as patients to have safe blood. In fact, the donor gets benefits to raise esteem in their community, because now they can be blood donors. So their self-esteem is a benefit and we get more risk

(Interview #14 – NLC consumer)

Several consumer stakeholders challenged the perception that the MSM policy was discriminatory, as illustrated by the comments from members of the NLC:

You know, I just do not know why it is stigmatizing not to be able to give blood. I mean I cannot give blood and many people that have left the country cannot give blood. You know, so it just kind of strikes me that it a one off issue. I mean, you could just make an excuse to explain why you cannot donate. I mean nobody has to know why you cannot donate. So I just do not see why it is a stigma. I mean, it is the same thing for people with sickle cell being told they cannot give blood. I guess you could argue we are stigmatizing black people. I just do not see that it is a stigma because you cannot give blood.

(Interview #16 – NLC consumer)

The fact that we object so much is because we are fearful. And they are creating undue fear and anxiety in the recipient population, and they will if they change this even more so. You know, you can say that we get emotional about this, but I think we have every reason to, you know. The gay community feels slighted, discriminated against, and you know there is some bullshit about suicide rates. Well, come on, "Are you really committing suicide because you were deferred from giving blood?"

#### (Interview # 13 – NLC consumer)

The juxtaposition of the "rights" of these two different stakeholder groups – stakeholders opposed to the policy and consumers in support of the policy – reflect Douglas' ideas about risk. For her, different cultures, or groups denote certain activities as taboo, not because of objective harm that may arise from carrying out these activities, but as a way of maintaining and reinforcing the moral, political, religious or social order that binds members (1966). These rules emerge from specific political, cultural, social, and historic contexts and reflect deeper anxieties, fears and moral codes. Because of this, different individuals and different communities judge a risk more or less seriously because they value the consequences differently—they value differentially what is being harmed, who is doing the harm, and who is responsible in any other way.

# Different Views on Science, Uncertainty and the Notion of Acceptable Risk

In his analysis of MSM advocacy efforts in the U.S., Pulver (2007) argues that advocates have focused too heavily on issues of discrimination and homophobia, ignoring the role of science and risk evaluation. Advocates, however, are increasingly seeking a change to the MSM policy in Canada have framed their arguments in relation to science and scientific evidence. They have argued that the policy is not scientifically justified and represents an inconsistency in evidence based risk policy (Canadian AIDS Society, 2007; Wainberg et al., 2010). This position is illustrated in the following Canadian AIDS Society (2007) press release:

The current discriminatory wording of the screening questionnaire needs to be updated. With new, highly accurate HIV testing, it is no longer scientific, as American blood banks have acknowledged with respect to their own similar policy. Criteria for determining eligibility to donate should not be determined by the demographic one belongs to, nor by one's sexual orientation, but by the risk involved for transmission of HIV. (para. 2)

A press release by EGALE (2010) makes a similar argument:

"Groups of people do not create risk to the blood supply," said EGALE Canada's Executive Director Helen Kennedy. "Unsafe behaviour creates risk to the blood

supply, and the continued stereotyping of gay and bisexual men causes real harm in our society." (para. 3)

In justifying this position, those opposed to the MSM policy also argue that, while men who have sex with men are indefinitely deferred from donating blood, other populations with similar risks are deferred for shorter time periods. This view is reflected in the following statement by the Canadian AIDS Society (2007):

There is clearly a double standard that discriminates against homosexuals and men who have sex with men. Heterosexuals are not subject to the same treatment, since they are deferred for a mere six months after having sex with an unknown partner. This deferral period was reduced from a year to six months in 2005. The current policy is not equitable. A homosexual man in a monogamous relationship, for example, could be at lower risk for HIV transmission than would a heterosexual man or woman who has had multiple partners, yet there is a significant discrepancy between the deferral periods for homosexuals and heterosexuals. (para. 3)

This concern has been echoed by Vamvakas (2009) who argues that the MSM deferral policy is based on risk assessments of sexual practices that are not in line with assessments for similar risk activities through heterosexual contact. For example, a female partner of a male who has had sex with another male since 1977 is only deferred from donating blood for one year. Yet, a man who has had sex with a man is deferred for life. Similarly, Wainberg et al. (2010) argue that the current permanent deferral of MSM in Canada is scientifically unjustified and that the MSM policy needs to better reflect scientific evidence. Both researchers suggest that both homosexual and heterosexual individuals with multiple sex partners and who participate in unprotected sex should be deferred from giving blood, whereas both homosexual and heterosexual individuals who

are low risk and in stable, monogamous relationships should be allowed to give blood. Wainberg et al. (2010) argue that, while there is a tendency for policy makers to focus on population based rates of HIV, these rates represent a small risk. For example, responding to the statistic that 5.4 percent of gay men are infected with HIV/AIDS compared to 0.08 percent of heterosexuals, Wainberg et al (2010) note that this means there are more than 94 percent of MSM who are HIV negative.

By contrast, consumer stakeholders support the continued exclusion of MSM on the basis of population-based data on HIV rates, as illustrated in the following excerpt from a CHS Position Paper on Donor Deferrals (Canadian Hemophilia Society, 2008):

Current epidemiological data shows that men who have had sex with a man are at greater risk for HIV/AIDS infection than other people. While HIV in Canada is not restricted to the MSM population, the infection rate is tragically high in this group. Assuming that 5% of the male Canadian population is MSM, current Canadian epidemiological data places the HIV/AIDS prevalence at approximately 4.2 per cent for MSM. This compares to 0.016 per cent in the non-MSM, non IV-drug user male population. In other words, using this analysis based on published Canadian data, a male truthfully answering YES to the MSM question is 263 times (4.2/0.016) more likely to be HIV infected than a male who truthfully answers NO. (para. 8)

Similarly, consumers tended to frame the MSM in relation to science:

So I asked myself, what has changed? The science has not changed. So what has changed? The only thing that has changed is political pressure and the willingness

to give into it. But this is not fair, they are undermining scientific process. Listen, if you change it because the science says you should then that is fine.

#### (Interview #13 – NLC consumer)

The governmentality perspective is particularly relevant in explaining this shift toward science. From the governmentality perspective, expert knowledge is used by government to determine how populations are to be surveyed (Foucault, 1988). This knowledge allows government to identify groups and populations deemed as high risk and requiring intervention. Castell argues that monitoring population risks represents a new form of surveillance, "systematic predetection" (1991, p. 288). This means that no longer does a person need to display dangerousness – it is enough to be identified as part of a risky population, based on a risk profile developed from demographic characteristics. With the MSM policy, while the general majority of men who have sex with men are not HIV positive, they are nonetheless part of a population group that has, historically, had higher rates of infection than other groups. Therefore, they are profiled as posing a risk to the blood system and excluded from donating blood on that basis.

# Acceptable Risk and Precaution

In arguing that the MSM policy is based on inconsistent science, stakeholders opposed to the MSM policy point to the technological advances in detecting HIV in blood. One technology is Nucleic Acid Testing (NAT), which is able to detect low levels of "viral genetic material" (CBS, 2010c, para. 3) that is produced when a person is infected, even before the development of antibodies. This reduces the *window period*, which is the "time between donor exposure to the virus and the appearance of antibodies" (CBS, 2010c, para. 3). Farrugia (2002) argues that the introduction of nucleic acid testing (NAT) has shortened the window period for HIV infection to 11 days from three to six months. This means, that rather than having to wait months to know if blood is infected with HIV, nucleic acid testing allows blood systems to know if a person is infected in a much shorter period of time. This means that excluding all men who have had sex with men even once since 1977, even those whose sexual experiences are months and years in the past, is difficult to scientifically justify. These advances greatly decrease the chances of an infected unit of blood slipping into the blood system. Indeed, research suggests that the NAT error rate in failing to identify persons who are infected is 1 in 10 million (Eleftherios, 2009). As Wainberg et al. (2010) argue, shortening the MSM deferral period to one year would result in one additional HIV-infected unit of blood escaping detection in Canada every 16 years, or 1 additional unit per 11,000,000 blood transfusions.

Research suggests that the current tolerated risk of HIV contamination for the blood supply is higher than the ALARA (as low as reasonably achievable), or what is considered a reasonable or acceptable risk when compared to other risks in the blood system (Vamvakas, 2010). For example, the residual risk of HIV contamination of the blood supply left after all safety measures have been applied, including testing of the donated blood and donor deferral, is 1 in 7.8 million donations (Leiss et al, 2008, p. 36). When compared to other risks present in the blood system, the risk of HIV is very small. For example, transfusion-related adverse events occur in about .5% to 3% of all transfusions (Public Health Advisory Committee, 2004). Two of the most fatal, yet rare, are transfusion-related acute lung injury (TRALI) and transfusion associated graft-versus-host disease (TA-GVHD). The case fatality rate for TRALI is 5 to 14% and over 90% for TA-GVHD (Public Health Agency of Canada, 2004, para. 2). TRALI is the third leading cause of death associated with transfusion (PHAC, 2004).

Consumers defend against these arguments by evoking the precautionary principle and raise the issue the potential fallibility of scientific knowledge and technology. This is illustrated in this comments from a Canadian Hemophilia Society spokesperson, "The tests for HIV and processes have to protect. In Canada, they are the best they have ever been, and they are best in the world. But they are not foolproof" (McKinnon, 2010, para. 29). This idea of technological fallibility is reiterated in the CHS Position on Donor Deferrals (CHS, 2008):

Much of the recent debate has centered around the risk of HIV transmission through the blood supply should the permanent deferral be relaxed to a 12-month deferral. Nucleic amplification testing (NAT) of each blood donation has reduced the risk of an HIV-positive donation escaping detection. The risk, however, is not zero. False negative tests and laboratory errors mean that testing is not foolproof. (para. 18)

This position is reiterated by a consumer on the NLC who stated:

If the science is there and the science proves otherwise, then they can make changes. But if the science is not there or if the science is unclear then you have to be as safe as you can be. To me, that means you have to make decisions that put safety first – even when there is little proof. Krever said it, and it is important to us and to the blood system.

(Interview #16 – NLC consumer)

Consumer groups also raise the risk posed by unknown pathogens and secondary infections as an important consideration, as illustrated in the following statement from the CHS Donor Deferral Policy (CHS, 2008): There is a concern about unknown pathogens that may be transmitted in a similar way to that of known pathogens. It is prudent, therefore, to continue to select donors for donation through application of criteria that reduce the chance of infectious blood being collected. Even more important from a safety perspective, in the opinion of the Canadian Hemophilia Society, is the increased risk from unknown or emerging blood-borne pathogens. The onset of symptoms could be several years. Evidence that the infection is blood-borne may take more time. Tests to detect the emerging pathogen may not yet be developed. (para. 20)

A consumer stakeholder representing the CHS on the NLC raised a similar concern: And our biggest fear is that we are worried about the next one, the next virus. I made this case back in 2001 in my statement to the consensus conference. And you know five or six years later, we have an example like HHV8 that shows us, you know, here is a virus, we did not know was there for a long time. We discovered it and it causes Kaposi's sarcoma, and we only recently proved that it was transmitted through blood transfusion. There is a clear demonstration that 15 to 20% of non-HIV or HIV-negative men who have sex with men are positive for this and only 3% of regular blood donors are positive.

#### (Interview #13 – NLC consumer)

These views exemplify the way consumers view the precautionary principle as the most effective defense against the threat of contamination. For them, the precautionary principle implies a zero-risk policy where even a small risk of contamination is too great of a risk, as demonstrated by the consumer comments below:

It is simply not acceptable to add any more risk from blood-borne pathogens that we know exist. We know this is a risk, so every time we may shorten that deferral

period...yes, it is only an incremental risk, but that .8 and then another .8...well, they add up to more risk. So, why would we do that? Why would we accept any more risk? That is just not right.

(Interview #14 – NLC consumer)

But when you put all these things together that it is the best possible thing we can do is the safest thing we can do. And that is what we demand. The risk, if you look at the down side of this decision, is all towards the recipients. They bear the risk. There is no risk for the donor so this shows you that, you know, there is no balance. The risks are too great even though they are small. There are no risks to the donor. Just to us.

(Interview #16 – NLC - consumer)

Recent epidemiological research has estimated that a change in regulation to a 12month deferral would result in one infectious donation entering the blood system in Canada every 16 years. This would result in three new HIV infections among recipients every 16 years as each donation is divided into three components. Secondary infection to a sexual partner increases the impact of relaxing the regulation. While this is a small increase in risk, it seems unreasonable to adopt a policy, which would increase risk to recipients.

#### (CHS, 2008 para. 19)

By contrast, stakeholders opposed to the MSM policy are willing to accept a small degree of risk comparable to other risks encountered by blood recipients in the system, particularly given the benefits derived from allowing a larger segment of population to donate.

These differing attitudes toward risk need to be situated within historical context to make sense. The attitudes of consumers who support the MSM policy are rooted in past experiences of contamination within their community, where thousands of their members died from receiving HIV-contaminated transfusions. These experiences constitute a moral framework in which risk is evaluated in relation to the moral responsibility of ensuring that such a tragedy never occurs again. In that sense, agreeing that any level of risk is acceptable would represent a failure in the moral duty of protecting individuals who rely on blood transfusions for their well-being. As Douglas states, risk is used as a metaphor to "legitimize policy or to discredit it, to protect individuals from predatory institutions or to protect institutions from predatory individuals" (1990, p. 5). In her analysis of the MSM policy in the U.S., Galarneau (2010) comes to similar conclusion that the notion of acceptable risk is not justified with evidence, but rather is a moral and normative question. Similarly, Hunt argues, "despite the scientization of risk assessment, explanations of risks are still frequently grounded in moral discourses" (2003, p. 171).

# **Different Views on Trust and Sufficiency**

The issue of trust is central to this dissertation. As I have illustrated, access points between policy makers, experts and the public have been established to rebuild trust in the blood system following the tainted blood scandal (Giddens, 1990). However, as Power (2003) suggests, not all stakeholders play an equal role in building trust. Consumer stakeholders, particularly those representing the hemophilia population, are more effective in that role because of their moral capital derived past experiences as victims of tainted blood.

The issue of trust was raised by stakeholders opposed to the MSM policy as one of the benefits of changing the policy. For these stakeholders, allowing MSM to donate blood would increase trust in the blood system and increase the blood supply. This point is echoed by Wainberg et al. (2010) who comment that the current policy is "counterproductive in regard to loss of donors, good will, student protests, potential boycotts and lawsuits, among other negative effects" (p.1324). The same point is made by the CAS Chair of the Board of Directors, "In a time when blood supplies are dwindling, everything possible should be done to encourage donations, in a safe and fair manner" (CAS, 2007, para. 3). This argument is reiterated by a lawyer for the CAS, "It is eroding confidence in the blood system, which turns away many youth and gay men who are not at risk of HIV at a time when Canada's blood supply is in need of donors" (CAS, 2007, para. 2). Freeman, the man sued by CBS for lying about his MSM status and giving blood, made a similar point, "I had been tested, I had been cleared. I felt the benefit of giving blood would outweigh the political position of Canadian Blood Services" (Gillis, 2010, para. 7).

By contrast, consumers feel that a change in this policy would contribute to decrease in trust and confidence, as suggested in the following interview quotes:

I think it would be devastating to how people feel about the blood system and to the trust that has been rebuilt. Now, maybe not something they will not recover from, but it will still be damaging to their image and to their collections.

#### (Interview # 13 – NLC)

I think they are playing with fire here with this policy. They [CBS] need to be standing firm on the ground and on the side of safety and patients and not just listening to everybody and appear or impartial.

# (Interview # 19 – NLC)

Other consumers spoke about how the safety of the blood supply was the best guarantor of sufficiency:

They can manage the supply part of it. We do not need gay men to keep the supply up. This is purely a safety issue. You know, if they would do better at getting people in then it would be easier. We get only 3% of the population to donate yet probably 50% is eligible. So work on something else. You do not have to open this whole can of worms to get more donors.

#### (Interview #13 – NLC - consumer)

It makes the MSM issue pretty hollow. I mean, how many more donors would you actually get if you changed that policy? So, we would be doing better with the issues of sufficiency not by changing the deferral policies, but actually getting out there and teaching people who could give but do not, how important it is to give blood. (Interview #14 - NLC - consumer)

Douglas suggests that views on risk are influenced by cultural, social, political and historical factors. In this dissertation, I have explored the views of non-consumer and consumer stakeholders about the risks posed by allowing MSM to donate and situated these views in their relevant historical, political and cultural contexts. In the next section, I examine the reviews of the MSM policy at the regulatory level and within CBS. I trace the positions of these two stakeholder groups and see how they are reflected in policy discussions. This serves to show how stakeholders participate in such discussions and the impact their participation can have on policy decisions.

# **Reviewing the MSM Policy: Examining Stakeholder Influence**

The EAC-BR and CBS have taken steps over the past decade to review the MSM policy and examine whether changes are required. In this section, I illustrate how the blood

regulator and CBS frame the policy and conceptualize the risks of MSM, as well as situate the positions of the two groups of stakeholders within these governance arrangements.

In previous chapters, I have illustrated the way in which issues of risk and responsibility have been redefined following the tainted blood scandal and Krever. I argued that ideas about risk are embedded in contextual experiences that shape how the various stakeholders understand them. As I will show, this is very much the case with the MSM policy. As noted previously, this policy was established following the contamination of Canada's blood system with HIV, which is still considered one of the worst public health crises our country has faced. These historical experiences serve to shape how the risk of MSM is conceptualized and influences which ideas are prioritized in blood safety policy decisions. As we will see, certain types of knowledge, and the ideas they support, are prioritized in policy decision-making regarding the MSM deferral policy. These ideas have strong links to notions of responsibility.

Additionally, I will explore how current challenges to the MSM policy illustrate how the access points between stakeholders and policy makers in the blood system that were created to legitimize risk decisions and build trust, are now being used by new groups of stakeholders to challenge the legitimacy of the blood operator's risk management practices. I will also show how these challenges have been resisted, in part as the result of the strong advocacy activities of consumer stakeholders.

In the sections below, I will first speak to the reviews done at the regulatory level, particularly the EAC-BR. Following that, I will examine the review of the MSM policy done by CBS.

# **Regulatory Reviews of the MSM Policy**

At the regulatory level, the EAC-BR reviewed the MSM policy in 2004, 2005 and 2006, and each time recommended that it should not be amended. These reviews involved only members of the EAC-BR and did not include input from external stakeholders groups such as the Canadian Hemophilia Society, members of the general public or stakeholders opposed to the policy. However, this is not surprising given that the mandate of the EAC-BR is only to provide expert advice to the federal regulator about blood risk. The EAC-BR is not required to be publicly accountable or transparent. While EAC-BR meeting minutes are posted online, they are not regularly updated. Moreover, many of the discussions happen *in camera*, which means that none of the views its members expressed about the MSM policy will be released to the public. Health Canada's website also does not provide any commentary or documents justifying their position in support of the MSM policy.

Other discussions about the MSM policy have taken place at the governmental level. The most recent review was done by the Standing Committee on Health (HESA), in 2001 and examined "certain donor exclusion policies to the safety of the blood supply" (Parliament, April 3, 2001), with a focus on the exclusion of men who have sex with men. These meetings brought together a range of stakeholders and experts including representatives from the Canadian AIDS Society, Coalition des Organismes Communautaires Québécois de Lutte Contre le Sida, Canadian Hemophilia Society, EGALE (Equality for Gays and Lesbians Everywhere), as well as representatives from the Department of Health, Blood Components Section and experts in the field of HIV/AIDS (Parliament, April 3, 2001). On June 12, 2001, the committee decided to delay the report until after the summer recess, but did not return to this issue in the fall. The lack of action

in this meeting suggests that there is very little desire by government to make a change in this policy.

In *Chapter 5*, I argued that, while participatory processes can be understood as access points, the exercise of building trust has shifted toward expert knowledge, safety and the scientific management of risks. Public trust has increasingly become a function of a technocratic approach to risk management that prioritizes scientific evidence and is guided by the precautionary principle. In the next section, I argue that the lack of public participation in the MSM reviews suggest that the precautionary principle has become a proxy for the public and is increasingly promoted as evidence of responsible risk management.

# **Regulatory Positions on Policy: Science and Visible Precaution**

In discussing the recommendations made by the EAC-BR to Health Canada, EAC-BR members highlighted the importance of basing those recommendations on scientific evidence:

Yes, we had seen it I guess about a year or two ago. We reviewed the evidence, and we had a summary issues paper, which had been prepared after an internal review, and we recommended keeping the policy in place. The evidence was not there to change it.

You know there are a lot of things that have to be considered when you are making these decisions. Science is the first thing – obviously. We look at the scientific evidence and see what it says.

(Interview #4 – EAC-BR lay member)

(Interview #1 – EAC-BR expert member)

However, there is no way to determine what evidence they reviewed due to the lack of publically available documents. Although stakeholders seeking a change to the MSM policy argued that there is no scientific justification for this policy, what they fail to realize is that the MSM policy might be based on the precautionary principle. As Wilson (2007) reminds us, the tainted blood scandal and Krever Inquiry resulted in significant changes in the use of science for policy development. Now, government and policy makers have to address scientific uncertainty and implement precautionary measures in response to any lack of knowledge. In *Chapter* 5, I argued that regulators must address theoretical risks, or what Ewald (2002) defines as a "risk beyond risk" (p. 294), disrupting our relationship with science. While HIV is not a theoretical risk, the influence of the precautionary principle and the "politics of visible precaution" (Roussel, 2003, p. 141) are well illustrated in the continuing deferral of men who have sex with men. In this way, we can see how the regulatory position on the MSM policy counters the one put forth by advocates seeking a change in this policy by invoking the precautionary principle. This point is illustrated by the following from an EAC-BR lay member:

We also have to look at the science, what does the evidence say? What does it not say? You know in this environment we are thinking about precaution, and the system is guided by the use of the precautionary principle. We have to think past evidence to what is possible. What *could* happen?

(Interview #5 –EAC-BR lay member)

The influence of the precautionary principle is further evidenced by this comment from a representative of the Blood Components Section of the Department of Health:

It is well recognized and acknowledged that this approach will, unfortunately, eliminate individuals who are healthy and unaffected by the disease. However, the seriousness and potentially devastating effects of these diseases have forced the operators and regulators of the system to choose the precautionary approach.

#### (Parliament, April 3, 2001, p. 1140)

This pervasive influence of the precautionary principle may be explained, in part, by the difficulties inherent in making risk management decisions under a regime of increased public scrutiny. Giddens (1990) argues that because of the complexity of managing modern risks, there is a need to address uncertainty surrounding science and expertise in such a manner as to make them accessible to the general public. In the case of the blood system, the precautionary principle can be translated into risk management policies that are easily understood by the public, in this case, a zero-risk policy.

However, this by no means suggests that precautionary decisions are necessarily based on good science, nor that are immune to political or moral influences. Haggerty (2003) notes: "as precautionary decision-making is generally not based on scientific types of evidence and calculation, such decisions are opened up to considerable influence" (p. 206). Hunt (2003) further argues that "despite the scientization of risk assessment, explanations of risks are still frequently grounded in moral discourses that call into play issues of ethnicity, sexuality and other social stereotypes" (p. 171). One can argue that particular moral judgments about what constitutes risky sexual practices have guided the decision to maintain the MSM policy. This point is illustrated by a document tabled by a representative from the Biologics and Genetics Therapies Directorate (BGTD) at the May 5-6, 2004 EAC-BR meeting. This document seeks to refute a proposal to replace screening questions targeting specific risk groups like men having sex with other men, with questions about risk behaviours, like having sex with multiple partners. More specifically, the document argues: A questionnaire aimed at eliciting individual risky practices is impossible to design to account for all types, variants and the particular context of risky practices and to clearly distinguish them from "acceptable" practices. For example, "unprotected sexual intercourse" cannot be considered a risk behaviour for heterosexual couples in stable relationship [sic].

# (Leiss, et al. 2007, p. 33)

The document ascribes low risk to heterosexual monogamous intercourse while implicitly recognizing that monogamous homosexual sex constitutes a high-risk behavior requiring life-long deferral. Further, the implicit recognition that heterosexual sex is less of risk for HIV transmission is not entirely supported by current epidemiological research. The most recent evidence from the Public Health Agency of Canada (PHAC) shows that heterosexual sex accounted for 36 percent of total new cases of HIV infections in 2008 whereas the proportion of new infections among women was at 26 percent (PHAC, 2008). These data suggest that heterosexuals pose a risk to the blood system, albeit smaller than MSM. However, despite posing some risk they are not necessarily subjected to the same level of scrutiny and targeted differently by deferral policies. While the existing evidence appears to support the need to change the MSM policy, this clearly has not been the case. In the next section, I will further explore the reason for the persistence of the MSM policy in relation to the public's perception of blood risk.

# **Public Intolerance of Blood Risk**

As Ewald (2002) notes, the "only rational attitude is to avoid the occurrence of a threat with irreversible consequences" (p. 296). Proponents of the MSM policy used this reasoning to justify the discriminatory nature of this policy. This point is illustrated by a member of the EAC-BR, who stated:
When it comes to blood and blood products, zero risk is the goal or as close to zero risk as we can get, and therefore [it] is appropriate in some cases, to "discriminate" against those that would cause risk.

#### (Interview #6 – EAC-BR)

A similar viewpoint was voiced by a representative from Health Canada (2006):

A proposed change in policy in the United States to 12 months deferral was driven by perceived discrimination, as voiced by interest groups. It is not in Health Canada's intent to change the present deferral. This is not a scientific issue, as science and the precautionary principle favor status quo. The mandate of the regulator should be primarily to ensure the safety of the blood supply and its recipients, irrespective of perceived political and social bias. (Item 10, para. 4)

In her analysis of the U.S. MSM policy, Galarneau (2010) argues that the FDA justification of the policy "reflects a classic framing of ethical dilemmas in public health: A collective good—blood safety—is posited as in conflict with the interests or rights of individuals—MSM interests" (p. 31). The justification of this discriminatory practice is based on the perception that the general public would be intolerant to any changes in the MSM policy. Similarly, during interviews with members of the EAC-BR, both expert and lay members expressed the belief that a change in this policy would be considered unacceptable to the Canadian public. As one of the members stated, "We also have to think about what is the public perspective. So how is the public going to react to this change of question for deferral? I do not think it is something that would be accepted by Canadians" (Interview #6 – EAC-BR). Another member commented:

I think it would be difficult to deal with the public if we faced any of the same risks such as HIV and Hepatitis C. But, I do think that if we explain it, which the media is doing better, then the public will understand it. But, I do not think it can be a big risk and it cannot be HIV...not the ones we have dealt with before.

(Interview #5 – EAC-BR)

A similar argument was made during the 2001 HESA meeting by two representatives from the Blood Components Section, Blood and Tissues Division, Department of Health (Parliament, April 3, 2001):

Although it is recognized that a no-risk transfusion is not achievable, the Canadian public and the regulator continue their demand to introduce new steps or tests that have the potential to add very small increments to the safety and sometimes, or often, at a very high cost. Following the unfortunate tragedies of the 1980s the public has, on the other hand, zero tolerance for any intervention that may potentially reduce the high level of safety we have achieved. (p. 1140)

Anyway, the bottom line is we must recognize that, right now, we have a very safe system. If we are going to change anything in the system, we are certainly going to require that sufficient scientific evidence is presented in order to reassure us that no negative impact will occur. (p. 1145)

In examining French blood system policies, Hergon et al. (2005) argue that there is a link between the use of the precautionary principle and the belief that the public favors a zero risk policy:

The sometimes incantatory use of the precautionary principle by public authorities lends credence to society's demands for zero risk in transfusion. By wanting to

reassure the public, but at the same time focusing attention on possible risks, public authorities have created a source of fear that has led to this additional demand for safety. (p. 277)

In a similar manner, Kirp (2009) argues that:

The lesson from AIDS is that it is politically astute to promote zero risk for groups that command popular support, even at costs that would not withstand cost/benefit scrutiny, while ignoring risks that will never be captured in vivid policy dramas. (p. 314)

The idea of public intolerance is interesting because, as we saw in *Chapter 5*, there is nothing to suggest that the public has any access to participate in the blood system at the regulatory level. Moreover, during the reviews of this policy, there was no way for members of the public to comment on the work of the EAC-BR, nor were they present in the HESA meetings in 2001 or 2008.

Thus, there is little to suggest that public perceptions are known to the members of the EAC-BR and the regulator, although there is research that suggests that the public is intolerant of risks, particularly those that affect one's health. Sjöberg (2000) reports that most surveys show that people demand zero-risk-levels, at least as the ideal target. Similarly, Renn (2008) argues, "health risks that are characterized by high ubiquity, high persistency and high irreversibility hence trigger responses of avoidance and desires for strict regulatory prohibitions" (p. 89). This evidence would seem to undermine the position taken by stakeholders who oppose the MSM policy. But, more importantly, it also suggests that adherence to the MSM is explained, not so much on the basis of sound scientific evidence about risk, but out of the need for the regulator to act with precaution and to cater to public understanding and tolerance for risk. Anything less than a zero-risk policy could

very well undermine the public trust in the blood system, and consequently jeopardize the supply of blood.

In the next section, I explore how CBS reviews of the MSM policy are quite different from the reviews done at the regulatory level, but are also influenced by a desire to maintain public trust in the blood system.

## **CBS Reviews of the MSM Policy**

CBS has done extensive reviews of the MSM over the past decade, including taking part in the Standing Committee of Health (HESA) discussions in 2001, a joint consensus conference with HQ in the same year, and another policy review in 2007. As stated in *Chapter* 6, CBS has a mandate that requires more public participation than the EAC-BR. Therefore, in each review, access points were created to bring stakeholders into the decision-making process. In the 2001 consensus conference, there were 29 experts, 129 attendees (from various backgrounds including the CAS, EGALE and the CFS), and a panel of 10 (one of whom was a representative of the CHS). The most recent review in 2007 brought together, over two days, a range of stakeholders. CBS management and other organizational observers attended a first meeting on April 16, 2007, with the active participants being representatives from seven groups:

- The Canadian AIDS Society
- Canadian Federation of Students
- Canadian Hemophilia Society
- Canadian Immunodeficiencies Patient Organization
- Canadian Thalassemia Foundation
- EGALE
- Seven Oaks Teachers Association

A second meeting on April 20, 2007 was attended by:

- Members of the Board of Directors
- CBS staff and management
- NLC members
- Scientific experts who work within CBS (Canadian Blood Services, 2007)

These meetings were organized as a way to have the various stakeholders come together with CBS to "explore and understand" stakeholders' positions with regard to the MSM donor deferral (CBS, 2007). As part of the review, a risk assessment was done by an outside body<sup>3</sup> that examined all available evidence and put forth potential options for a change in the policy.

As we can see, the reviews of the MSM policy within CBS demonstrate the way in which the stakeholder society is reflected differently than in the EAC-BR. Unlike the EAC-BR reviews, CBS reviews of the MSM policy formally integrated a range of interested stakeholders as a way to legitimize the policy review process. However, these reviews still did not have mechanisms to consult with the general public about their views on this policy. Rather, the public perspective remained an imagined response by members of CBS management, as illustrated by this comment:

So in my mind, the public are people who are not using the system today. But they have a very legitimate voice to help us inform blood donor screening tools, because we are targeting them as members of the public to come in and donate blood. We are saying, come in and donate blood, so it is very important for us to know how

<sup>&</sup>lt;sup>3</sup> CBS hired McLaughlin Centre for Population Health Risk Assessment out of the University of Ottawa to do a report for them.

you feel about those questions. So the general public, I think their views today are very important when it comes to policies with respect to screening blood donors.

#### (Interview #1 – CBS Management)

Despite the fact that there were no mechanisms to communicate with the general public about their views on this policy, there is a perception that the Canadian public is overly intolerant to any change in this specific policy. As with the regulator, this perception is used as one of the justifications for maintaining the MSM policy. This perception will be discussed further in the next section.

In the next section, I will also discuss the risks created by this type of consultative effort, particularly in terms of alienating consumer groups supporting the MSM policy. I will illustrate how risk management decisions by the blood operator necessarily involve politics in balancing the needs and concerns of various stakeholder groups.

# Access Points and Contingent Trust

Throughout this dissertation, I have drawn upon Giddens' notion of access points and their relationship to trust as a way to explain participatory processes in the blood system. As I illustrated in *Chapter 6*, almost every participant interviewed in CBS felt that the inclusion of stakeholders, particularly consumers, into discussions about blood safety was critical to legitimizing blood safety decisions and rebuilding public trust. Therefore, it is not surprising that, in discussing the MSM review process, members of CBS management and the Board expressed the view that such processes helped to provide legitimacy and build support for the decision. As a member of CBS management explains:

So many other blood systems around the world just decided, and simply said we think the policy should change from one year to five years or 10 years. Yet there was no rationale given for why these countries made the decisions they did. There

is no reason for why policies went from being a permanent deferral to a deferral that was no longer permanent. So, if you are going to make a decision in that mindset, then expect your stakeholders not to buy into it. We are doing the risk assessment and stakeholder consultations to get their feedback. Then hopefully we can make an informed decision that most people, even if they do not agree with it, they buy into the process of legitimacy. And then we feel we can, at least, make an informed decision to the regulator about changing that policy.

(Interview # 1 – CBS management)

Now at the end of the day the policy may not change. But at least I think we will have lived up to our commitment of listening to the voice of the stakeholders. So the gay community accuses us of remaining homophobic. I think we can say with all due respect, I disagree, and here is why. And if the patient community wants to say you are adding risk to the system. I can say well, through the process, we demonstrated that we do not think that is the case and here is why.

(Interview #2 – CBS management)

In their research on the French blood system, Hergon et al. (2005) argue that the participation of "all interested parties contributes to confidence in experts, transfusion institutions, and public authorities, which in turn renders risks, particularly those considered uncertain, more acceptable" (p. 276). Moreover, Hergon et al. (2005) argue, "policy decisions derived from a collective development process make subsequent legal action difficult, if not impossible" (p. 279). However, when discussing the MSM review with consumers on the NLC and the Board, they expressed a much different view. It became evident that, while they conceptualized their participation as important to building trust, the inclusion of external stakeholders, in this case stakeholders seeking a change in

the MSM policy, was not seen the same way. Two consumers from the NLC expressed the view that this review process actually reduced their trust in CBS and had the potential to lose it entirely.

The men having sex with men issue is a really fundamental issue and I am very disappointed in the response from CBS. If we had had this interview a year ago or two years ago I would have been much more positive, because a lot of the things we did were not really tough decisions for them. You know some of the issues we brought to them were addressed really well, which has shown how consumers have been responsible and how we have helped to bring real improvements in the system. But this issue is one that is shaking my confidence in CBS' ability or actually their commitment to consumer involvement.

#### (Interview #19 – NLC consumer)

It took CBS a long time to build trust backup and they did that with our help. You know, if you look at their last annual report they are bragging all over the place about the CHS report card. But the fact is that this year, with this review that was not needed, it is going to be devastating. We are going to present a different picture.

## (Interview #13 – NLC consumer)

In discussing why they were unhappy with the review process, other consumers felt that politics, not science, prompted the decision to review this policy. As one of the consumers on the Board stated, "Listen, if you change it because the science says you should, then that is fine. But, with this issue, there is no science so I do not see why we would bother to do this" (Interview #6 - CBS - Board consumer). Two other consumer representatives on the NLC made similar statements:

It was totally inappropriate, and then at the end, one of the management of CBS was tiptoeing around answering the question of why we were doing this again. You know, she did not want to admit that this was a political decision, but after Smithermans' interview in Extra, the gay magazine, it is pretty hard to deny that this is a political maneuvering. You know, the Minister of Health has waded into this issue and we are quite angry about this.

### (Interview #19 – NLC consumer)

You know, I think this was a very knee-jerk reaction to the groups that came to them. You know, I realize the Canadian Federation of students that there are a lot of them. But, I mean, what is their data? What are they looking at? Have they thought about it? I really think a lot of these arguments have all been based on emotion and not on science.

## (Interview #16 – NLC consumer)

Interestingly, these consumers felt justified in their opinion on the basis of the lack of scientific evidence for changing the MSM policy. As with the regulator, they mentioned the precautionary principle as justifying the ongoing deferral from donating blood of men engaging in homosexual sex.

In the section below, I examine CBS' position on the MSM policy, and navigate the manner in which its views reflect the position of various stakeholders in the blood system on this issue.

## The Relationship between CBS and Health Canada

CBS is regulated by Health Canada and must implement regulations passed down from the regulator. Therefore, the position of CBS is in line with the regulator, which means that it must permanently defer MSM from giving blood. CBS has made it clear that they do not support a change of the policy (CBS, 2007):

Currently, Canadian Blood Services indefinitely defers any male from donating blood if he has had sex with another male, even once, since 1977 (MSM). The MSM deferral is part of our screening procedures that are designed to identify a variety of behaviours and circumstances known to increase risk to the safety of the blood supply. (para. 3)

The scientific data that CBS used in reviewing the MSM policy came from a risk assessment that examined the risks associated with deferrals for one year, five years and ten years. For the one-year deferral, the assessment estimated an additional HIV-contaminated unit for every 136,000 donations, representing an 8% increase in risk. Changing to a five-year deferral would result would not increase the risk of transfusion-transmitted infection for blood recipients (Leiss et al., 2007). Moreover, the data suggest that a five year deferral period would provide a "reasonable time-frame" to detect any "novel pathogens" (Leiss et al., 2007, p. 46) that are relevant to the MSM population. Because the five-year deferral period did not result in any additional risk, there was no risk assessment done for the 10-year deferral period. The assessment concluded (Leiss et al., 2007):

We ought to accept no longer a period of deferral than what the risk hurdle can clearly support, using an evidence-based argument with a little help from the precautionary principle. In other words, we should avoid trying to be more precautionary than our knowledge enables us to be. (p.50)

Despite these findings, CBS decided to maintain its MSM policy. In explaining the reason for this decision, a member of the Board said:

You must remember the central goal coming out of Krever in which guides us in all of our decision-making is that safety is paramount. We do not know enough. We do not have the science to make a change. The science that was available, would not have given us the ability to change this policy. It is that simple. As more science becomes available, then we can change our decision if that is what the science indicates. But safety is paramount, it is that simple.

(Interview #7 – CBS Board)

A member of CBS Management also highlighted the lack of science to support changing the policy:

There is one on the table right now, where you can see how very difficult it is. And this is the issue of deferring as blood donors men who have sex with men. This is the classic one where there is very little in the way of hard data. There is very little in the way of scientific evidence. There is some but it is scant, and so absent that good scientific data, you have to start moving to things like the precautionary principle.

(Interview #1 – CBS Management)

These comments suggest that other factors played a role in the decision of CBS to maintain the policy. In the section below, I will examine how governance arrangements, as well as concerns about trust influenced CBS' decision to maintain the status quo.

# Impact of Regulatory Responsibility on CBS

CBS has faced pressure from stakeholders who are seeking to change the MSM policy. These stakeholders have organized bans on blood donor clinics at various Canadian universities, and lawsuits targeting at the organization. Yet these actions have little impact in changing CBS risk management policies because they are bound by their mandate to

follow the regulations put forth by Health Canada. They can implement more stringent deferrals but cannot change a policy in such a way that it adds any risk, regardless of how small. Despite its inability to change the MSM policy, CBS continues to be the target of advocacy efforts and legal challenges when they should really be targeting Health Canada, which is responsible for issuing this regulation. Unless the regulator changes the policy, CBS cannot make a decision to change it on its own. As the CEO of CBS explained in the HESA meetings (Parliament, April 3, 2001):

As the operator of the blood system, we are certainly free to recommend changes to the questionnaire, and we do that all the time. We have an active, ongoing joint working group of CBS and Héma-Quebec that reviews every criterion concerning donor screening. We have a thick binder of criteria that address the safety of donors and the product. We do make recommendations to change it on a regular and ongoing basis. In order for the changes to be implemented, they require the approval of Health Canada. (p. 1215)

This is also confirmed by a previous Minister of Health from Ontario (Rau, 2007):
Canadian Blood Services (CBS) will not lift its ban on gay men donating blood,
Smitherman says, despite holding consultations with queer groups last month. The problem, he says, is that Health Canada — the federal department that regulates
CBS — is reluctant to deal with the issue. "If Health Canada is not one of the groups talking about it, it is like banging your head against the wall." (para. 4)
Similarly, a recent article confirms the role of Health Canada in mandating the MSM deferral policy (Ginsberg, 2008):

There is also evidence that bans on blood drives may be targeting the wrong organizations. At the meeting with McGill students and Héma Québec, a Héma

Québec representative said that the blood collection agency was "prepared to relax their criteria" from a permanent ban on donations from men who have sex with men to a one-year ban. The only stumbling block, he insisted, are federal regulations and patient groups who wish to keep the ban in place. Although there is an element of bureaucratic buck-passing here, as blood collection agencies regularly review their policies and make recommendations to the higher-ups, Héma Québec's statement uncovers a problem with narrowly focusing activism on blood drives. The federal government has the final say on who can donate, and lobby groups, particularly the Canadian Hemophilia Society, play a major role in setting policy. (para. 8)

This article confirms that, while the blood operator in Québec, Héma Québec, is willing to have the MSM deferral policy relaxed, they are unable to do so because the regulator is not supportive. It appears there is no interest on the part of Health Canada to change that policy as indicated in this comment from a member of CBS Board:

Well, I think that Health Canada as the regulator had not enough evidence that would suggest to them that they should review it or change this regulation. So CBS gathered whatever available evidence there was and we would have gone back to Health Canada and said we think you should look at this again. But Health Canada would not, because there is not sufficient evidence.

#### (Interview #7 - Board)

What is guiding Health Canada in its decision-making is a stringent adherence to a zero-risk policy based on the precautionary principle, which is the approach that was mandated by the Krever Inquiry. However, this approach to blood risk management creates challenges for CBS in responding to the demands of the two groups of stakeholders in this

regulatory context. There are those stakeholders who wish they could donate blood and who do not appear to pose a threat to the safety of the blood supply on the basis of existing evidence. CBS' role is further complicated by the advocacy efforts of consumer stakeholders, particularly those from the CHS, whose views of the MSM policy are very much aligned with those of the regulator.

### Acceptable Risk, Consumer Endorsement and Trust

In this research, I have argued that consumer stakeholders play a unique and more influential role than other stakeholders involved in the blood operator. As I demonstrated in *Chapter 6*, because of their moral capital derived as past victims of tainted blood, stakeholders are able to help build trust and manage reputational risk for CBS. This moral capital, in turn, ensures their interests, and ideas about acceptable risk, are reflected in blood safety policy. In the case of MSM, this influence is particularly acute. This is illustrated in the comments by both a member of CBS staff and by a Board member:

Because of Krever and because of all the attention that was around the blood scandal I do not think we could make a significant change in the system, particularly if we were not confident that the stakeholders had the most direct involvement, the ones we are closest to, if they had a different opinion, or were opposed. It just never would happen. We would not be able to make the change happen. Now, they can be neutral and that can happen, but we would never be successful in making change, if the minute we made the change they would be saying, this is the wrong decision. And here is why. We would be toast. So that is the challenge we have with this policy.

(Interview # 3 – CBS Staff)

You know, obviously there would be a diminishing in the level of trust in blood and blood products if there was a change in this deferral policy, and it would take a long time to build the trust back up. There would have to be ongoing research to demonstrate that the blood is safe. You can understand, I think, why recipients do not want anything changed that would increase the risk to the blood supply.

#### (Interview #5 – CBS Board)

Health professionals on the NLC expressed a very similar view to that of management and the Board. Many of these individuals spoke about the repercussions to organizational trust if consumers, particularly those representing past victims, did not support the decision made by the CBS with regard to the MSM policy.

I do not think anything could change. I think this is a tough one. I think this is a lose-lose situation for Canadian Blood Services, but I think they did the right thing. I think they did the things they had to do. They listen to all the stakeholders and they held meetings that were very open. They are kind of stuck between a rock and a hard spot. I am sure that they do not want to change the policy and whatever they do, it is not going to be right.

#### (Interview #10 – NLC stakeholder)

And I think you really saw this during the MSM debates. Again, you know those groups are so concerned about unknown pathogens and the mutating or transmission of unknown pathogens given through blood, which they do not care. They just do not want to have to deal with that concern. So there is no way those groups are ever going to allow a change in this policy.

(Interview #15 – NLC stakeholder)

Interviewer: So, do you think, if they change this policy, there would be an impact on the way the public saw the blood system?

Respondent: Absolutely. You know, I think they would be really nervous about receiving blood if this policy changed.

(Interview # 10 – NLC stakeholder)

Both consumers and other members of the NLC expressed the view that the consumer population would rally against any change in this policy, which would have detrimental effects for CBS.

*Interviewer*: How do you think Canadians would respond if the policy was changed?

*Respondent*: I think there would be a backlash. Quite frankly, I think the CBS is in dangerous territory here. They would not get support and in fact would be opposition from user groups like us and we would do it publicly. And then I suspect there would be a backlash. It is a human substance and we have criteria that are decided upon scientifically. And that is the criteria used to determine if one is able to give blood. I think that is what anybody would want when they get down to it. They do not want something that is politically correct. They want something that safe.

(Interview #13 – NLC consumer)

I think there is going to be a massive campaign from these groups. I think there is going to be huge butting of heads between the hemophilia groups and the AIDS groups and the gay groups. And, unfortunately I think the gay group is going to lose. You know, I do not care how much society has changed there is still stigma for being gay. You know, I think when you compare a social statement to, you know disease... I mean let us face it, people are going to be okay with them not donating. When you put a picture of one child with hemophilia saying, you know, this child may get Hep C or may get HIV... you cannot win against that. What would you think Canadians would do? It could get ugly.

(Interview #15 – NLC stakeholder)

Participants from CBS management and non-consumer stakeholders also expressed concerns about the consequences of making changes to the MSM policy, particularly in terms of targeting behavior rather than sexual orientation, and the impact this would have on trust and issues of blood sufficiency.

If we are going to change this question as the gay community would like us to and say to anybody, "have you had unprotected anal sex in the last six months?" I think it is now very legitimate to go to your members of the public in upper Alberta and say how would you respond to this question because they may be deeply offended and if they are deeply offended then they are not going to come in and donate blood. Then we have got a big problem on our hands, and all of a sudden we do not have a blood supply.

## (Interview #1 – CBS management)

So if you go after the heterosexual population and start looking at their risks, then when we get down to the blood system, you will not have enough blood. So that sufficiency is gone.

## (Interview #15 – NLC - stakeholder)

Canada has a more than adequate blood supply and there is no need to introduce blood from high-risk donors into the system. There has not been a blood shortage in Canada in recent history.

#### (Baklinski, 2010, para. 11)

The comments above support the argument, that while trust is a central issue for CBS, this depends on the population. As Powers (2003) implies, some populations are more valuable for organizations and organizational reputation than are others. In the case of CBS, it is the trust of consumers and the donating public that is primarily important. While future donor pools, or untapped donor pools from MSM could help to increase sufficiency, it is not as important as losing the trust of those already giving and receiving blood. Thus arguments about discrimination put forth by stakeholders seeking a change in policy are of little consequences to CBS when one considers not the sound scientific evidence justifying this demand, but the moral and political implications such decision has in term of alienating an existing (and presumably conservative) donor pool. MSM offer CBS little in terms of helping CBS maintain its reputation and trust. It is more critical for CBS to maintain the support and endorsement of consumers, particularly the ones representing the hemophilia community who have the moral capital to enhance the operator's reputation and maintain the trust of the Canadian public in their blood system.

# **Summary and Conclusions**

In this chapter, I have drawn upon the MSM blood donor deferral policy as a way to examine how stakeholder participation functions in relation to policy making. In particular, I have used this policy as a way to examine how other interested stakeholders,

meaning those not formally included in organizational and regulatory participatory processes, are included and their impact on policy decisions.

Drawing upon the work of Douglas and others, I demonstrated the way in which the two groups of stakeholders – those opposed to the MSM policy and those in support of the policy – differently conceptualized the risks of MSM, and the way these ideas served to frame their positions on the policy. As I illustrated, in advancing their position stakeholders opposed to the MSM policy tended to focus on three dominant and interrelated arguments. First, the policy is discriminatory and ignores the rights of MSM to give blood. Second, the policy is unscientific and does not take into consideration the advances in testing technology. Third, that a change in policy would help to restore public trust and confidence and thus increase blood sufficiency as the population of potential blood donors would increase. In response to these arguments, I showed how consumer stakeholders who support the MSM policy responded in ways that were culturally, socially and morally relevant to them and their past experiences with tainted blood. In particular, consumers tended to draw upon arguments that centered on their right to safe blood and the moral responsibility of the system to protect them from harm. In doing so, they highlighted the uncertain nature of scientific evidence and advanced the notion of the precautionary principle as a demonstration of responsibility.

This analysis also examined the reviews of the MSM policy that took place at the regulatory level, through the EAC-BR, and within CBS. As I illustrated, there are differences in how each of these levels of the blood system has integrated access points into their discussions regarding the MSM deferral policy, with only certain publics and ideas about risk being brought into such discussions and reflected in the policy. At the regulatory level, within the reviews of the policy completed within the EAC-BR, there

were no external stakeholders included in such discussions. I argued that the precautionary principle has become a proxy for the public and can be understood as a representation of governmental responsibility.

In contrast to the EAC-BR, I demonstrated how CBS integrated a range of interested stakeholders into the MSM review as a way to legitimize the policy process and build trust in the outcome of the decision. However, as we saw, for blood consumers this strategy of participation did not contribute to trust, but worked against their trust. As I showed, while consumers saw their participation as trust building, the inclusion of external stakeholders, particularly those from the GLBT community was not conceptualized in the same way. Their participation was seen as politically motivated, rather than contributing to safety and public legitimacy. In line with Power (2003), I suggested that this supports my argument that, while trust is critical for CBS, it is only the trust of certain populations that provides the organization with value. In the case of CBS, it is the trust of consumers and the donating public that is primarily important, rather than the deferred public. This analysis also revealed the way in which CBS is caught between some publics that want to see change, some that do not, and a regulatory structure that will not allow them to make certain changes.

Finally, I examined how the different ideas about the risk of MSM held by the various stakeholders were situated into the MSM reviews within the EAC-BR and CBS. I argued that the conceptualization of risk held by stakeholders who want to see a change in the MSM policy are not those that hold resonance with policy makers. As I illustrated, the historical experiences with tainted blood have shaped the types of discourses that are held relevant by policy makers. First, while stakeholders opposed to the MSM policy acknowledge the role of science, and indeed, draw upon scientific evidence to support their

positions, they do not acknowledge the role of precaution. There is no evidence that they understand the role that precaution plays following the tainted blood scandal and the Krever Inquiry. This leads us to a second weakness with the position of these stakeholders – the issue of discrimination and rights. As I have discussed, there is a strong sentiment that the risk of MSM justifies the need to discriminate against this population. The right to give blood is framed against the right, and indeed responsibility, for blood safety, as portrayed by consumers, as well as policy makers. Third, there is little to suggest that the trust of stakeholders opposed to the policy is valuable to policy makers and CBS. As I demonstrated, as blood consumers act as agents of legitimacy and serve to endorse the blood system as safe and the blood operator as trustworthy, stakeholders opposed to the MSM policy have little capital to draw upon.

Chapter 8:

## Conclusion

The Canadian blood system has undergone significant changes following the tainted blood scandal and Krever Inquiry. As I have shown in this dissertation, these changes have resulted in new governance structures and mechanisms of accountability as a way to re-establish trust and confidence in the safety of the blood system. One of these changes, and the focus of this dissertation, has been the integration of participatory processes to bring stakeholders into blood safety governance arrangements. However, these participatory processes are situated within a context of a recent and remembered history of contamination, tainted blood scandals, the Krever inquiry and renewed responsibilities for blood safety. I argued that these were, and continue to be, socially, culturally and historically significant events that frame the Canadian blood system. This shapes how participation functions in practice, influencing who is involved and the roles that they play at the regulatory level and within CBS. These past historical experiences also redefine how risks are interpreted and managed in new governance structures.

While previous research has examined some of the changes that have occurred within the blood system, less attention has been spent on explaining how stakeholders' roles are viewed by governments, regulatory bodies and blood operators, and what factors shape the conceptualization of stakeholders and their roles. Previous research has also paid

little attention to understanding how the prioritization of some stakeholders, namely consumers, can impact the participation of other stakeholders.

My research has addressed these gaps. By investigating the involvement of stakeholders in blood safety policy decisions, and by examining the mechanisms through which they are integrated into the blood system, I have shown how the various stakeholders, regulatory experts and CBS representatives understand and negotiate decisions about risks and safety, and the implications on maintaining a safe, sustainable and sufficient supply of blood. My particular focus has been on the way in which stakeholders, namely blood consumers representing the hemophilia population, understand the precautionary principle as a safety measure. In addition, I have examined the potential impact of stakeholder processes on donor motivation and the sufficiency of the blood supply. By comparing different stakeholders, I have also demonstrated the different roles that various stakeholders play and the influence that certain stakeholders have on approaches to blood safety and blood policy.

In this concluding chapter, I outline the core arguments made in this thesis. In doing so, I also consider the larger social, theoretical and policy implications of the research findings offered here.

# Building Trust: Responsibility, Precaution and the Role of Moral Capital

A dominant theme in this dissertation is the role of participatory processes in rebuilding public trust in the blood system following the tainted blood scandal. Surveys from that time indicate that trust was at an all time low, with levels below 50% (CBS, 2010). The impact of this loss of trust was significant, with decreasing rates of blood donors and, as a result, an insufficient supply of blood (CBS, 2010). It is not surprising,

therefore, that Justice Krever spoke directly to the loss of trust by recommending actions that would help to rebuild it. As outlined in *Chapter 2*, two of the central mechanisms included increasing blood safety by implementing the precautionary principle and integrating stakeholders into blood system decision-making. In response to these recommendations, participatory processes have been integrated at the regulatory level and in CBS. In addition, the precautionary principle has been implemented and now guides blood safety decision-making.

Some of the blood literature that has examined changes to the blood system has highlighted the role of public participation in rebuilding trust (Hergon et al. 2005; O'Neill, 2006; Ponte, 2006; Wilson et al, 2007). My research has built upon this work by demonstrating the way in which some stakeholders play a more influential role in relation to trust. As I will discuss in the upcoming sections, not all participatory processes are trust building, just as not all stakeholders are able to contribute to public trust. In the context of the blood system, those stakeholders with the most historical relevancy are more able to help build public trust.

Theoretical work has also highlighted the role of participatory processes in building trust. Of particular value to this dissertation has been the work of Giddens (1990) on risk and trust. Giddens (1990) argues that trust is essential to modern institutions, particularly expert systems. From his perspective, trust is not vested in individuals, but in abstract capacities such as symbolic tokens and expert systems. However, he warns that the public is increasingly wary of expert knowledge therefore access points need to be established between expert systems and the public as a way to gain public trust (Giddens, 1990).

In this dissertation, I have used Giddens' notion of access points as a way to explain the integration of participatory processes into the Canadian blood system in relation to

trust. As illustrated in *Chapters 5 and 6*, access points have been established within CBS, with the creation of the National Liaison Committee (NLC) and consumer members on the Board of Directors. Similarly, on the EAC-BR three lay members representing the public have been integrated. Not surprisingly, during interviews with these individuals, there was a consensus that these participatory processes were important factors in rebuilding trust in the blood system. However, despite Giddens' comments and the dominant perception by participants that such processes are important for building trust, there is little understanding in the existing research of how stakeholders build trust, what mechanisms stakeholders use to promote public trust in blood safety, and whether there are differences in this regard between the various stakeholders. As Porter et al. note (1975):

Trust...tends to be somewhat like a combination of the weather and motherhood; it is widely talked about, and it is widely assumed to be good for organizations. When it comes to specifying just what it means in an organizational context, however, vagueness creeps in. (p. 497)

Also, as became evident during the study, there is a need to understand what role the precautionary principle plays in trust building and how it may shape stakeholder participation and vice versa. As I will discuss in the section below, my research has addressed both of these gaps.

#### **Trust, Precaution and Certain Publics**

In *Chapter 5*, I examined the roles of lay members on the EAC-BC. As I illustrated, members of the EAC-BR spoke to the value of the including the general lay public as a way to rebuild trust. However, in practice lay membership functioned very differently because of the contextual factors at play. First, the data indicated that the responsibility of the regulator to ensure blood safety – defined in that context primarily through issues of

contamination – meant that only certain segments of the public could participate. Given the scientific nature of the work required by the responsibilities of the regulator, lay members needed a requisite level of scientific understanding. This served to restrict membership on the EAC-BR to those individuals possessing scientific literacy. Second, there was little to suggest that the public has any idea that participatory processes are in place at the regulatory level of the blood system. One would assume that the public would have to know about such processes if they were going to help re-establish trust. However, there is very little public access to this Committee.

Since there was little to suggest that the engagement of lay members was instrumental in building trust, it was important to examine if there were other processes that contribute to trust building. A central finding of this study is that the implementation of the precautionary principle, and adherence to it, played a significant role in increasing the public's trust in expert systems. Therefore, I argued that trust is generated not by public participation and transparency, but rather by the ability of the EAC-BR to make sound scientific recommendations to Health Canada on the basis of the precautionary principle. By addressing scientific uncertainty and potential or theoretical risks through an adherence to the precautionary principle, the regulator has been able to avoid adverse events, such as other contaminations, which could negatively impact trust.

These findings expand on Giddens' (1990) conceptualization of access points. In his discussion, Giddens does not distinguish between the types of publics that are included in participatory processes, nor does he comment on how other factors, in this case governmental responsibility, might influence who is able to participate in access points. However, as I have shown, the scientific nature of risk decisions in the EAC-BR served to exclude members of the general public as they lack the expert knowledge required to

effectively participate. Thus, while there is a conception of legitimacy attached to public involvement, in practice there are certain publics and types of knowledge that are more valuable than others in the management of blood risk.

While Giddens' notion of access points provided an important framework for understanding the implementation of participation processes, there remained a need to utilize other theoretical approaches to address the issues, policy design and its implementation of power. For this, I drew upon the Foucauldian (1991) notion of governmentality that provided a framework by which to view access points in a way that addresses the role of state responsibility and power. The implications of regulatory responsibilities for blood safety required us to consider that these access points serve as an extension of governmental responsibility. While these processes bring the public into risk governance structures, they are embedded within broader political arrangements that serve the needs and governance interests of the state. Hence, Marinetto's (2003) argument that government cannot be seen as an "impotent force" (p.116) in such matters, rings true. As this analysis demonstrated, the responsibility of the regulator to protect against contamination threats, shaped which publics could be involved, what roles lay members played, and how public concerns were integrated into policy decisions.

Giddens does not explicitly discuss the use of precaution in addressing scientific uncertainty. However, I have suggested that the implementation of this principle can be examined from a risk society perspective because it deals with issues of uncertainty and public trust. In the blood system, a key consequence of the redefinition of risks has been the application of the precautionary principle to address scientific uncertainty and the theoretical risks such as vCJD. In this way, we can understand the precautionary principle as a symbolic token of safety and good decision-making. As Giddens (1990) suggests,

symbolic tokens are a "media of interchange which can be passed around without regard to the specific characteristics of the individuals or groups that handle them at any particular juncture" (p. 22). The precautionary principle serves as a way for governments to demonstrate their commitment to safety by ensuring that even theoretical risks are dealt with in a manner that prioritizes both known and suspected contamination risks. This is important, as illustrated in *Chapter 7*, when discussing the MSM deferral policy, though two decades old, the tainted blood scandal remains in the minds of Canadians and continues to influence how people evaluate the blood system.

## **Building Trust: The Unique Role of Hemophilia Consumers**

A central argument of this dissertation has been that contextual factors, particularly the formal responsibilities of the various players in the blood system, serve to shape how participation functions in practice, particularly in relation to trust. To that end, in *Chapter 6*, I illustrated how trust functions very differently within CBS than on the EAC-BR. This occurs both in terms of how it is conceptualized in relation to stakeholder participation, including the way in which it is tied to CBS' responsibility, and the actions taken to rebuild it.

To better understand how participatory processes operate within CBS, I drew upon the notion of the stakeholder society as a way to complement Giddens' notion of access points. The stakeholder society (Macintyre, 1999; Petersen, 2003) draws attention to the different publics that exist and their varying roles in contemporary health care decisions. This is a critical distinction within this research.

Trust is central to CBS, as it is through the trust of the public that the organization is able to recruit donors and ensure a sufficient supply of blood. However, because of the history of tainted blood, trust is also quite fragile and is somewhat dependent on the

support of stakeholders. This requirement creates multiple and different roles and opportunities for stakeholders within access points to CBS. In particular, I illustrated the unique and influential role that one specific type of stakeholder – the hemophilia consumer - plays in helping CBS re-establish public trust, and the impact this has on the participation of other stakeholders in CBS. I argued that participatory processes work as trust mechanisms because the consumer stakeholders involved have specific histories in relation to the tainted blood scandal. As discussed in *Chapter 6*, CBS gains legitimacy from associating itself with an identifiable consumer community, particularly hemophilia consumers who are, or represent, victims of tainted blood. Because of their past experiences hemophilia consumers have a moral capital not available to other types of stakeholders. Their association with those possessing this moral capital can then be drawn upon by CBS to maintain its reputation as a trustworthy overseer of a safe blood supply and therefore build public trust.

In this dissertation I have argued that, while previous research has pointed to the role that participatory processes play in building trust, there is very little description regarding how such processes facilitate trust building. In studying the roles of consumers in CBS, I was able to illustrate distinct actions taken by hemophilia consumers to rebuild trust in CBS. In particular, I examined the way in which these consumers endorse the organization to the public through the media, including newspaper articles, as well as online through their own website and that of CBS. For example, the Canadian Hemophilia Society (CHS) responds to requests by CBS to post notices on their website regarding blood safety policies and publicly support policy decisions, such as the MSM deferral policy.

## Moral Capital and Trust as Power in the Stakeholder Society

The present analysis has also articulated the concept of the stakeholder society (Macintyre, 1999; Power, 2003), and the way in which stakeholders can utilize their involvement to advance their own interests and gain power. Kane (2001) argues that moral capital is a resource that can be used to legitimate positions, organizations and individuals, and to garner support for one's interests.

Drawing upon Kane's (2001) ideas, I argued that the moral capital derived by being victims of bad blood, gives hemophilia consumers leverage to advance their own vested interests in the blood system. As their endorsement is important in relation to trust building and organizational reputation, they can request that their perspectives on risk be of primary importance to the organization. The data suggests that their ability to influence public perceptions of blood safety does indeed play a role. This influence is illustrated in *Chapter* 7, where I discussed the MSM blood donor deferral policy. Comments from a member of CBS management illustrate the perception, held by those in management, that if consumers did not agree with the policy decision then it would be difficult to make any changes.

I do not think we could make a significant change in the system, particularly if we were not confident that the stakeholders had the most direct involvement – the consumers – the ones we are closest to, if they had a different opinion, or were opposed. It just never would happen. We would not be able to make the change happen. We would never be successful in making change, if the minute we made the change they would be saying, this is the wrong decision.

### (Interview # 3 – CBS Staff)

The role that consumer stakeholders play in helping CBS demonstrate legitimacy for blood safety and thus trust and organizational reputation means they also become a risk to the organization. As the comment above suggests, there is a perception that without the support of hemophilia consumers, the organization would lose public trust. Because of this, their interests must be appropriately addressed above those of other stakeholders.

These findings provide a further elaboration of Giddens' work on access points by illustrating how the process of engaging consumer stakeholders translates into a form of power for these stakeholders. As past victims of bad risk decision-making, hemophilia consumers have the moral capital that enables them to be agents of reflexivity. That is, they are able to remind the public about the uncertainty of expert knowledge and do so in a way that is historically framed in relation to the tainted blood scandal. They thus ensure that their priorities around risk, namely that of contamination and precaution, are prioritized within CBS.

These findings also contribute to what has been identified as a neglected aspect of the governmentality research: power (Garland, 1997; Stenson, 1998). Petersen (2003) argues that governmentality theorists have neglected to consider the nature of "strategies and practices initiated from below" (p. 197), as not simply a product of adaptation or resistance but, instead, as essential aspects of consumer identity that contribute to power for these communities. Consumer stakeholders representing past victims exert their influence from below and within the context of being able to draw upon their historical experiences to legitimize the work of CBS. Combining the work of Giddens on access points and Foucault's notion of governmentality with that of the stakeholder society allows for a more nuanced understanding of how participatory processes operate in practice and of the way in which blood consumers are able to access power and serve the interests of their community.

However, we also must remember that this is an expert-driven, centralized blood system in which the CBS must implement the blood safety policies, such as the MSM deferral policy, of the regulator. CBS has no ability to make changes to deferral policies that would increase safety even incrementally. Therefore, while consumers seem to exert pressure on the CBS – or that is the perception of CBS management, board and other stakeholders - they are functioning within a regulatory system that makes all safety decisions. Thus, it is hard to say whether the input at the operator level has any influence on regulatory risk governance.

#### Limitations

This study was centered on a series of 27 interviews within the CBS and EAC-BR. One of the limitations of this study was the small sample size and the challenges of getting participants to agree to be interviewed. I think more time would be required for interviews, as it took over a year to organize the series of interviews completed for this research. It was very difficult to convince representatives some groups of participants to agree to be interviewed. For example, while letters of introduction were sent to each Board member, I had very few members of the CBS Board of Directors agree to be interviewed. As the organization purports to be open and transparent, one would assume that it should have been easier to recruit more respondents. However, that did not prove to be the case.

In hindsight, it would have been beneficial to interview persons in Health Canada who oversee the EAC-BR. It would have been valuable to understand how they conceptualized the roles of members and the differences in how they saw the roles of expert members as compared to lay members. As Health Canada sets the terms of reference for this committee, such interviews would have served to contextualize the roles

of members on the EAC-BR and thus, been used to compare the formal expression of their roles to how members saw their roles on the Committee. However, early in the research process I spoke with a representative from the Biologics and Genetics Therapies Directorate (BGTD) who stated that interviews with representatives from the BGTD would be difficult to set up and the EAC-BR would provide the most valuable data, as they are the expert body.

At later stages in this research on the MSM policy and in particular, the court case between Freeman and CBS arose as a prominent public issue. It would have been valuable to interview members of the GLBT community who were advocating for a change in policy, in terms of their understanding of science and the use of the precautionary principle in relation to the MSM blood donor deferral policy. As discussed in *Chapter 7*, published reports by stakeholders advocating against the MSM policy suggested there exist a lack of understanding regarding the impact of this principle in risk decision-making in relation to blood. However, to do so would have required a delay in the research process, as I would have had to go through ethics again to gain access to this community. Thus, a decision was made to review public materials from each of these groups to determine their positions on the policy.

#### **Future Research**

As stated in the previous section, future research on the role of stakeholders in blood safety decision-making would benefit from expanding the pool of interviewees, particularly those representing the federal regulator. Public participation strategies have been implemented in regulatory bodies as a result of governmental policies, thus having the change to interview individuals who made, and continue to support, such practices

would help to illuminate the reasons for such decisions. As was illustrated in *Chapter 5*, both expert and lay members expressed the view that science and not public engagement, was central to the work of the Committee. Moreover, because of the dominant role of science in the work of the EAC-BR only certain members of the public could participate. In particular, lay members required a level of scientific literacy that allowed them to understand the evidence used to provide advice to Health Canada.

Follow up research on the integration of stakeholder within the CBS would be valuable to see whether membership changes (as required by the terms of reference) result in changes to the influence of certain stakeholders, namely those representing the hemophilia population. As discussed by one member of the CHS, as time passes from the tainted blood scandal the remembrance of that tragedy lessens in the new generation of hemophiliacs. Will this mean that members of this community are less resistant to policy changes that focus on issues of cost and sufficiency rather than precaution? And if so, how will this affect policy decisions?

The MSM policy is of particular interest as many Western countries, including Canada, have committed to reviewing the policy to decide whether changes are necessary. Thus, it would be useful for future research to follow the reviews of this policy nationally and internationally to identify what role stakeholders play in this process. Are the roles of stakeholders, particularly consumer stakeholders different than what takes place in Canada? With other Western countries, such as New Zealand and Australia, reducing the deferral period to five years, it would be interesting to see whether Canada decides to change their policy in accordance with other Western nations. Moreover, as I illustrated in *Chapter 7*, there was a perception by those participating in the CBS that the organization could face negatives repercussions on their reputation if they made policy decisions (such

as the MSM) that went against the CHS. What would be the implications if the CBS made a decision to reduce the deferral period against the wishes of the CHS? Are the fears of CBS management valid with regard to reputational risk and the impact on sufficiency?

In both *Chapters 5* and *6*, respondents spoke about the lack of cost containment initiatives on the blood system. Many commented that compared to other aspects of the health system, the blood system has been able to implement policies that would not be considered due to their expense. Similarly, research by Wilson (2007) suggests that the rising costs of the blood system, with cost per quality-adjusted life years in the millions, may have to be addressed at some point. Therefore, future research should also examine whether political changes, particularly related to health transfers and health funding, may impact decisions to implement expensive blood safety technologies.

#### Implications of Engaging the Public in Risk Decision-Making

This research has focused extensively on the integration of participatory processes into the Canadian blood system and the implications of this engagement on blood safety policy decisions. As my research has illustrated, the types of stakeholders involved and their roles in blood safety decision-making are shaped by historical and contextual factors, including the tainted blood scandal as well as new responsibilities for blood safety such as the implementation of the precautionary principle.

However, the blood system is not the only place where public participation strategies have been integrated. Over the past decade within Canada, there has been a concerted effort to integrate the public into governance arrangements and decision-making bodies. This is particularly true in relation to health. For example, Health Canada established the Office of Consumer and Public Involvement (OCAPI), which functions to

connect the public with opportunities to participate in health decision-making at the federal level of the government. In addition, there have been efforts to establish consumer boards and advisory groups that work with researchers to establish research priorities and assist in making decisions about health care spending. One example of this is the Consumer Advisory Council of the Canadian Arthritis Network, which is one of the National Centres of Excellence. This advisory body participates in all levels of decision-making including peer review, management and all funding decisions (Canadian Arthritis Network, 2010). Similarly, most provinces in Canada have established mechanisms to engage the public in making decisions about which drugs to include on public drug formularies (British Columbia, Ministry of Health, 2010; Common Drug Review, 2010).

The research presented here suggests that there are important considerations for governments and organizations when integrating participatory processes to ensure effective participation. In particular, there is a need to consider how to engage a diversity of stakeholders in a way that provides them with a fulfilling experience, while serving the interests of an organization or government.

First, there is a need to recognize how contextual factors, such as formal responsibilities, cost containment strategies and political changes, shape participation and the types of publics that are involved. As I have illustrated, the responsibilities of the regulator and CBS influence which publics can participate and the level of engagement that they are able to have. In the case of the EAC-BR, I showed how the responsibility of the regulator to ensure blood safety by monitoring the scientific research meant that members of the lay public could not participate. However, even lay members with an acceptable level of scientific knowledge, struggled to understand their role. This situation is illustrated in the comments of one of the lay members on the EAC-BR:
I would say that I have very limited impact and input on this committee. Quite frankly, if I stop going tomorrow I do not see how it would impact negatively on this committee. On this committee, I think you would want to look at what the value is of even having lay representatives on it. I mean, if they cannot contribute very much and they are not out there promoting the work of the committee then what is the point? What is the true value of having someone there? Is it just because you have to have a lay represent on the committee or do you want something specific out of that person? You know if they do want something specific, then they sure are not asking for it. They are not asking much of lay representatives.

(Interview #4 – Lay member EAC-BR)

This comment suggests that either a decision must be made to include only certain segments of a population, in this case those who are experts, or, governments and organizations need to dedicate resources towards training and education of consumers and lay members to ensure that these individuals are able to effectively participate.

The research presented in this dissertation also implies that it is critical to understand that, even though there can be a diversity of stakeholders engaged in participatory processes, this does not mean they all play the same role. Nor do they all have the same influence.

While there is no need for all stakeholders involved the play the same role, there are important and potentially negative outcomes that may arise from prioritizing certain types of stakeholders. Within the context of this study, one outcome of these different roles is that other stakeholders felt their views are unimportant and that their voices were given less consideration in organizational decision-making. For example, as we saw in *Chapter* 

241

*6*, most of the NLC health professionals interviewed expressed a view that the risk of blood insufficiency was not given serious enough consideration within the organization. Instead, contamination risks, even those theoretical in nature, were prioritized. Additionally, many of the non-consumer stakeholders expressed concerns about the costs of risk management measures, particularly in light of the fact that many of them working in the health field have experienced budget cuts. Two health professionals on the NLC expressed these concerns:

I think cost is a big issue. As a person that works in the health care field, we see cuts daily to our programs...there is not enough money for the work that needs to be done. I think most areas of health care are seeing this, but with blood it is different. There is very little tolerance to implement any restrictions on funding because of the fear of contamination. I get it because of what happened, but at the same time it can be very frustrating.

#### (Interview #11 – NLC)

To the consumer groups no cost is too much if there is an increase in safety. Now I am not sure if the consumers entirely understand how much more it is going to cost. I mean, the risks are so low already that we have to ask ourselves if it is worth it. When does it become too costly? I mean, if we have to, if there is a good reason for it then you have to add another test in, but not just because. And I really think with the consumer groups there is no understanding of the cost.

#### (Interview #12 – NLC)

Starr (1998) argues that "AIDS ushered in a new period of blood economics" (p. 350) as the cost of testing procedures has substantially increased costs. Indeed, Wilson et al. (2004) demonstrate the cost of implementing precautionary safety measures in the Canadian blood system. They report that there has been a 50% increase in blood system costs (Wilson et al., 2004).

While we cannot attribute the increase in costs to the inclusion of consumers, it has been suggested by Wilson et al. (2007) that the propensity to implement expensive risk management procedures to address remote risks is an example of what happens when expert science is no longer under public scrutiny. These researchers speculate that such expensive risk management measures might have not been implemented had members of the external general public been involved, because those members would have given more consideration to issues of cost effectiveness than do consumers who have a direct interest in the system (Wilson et al., 2007). It is hard to know if this would be the case. As we saw in *Chapter 8*, there remains a perception that the Canadian public continues to be risk averse when it comes to the blood system. However, because of the unique and influential role that blood consumers play in the blood system, their focus on safety likely contributes to the costs of the blood system.

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## **Appendix A – Contact Letter**

Date

Department of Anthropology and Sociology 6303 N.W. Marine Drive Vancouver, B.C. Canada V6T 1Z1 Tel : 604-822-2878 http://www.anso.ubc.ca

Dear\_\_\_\_\_

I am writing to invite your participation in a doctoral research project at the University of British Columbia entitled **Negotiating Trust in the Canadian Blood System**, is funded by a Social Science and Humanities Research Council fellowship and a Canadian Institute of Health Research Fellowship in Transfusion Science administered through the Centre for Blood Research at the University of British Columbia. The goal of this research is to understand how consumers and stakeholder groups have been integrated into blood-system decision-making and the potential implications of their inclusion on building public trust in the safety of the blood system

If you agree to participate, I would like to arrange either a telephone or face to face interview at a time and place that is convenient for you. Your involvement would consist of being interviewed about your role and experience in the blood system, particularly in relation to public engagement initiatives, as well as your views with regard to issues of risk and blood safety. The interviews would last 30 to 45 minutes. Participation is wholly voluntary, and your name will never be associated with any information that you choose to share. A consent form will be sent to you prior to the interview and you will be presented with a copy for your files at the time of the interview.

I hope that you are interested and willing to participate in this study. To participate, or for further information about this research, you are able to contact me in one of the following ways: 1) by telephone at (604) \*\*\*\*\*\* (Jay Fiddler); 2) by email at \*\*\*\*

Thank you for considering this request. I look forward to meeting with you.

Sincerely yours, Jay Fiddler, Ph.D. student

### **Appendix B – Interview Questions**

#### Negotiating Trust Interview Guide: Interview protocol for potential interview participants

Thank you for agreeing to participate. I will be asking you questions that focus on three areas: your role in the blood system, consumer stakeholder involvement in organizational and, or group activities and understandings of risk and safety. These questions are meant to guide our conversation, but if you think of anything relevant that I don't directly ask you about, please bring it to my attention.

#### **Background:**

To begin with, I'd like to ask you about your current position/role in your group/committee/organization.

- 1. What is your position in \_\_\_\_\_(name the group/organization)?
- 2. How long have you been involved in this capacity?
- 3. What is your role?
- 4. What is the role/responsibility (activity) of the group? (say specific group, organization, committee, e.g. EAC-BR, CBS, etc)
- 5. How long has this group been around and who was responsible for its creation?
- 6. How do the members of this group become involved? *Probe: You want to understand how members are chosen and who chooses the membership*
- 7. With regard to this specific group (name group), what consumer stakeholders are involved and what is their role?

Probe: You want to find out the members of the group in particular what consumer/public/lay representatives are involved. In particular you want to explore the role of public/consumer stakeholders in relation to other members within the group; re: experts.

#### **Understandings of Risk and Safety:**

I'd like to ask you a few questions about how the different stakeholders in the blood system understand issues of safety and risk. These will include both some general questions related to views on safety and risk, as well as specific ones related to your role, or the work of your group or committee.

8. Do you think the blood system has done a good job of ensuring a safe blood supply?

### If yes:

9. Please explain why you feel this way?

## If no:

- 10. Please explain why you feel this way?
- 11. In general, do you think there are differences between how "experts" view issues of risk and safety as compared to stakeholders?

### If yes:

12. Can you explain what these differences are and why they may exist? *Probe:* Are these related to social/cultural ideas? Tolerance of risk held by consumers? Ask respondent to speak about what factors may be related to these differences.

### If no:

- 13. Can you speak to why you think there are no differences?
- 14. In general, do you think there are there are differences in how the various stakeholders view issues of risk and safety?

## If yes:

15. Can you explain what these differences are and why they may exist? *Probe:* Consumers? Are these related to social/cultural ideas? Tolerance of risk held by consumers? Ask respondent to speak about what factors may be related to these differences.

## If no:

16. Can you speak to why you think there are no differences?

#### **Stakeholder Participation:**

I'd like to ask you a few questions about the involvement of consumer stakeholders in the blood system. First, I'd like to ask some general questions and then specific ones related to your experience.

- 17. Generally, from your perspective, what role do you feel stakeholders play in the blood system?
- 18. What contribution or value do you feel stakeholders bring to the blood system in relation to the identification and management of risks in the blood system? Probe: What do they, or can they, bring to the process?
- 19. More specifically, what do you think is the value of consumer stakeholders in relation to the expert representatives of government and the CBS in risk decision-making?
- 20. The involvement of consumer stakeholders is often raised in conjunction with issues of public trust and safety; do you think their/your (depending on interviewee) involvement is effective in building public trust in the safety of the blood system?

#### If yes:

- 21. Please explain why you feel this way. *Probe: Ask about particular examples, public trust or consumer trust?*
- 22. What do you think are the benefits (for the blood system) that come from increased trust?

*Probe: Does this encourage greater participation from the public/more blood donors?* 

## If no:

- 23. Please explain why you feel this way. Probe: Ask about particular examples.
- 24. Are there any particular situations you can recall from your experience in which there were differences between how consumers and stakeholder groups viewed risk and safety as compared to "experts" of government and the CBS?

Probe: For example, have there been differences in member' views of various risks

or policy decisions?

If yes:

25. Please explain why you thought these differences occurred? *Probe: what influenced these differences?*  26. How were these differences reconciled within the committee or group?

#### If no: go on to question #30

- 27. From your perspective, how has the inclusion of consumer stakeholders influenced the development of regulatory and organizational policies and practices to manage risk? Probe: Ask for examples such as deferral policies, i.e. vCJD and tie to the role of the group, i.e.: Are there differences between how these stakeholders view the issues of voluntary donation or MSM?
- 28. In your opinion, what are some of the benefits (other than trust) that come from the involvement of multiple stakeholders in blood system decision-making?
- 29. In particular, what are some of the benefits that come from the specific inclusion of consumer stakeholders?

Probe: ie: increased donation; safety; etc.

- *30.* In your opinion, what are some of the challenges that come from the involvement of multiple stakeholders in blood system decision-making?
- 31. In particular, what are some of the challenges that come from the inclusion of consumer stakeholders in the blood system?
   Probe: cost-effectiveness due to risk differences, ie: over-cautious.
- 28. Is there anything else you want to speak about or that I have not asked you about, but which

you find important?

# Appendix C – Documents Analyzed

## A. Canadian Blood Service Documents

- > Policy Statements:
  - CBS statement regarding the MSM Donor Deferral Policy March 16, 2007
- > Annual Reports/Performance Statements:
  - Performance Review of the Canadian Blood Services Final Report October 15, 2002
  - Canadian Blood Services Response and Action Plan Summary
  - Report to Canadians 2001-2002
  - Report to Canadians 2002-2003
  - Report to Canadians 2003-2004
  - Report to Canadians 2005-2006
  - Report to Canadians 2007-2008
- Consensus Conferences:
  - April 2004 Proceedings of a Consensus Conference: The Screening of Blood Donors for Variant CJD (Transfusion Medicine Reviews (April 2004, Volume 18, Number 2)
  - 2002 Consensus Statement from the Consensus Conference on Blood-Borne Human Immunodeficiency Virus and Hepatitis: Optimizing the Donor-Selection Process published in Vox Sanguinis (2002) 83, 188-193
- ➢ Website:
  - Public Involvement (http://www.bloodservices.ca/centreapps/internet/uw\_v502\_mainengine.nsf/pa ge/E\_Public%20Involvement)
  - "About Us" webpage (http://www.bloodservices.ca/CentreApps/Internet/UW\_V502\_MainEngine.ns f/page/About%20Us?OpenDocument&CloseMenu)
  - Statements and Reports Questions and Answers MSM Policy Decisions (http://www.bloodservices.ca/centreapps/internet/uw\_v502\_mainengine.nsf/pa ge/MSM\_QA?OpenDocument)
- MSM Donor Deferral Risk Assessment: An Analysis using Risk Management Principles – A Report for Canadian Blood Services. Leiss, W., M. Tyshenko and D. Krewski. January 31, 2007

# **CBS Board of Directors:**

Meeting minutes (found at:

http://www.bloodservices.ca/CentreApps/Internet/UW\_V502\_MainEngine.nsf/pag e/Board+MinutesAgendas?OpenDocument):

- October 25, 2006
- May 17, 2007
- June 21, 2007
- January 24, 2008
- March 6, 2008
- Final Report of the Task Force on Public Participation to the Board of Directors of Canadian Blood Services. Leiss, WL., Plumptre, T. and Segal, H. November 1, 2000
- Response to the CBS Board of Directors to the Final Report of the Task Force on Public Participation. December 18, 2000

# National Liaison Committee (NLC)

- National Liaison Committee Terms of Reference October 2005 (http://www.bloodservices.ca/CentreApps/Internet/UW\_V502\_MainEngine.nsf/pag e/E\_National%20Liaison%20Committee?OpenDocument)
- NLC Consultation on MSM deferral Friday, April 20, 2007 (presentation)
- Summary notes o f meeting minutes analyzed (all located online at: http://www.bloodservices.ca/CentreApps/Internet/UW\_V502\_MainEngine.nsf/pag e/E\_National%20Liaison%20Committee?OpenDocument):
  - October 22, 2001
  - October 23, 2001
  - January 30, 2002
  - July 8, 2002
  - September 23, 2002
  - May 27, 2003
  - October 27, 2003
  - October 28, 2003

- February 2, 2004
- October 24, 2005
- October 25, 2005
- February 20, 2006
- June 5, 2006
- October 23, 2006
- October 24, 2006
- April 21, 2007

# B. Governmental/Regulatory:

## > Health Canada

- Health Canada's role in blood and blood components (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/blood-sang/qa\_qr\_07\_2006-eng.php)
- Health Canada/Biologics and Genetic Therapies Directorate (found at: http://www.hc-sc.gc.ca/ahc-asc/pubs/index-eng.php)
  - Health Products and Food Branch Public Involvement Performance Report 2005-2007
  - Health Products and Food Branch Public Involvement Annual Performance Report 2004-2005
  - Health Canada Policy Toolkit for Public Involvement in Decision Making
  - Health Products and Food Branch Public Involvement Framework
  - Stakeholder Consultation on the Proposed Regulatory Framework for Blood and Blood Components – March – November 2007

## > Expert Advisory Committee-Blood Regulation:

- Record of meeting 2007-09-24
- Record of meeting 2006-05-17
- Record of meeting 2005-0-12

# Krever Inquiry – Volumes 1, 2 and 3

## C. Consumer Groups:

- Canadian Hemophilia Society (found at: http://www.hemophilia.ca/en/)
  - Report Card on Canada's Blood System 1999
  - Report Card on Canada's Blood System 2000
  - Report Card on Canada's Blood System 2002

- Report Card on Canada's Blood System 2003-2004
- Report Card on Canada's Blood System 2005-2007
- Other website pages that explain the organization, their mandate and history (*http://www.hemophilia.ca/en/about-the-chs/*