UNPACKING THE SENATE OF CANADA DEBATE ON BILL S-232 - AN ACT TO AMEND THE PATENT ACT: INCONSISTENCIES AND IMPLICATIONS FOR GLOBAL PUBLIC HEALTH

by

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ABSTRACT

**Background:** This paper explores Canada’s role in the global access to medicines crisis. In 2003, the Canadian government committed to implementing the WTO’s August 30th Decision ratifying the Doha Declaration by creating Canada’s Access to Medicines Regime (CAMR). CAMR allows for on-patent production of generic low-cost medicines for export to countries that lack manufacturing capacity. After nearly seven years of legal delays and bureaucratic flaws, the law was used only once and proved to be ineffective in practice. As a result, its supporters introduced two reform Bills (S-232 and C-393) for review in the Parliament of Canada. On March 9, 2011, Members of Parliament voted in the House of Commons to pass Bill C-393. The Bill—now before the Conservative-controlled Senate—faces fierce opposition and there are growing concerns that the Senate will not uphold the will of the House of Commons.

**Methods:** This paper examines the Senate of Canada debates on Bill S-232, An Act to amend the Patent Act (drugs for international humanitarian purposes). It analyzes the transcripts using a content analysis approach. The primary conceptual framework used for analysis was Wendy Larner’s interpretation of three dimensions of neo-liberalism.

**Results:** Four major themes emerged from the debates: Canada’s conservative approach to the August 30th Decision; contradictory arguments against reform; circumventing the issue on the table for debate; and policy chill. The dominant ideology in the debates appeared not to be a moral, humanitarian perspective primarily concerned with human health, but rather a neo-liberal set of assumptions oriented toward maintaining the health of markets.

**Conclusions:** Opposition to reform CAMR is shaped by contradictory arguments informed by neo-liberal principles. CAMR has the potential to provide an expeditious solution to the global access to medicines crisis. The Canadian Senate should uphold the decision to reform CAMR and ensure that the law is one policy tool—among many others—to be used to increase global access to affordable medicines.

**Keywords:** Access to medicines; WTO TRIPS; August 30th Decision; CAMR; Bill C-393, Bill S-232, neoliberalism
DEDICATION

To my younger siblings, Alicia and Brandon, who inspire me in so many ways.
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1: INTRODUCTION

Millions of the world’s poor in need of medicine die each year because they lack access to existing pharmaceuticals (WHO, 2004; MSF, 2008; UAEM, 2010). One barrier to access is the high price of drugs, which is directly impacted by patents. The purpose of this paper is to explore Canada’s role in the debate over patent law and global access to medicines, which takes place within the parameters of Canada’s Access to Medicines Regime (CAMR). CAMR became the first implementation of the World Trade Organization’s (WTO) August 30th Decision, a resolution designed to allow poor countries to fully utilize compulsory licensing mechanisms built into the WTO agreement governing patent law, known as the Trade Related Aspects of Intellectual Property Rights (TRIPS).

Following the adoption of TRIPS, debate ensued over how poor countries, in the absence of pharmaceutical manufacturing capacity, would utilize compulsory licensing mechanisms in order to access essential medicines for public health purposes (Mayne, 2003). In recognition of this challenge, WTO member countries adopted the Doha Declaration on the TRIPS Agreement and Public Health 2001 (hereinafter, the “Doha Declaration”), which declares that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” (WTO, 2001, para 4). On August 30th, 2003, WTO member countries implemented the Doha Declaration in a resolution entitled the WTO General Council Decision 2003, and often referred to as the
August 30th Decision (hereinafter, the “Decision”) (Rimmer, 2008). Canada became the first country to implement the Decision and amend its patent laws by creating CAMR (Cohen-Kohler, Esmail & Cosio, 2007). CAMR allows Canadian generic pharmaceutical companies to produce on-patent drugs for export to countries that lack the capacity to manufacture drugs for domestic public health purposes. The government has used CAMR once since its inception, and it has been highly criticized for its failure to provide an expeditious solution to the global access to medicines crisis (HIV/AIDS Legal network). Other critics have suggested that CAMR will never work (Attaran, 2009).

In May 2009, a Bill outlining proposed CAMR reform was introduced in the Senate of Canada, entitled the Proceedings of the Standing Senate Committee on Banking, Trade and Commerce on Bill S-232, An Act to amend the Patent Act (drugs for international humanitarian purposes). At the same time, a companion Bill was introduced into the House of Commons, known as Bill C-393. This “two pronged” approach turned out to be a wise one, since the Senate Bill died following the prorogation of Canadian Parliament in December 2009. Bill C-393 survived however, and on March 9, 2011, the House of Commons passed Bill C-393 (172 yays to 111 nays) with its “one-license solution” (Canadian HIV/AIDS Legal Network 20 Q&A, 2010; R. Elliott, personal communication March 9, 2011). The Bill is now before the Conservative-controlled Senate for approval but some commentators are concerned the Bill’s progress is being stalled (Taylor, 2011). This is occurring despite the Senates experience with its companion Bill S-232.
that passed two readings in the Senate before Parliament was prorogued in
2009.

The aim of this paper is to identify some of the underlying reasons for the
opposition to CAMR in the Senate. It aims to provide insight into the debate
around CAMR reform, generally, by examining the transcripts from the Senate
debates on Bill S-232. This examination aims to unpack arguments opposing
CAMR to reveal whether opposition to the Bill is evidence-based and whether the
Conservative-controlled Senate will seek to block the House of Commons
decision.

1.1 Overview of the Paper

This paper first presents the public health problem of global access to
affordable medicines and the role patents play in that problem. It then provides
an overview of some of the origins of multilateral trade, with a focus on the WTO
and TRIPS. Next, the paper addresses a legal option enshrined in the TRIPS
agreement known as compulsory licensing, which allows national governments to
override patents where there is an urgent public health need. The paper then
turns to a WTO decision (the August 30th Decision) on public health, which
Canada implemented into domestic law as CAMR in order to deliver medicines to
poor countries. It identifies some of the challenges with CAMR and the proposed
objectives for reform. This discussion is followed by a synopsis of the conceptual
framework and methodological approach used to examine the Senate transcripts
on Bill S-232. Last, the paper sets out the research findings, and concludes by
making recommendations for the future.
2: THE PUBLIC HEALTH PROBLEM

2.1 Lack of Access to Existing Pharmaceuticals

Millions of the world's poor die needlessly each year because they lack access to existing pharmaceuticals (UAEM, 2010). According to the World Health Organization (WHO), approximately 10 million people—most of them living in low and middle-income countries—die each year due to access barriers (WHO, 2004). The fight to reduce the cost of antiretroviral drugs necessary to treat HIV stands at the centre of the access to medicines debate (Nattras, 2008; MSF, 2008; Schwartländer, Grubb & Perriëns, 2006). Globally, an estimated 33.4 million people are living with HIV/AIDS, including 2.1 million children. Approximately 95% of these people live in developing countries and over half of these cases are aged 25 years and younger. Over 8,000 people die every day due to HIV/AIDS related illnesses. In sub-Saharan Africa alone, the HIV/AIDS epidemic has orphaned more than 14 million children (Watal, 2000; MSF, 2008; UNAIDS, 2009; WHO, 2010).

Despite advances in medical sciences and a substantial global demand for existing antiretroviral therapy (ART), only 42% of people in need of treatment had access in 2008. This is but a small improvement, up from 35%, in 2007 (UNAIDS, 2009). According to the WHO and UNAIDS, 9.5–10 million people worldwide still lack access to HIV treatment (UNAIDS, 2009; WHO, 2010). While there are multiple factors that impede access to drugs—such as, poverty, underdeveloped
health infrastructure, human and financial resource shortages and limited economic incentive to research and develop drugs for diseases that predominantly affect the poor—the cost of medicine significantly limits access (MSF, 2008; MSF, 2009; ‘t Hoen, 2009). Although structural and societal factors impede access to medicines in poor nations, these factors do not eliminate the importance of reducing the cost of drugs. Indeed, the US government, the pharmaceutical industry and lobbyists often focus on these structural factors in order to uphold strict patent protection and avoid generic competition to drive costs down. It is well recognized that all of these factors make regular access to treatment in the global south very challenging but not insurmountable. We cannot avoid addressing the impact of price on access just because structural and societal barriers also exist (Sridhar, 2009).

For over a decade, non-governmental organizations and AIDS activists have argued to lower drug costs (Smith & Siplon, 2006; ‘t Hoen 2003; Lucchini et al., 2003; Coriat et al., 2003; Piot, 2003; Schwartlander, 2006; Shadlen, 2007). In 2000, Medecins Sans Frontieres’ (MSF) led the charge to achieve affordable access to a Yale University-discovered HIV drug owned by Bristol Myers Squibb (BMS). At this time, the cost to treat HIV/AIDS patients with a brand name first-generation antiretroviral (ARV) drug—that also happened to be the mostly frequently prescribed ARV at the time—was US $10,000 per year, making it very difficult for most patients and governments to afford in developing countries (MSF, 2008). In recognition of this barrier, MSF and Yale University students campaigned for BMS to license the drug for generic production in order to
decrease its cost. Yale and BMS were initially reluctant but following a contentious public relations battle, Yale and BMS relaxed the patent for generic production. This had a significant impact on the price of first-line ARVs. In fact, the cost of first-generation ARV drugs has fallen by 99% since 2000. Competition among multiple manufacturers—particularly those in India—drove the price down from US $10,000 US to less than US $90 per patient per year in developing countries (MSF, 2008). This effort resulted in a major scale up HIV/AIDS treatment globally (UAEM, 2010).

These efforts—among many others—have contributed to placing approximately 5.2 million people on ARVs in low-and middle-income countries (WHO, 2010). This was possible because many countries, like India, did not enforce patents and were positioned to supply cheap generic versions of on-patent drugs to poor countries. However, the access landscape has changed dramatically. As of 2005, all countries—with the exception of least developed countries as defined by the United Nations—are forced to comply with international patent rules. This means that new drugs—which are often more adaptable in tropical climates, less toxic and necessary to treat patients who develop resistance to older drugs— are very expensive due to increased patenting in developing countries with existing generic industries (MSF, 2008).

Compounding these challenges is the grave reality that research and development of new drug classes, including those for ARVs, is primarily driven by demand for these drugs in developed country markets. The data obtained from clinical trials in wealthy countries are not designed to meet the needs of patients
in developing countries. For instance, data relevant to HIV positive pregnant women, patients with tuberculosis co-infection and paediatric doses are lacking (MSF, 2008). Furthermore, treatments are not often developed for diseases that are endemic to poor countries since there is little economic incentive to develop drugs for poor patients who cannot pay brand name prices. This represents a significant market failure, as the greatest disease burden is in developing countries (Orbinski, 2003).

For instance, of the 1,353 new chemical entities that came to market as medicines between 1975-1999, only 1% was developed for neglected tropical diseases (NTDs) that predominantly affect people living in poor countries. This situation does not seem to be improving. In 1999-2004, 163 new chemical entities came to market and of these only three were for neglected diseases (Boulet, 2008). These figures illustrate that access to medicine is severely restrained by market-driven research since there is little economic incentive to develop treatment for NTDs because the people who need the drugs often do not have the purchasing power; this market is simply not attractive to private investment (Orbinski, 2003).

2.2 The Impact of Patents on Access

Medicines are a fundamental component of almost all health systems; they complement other services necessary for the prevention and treatment of prevalent diseases. The use of medicines along the continuum of health care provision also contributes significantly to total health expenditure (Pecoul et al., 1999). In many high-income countries the cost of many pharmaceuticals is
publically funded. However, this cannot be said for many low-and middle-income countries where the majority of people pay out-of-pocket for essential medicines (WHO, 2004). One factor contributing to the high cost of drugs is the relationship between patents and price. Patents are issued when a government grants exclusive rights to an inventor or assignee for the invention—which can be a product or a process—for an established period of time in exchange for public disclosure of the invention (WIPO, 2010). In theory, patents are granted to allow inventors to benefit from their discoveries and to provide an incentive for further innovations. But they are time limited to ensure that intellectual property is subsequently shared within the public domain so that society can benefit from the knowledge and prevent it from being held permanently in secret (MSF, 2008).

Supporters of the existing patent system argue that, in the absence of patents, industry would not invest in the research and development necessary to bring a product to market (Sampat, 2010).

Internationally, patents are now governed by TRIPS, which sets the global minimal standards for patent rules – including on medicine – for all member countries (currently 153). These rules require that patents be issued for a minimum of 20 years; that they protect both products and processes; and that pharmaceutical test data be protected against ‘unfair commercial use’ (MSF, 2008). In so doing, TRIPS confines domestic patent laws to a “one size fits all” model that does not take in account the socio-economic status of each member country (MSF, 2008). In the context of medicine, this means that patients, or nations, with the money to pay the price demanded by patent holders can access
a drug, but patients and countries who are too poor to afford the drug cannot, unless they gain access through some other mechanism. The WHO reports that patients living in developing and transitional countries, pay for 50-90% of needed pharmaceuticals out of their own pockets (WHO, 2004). This accounts for a significant expense especially for poor households across the globe (Quick, 2002; Elliott, 2007). In extreme, but all too common circumstances, access to patented drugs is a matter of life or death.

2.3 Overcoming Patent Barriers

If the public health needs of patients in developing countries are to be met, then access to medicines for those who require them must be dramatically scaled up. Expanding access is not only a moral issue. It is also economically beneficial for developing countries to improve population health. After all, a healthy and productive population is a vital component of economic development and stabilization (Elliott, 2007). One means by which this is possible is through donation, and indeed donors have contributed large sums of money to provide patented drugs to poor patients in developing countries (WHA, 2008). Donation, however, only goes so far. There remains enormous unmet demand for patented medicines in developing countries. Moreover, donation is an uncertain and unpredictable mechanism by which to secure long-term and affordable access to essential medicines, as the supply of such medicines lies in the hands of others. Global access to medicines will therefore require countries to utilize existing public health safeguards, such as compulsory licensing that allow governments to legally circumvent patents in circumstances of urgent humanitarian need.
Increasing access to expensive medicines will require all WTO member countries to find a pragmatic solution to a common cause of their high cost: the patent. Under the TRIPS agreement, all countries—with the exception of the UN defined least developed countries—are required to grant and enforce patents globally. This has had a significant impact on key manufacturing countries including Brazil and India, which until 2005 were able to supply developing countries with affordable medicine. As a result of increased global patenting rules, the availability of cheap generic drugs has been systematically reduced (MSF, 2008). Some advocates of access to medicines argue that the way patents are protected, globally, must be systematically reformed. But reform can take time, especially if all WTO member countries are to agree on a workable solution to existing patent barriers.

There are however, two ways in which monopoly control of drugs can be overcome. One is by way of voluntary licensing—whereby the patent holder voluntarily allows for generic production of their product. The other is by utilizing a public health safeguard known as compulsory licensing. Compulsory licensing allows governments to override patents and allow generic manufacturing of pharmaceuticals without consent from the patent holder in exchange for a royalty payment. Although this is a legal mechanism enshrined in the TRIPS agreement, developing countries continue to face barriers in the use of this option even though they are within their rights as WTO member countries. Some have even faced severe political backlash when attempting to do so.
In late 2006 and early 2007, the government of Thailand issued a compulsory licence for two AIDS drugs and one antihypertensive treatment, which resulted in significant opposition from the US government and US pharmaceutical industry (KEI, 2007). The Office of the United States Trade Representative’s (USTR) placed Thailand on its “Special 301 Report” – a priority watch list that is “is an annual review of the global state of intellectual property rights (IPR) protection and enforcement” (USTR, 2010). As the USTR (2010) states, “[t]his Report reflects the Administration's resolve to encourage and maintain effective IPR protection and enforcement worldwide”. The retaliatory pressure resulted in Abbott, a large pharmaceutical company, declining to market a new drug in Thailand. The drug was a second-line heat-stable HIV medication more suitable for use in warm countries and which was needed to treat patients who were resistant to older drugs. Abbott took this step even though compulsory licensing is within the rights of all WTO member countries and despite the broad support given to compulsory licensing by organizations such as MSF, the WHO and USAID (MSF, 2007).

Other countries, such as Brazil, have been more successful in leveraging the option of compulsory licensing. Their success appears to be due to the existence of a substantial public and private pharmaceutical industry coupled with reforms to its intellectual property laws to include social safeguards in response to international pressure (Cohen, 2006). Few countries, however, have these options available to them. Most developing countries in need of affordable medicines do not have regular access to cheap drugs or the pharmaceutical
industry necessary to produce them. A more systematic solution will therefore be necessary to offset the negative effects of patents on global public health.
3: BACKGROUND:

3.1 The Origins of a Multilateral Trading System: GATT and beyond

For over four decades, the General Agreement on Tariffs and Trade (GATT) provided the institutional framework for international trade. The GATT was created in the years immediately following WWII. Its creation coincided with the establishment of two other Bretton Woods institutions (the International Monetary Fund and the International Bank for Reconstruction and Development, which was the precursor to the World Bank). Its objective was to reduce international trade barriers and trade discrimination between nations by creating “reciprocal and mutually advantageous arrangements” (Velásquez & Boulet, 1999). Multilateral negotiations in a number of subsequent GATT 'rounds' led to further reductions in trade barriers and custom duties on goods between participating states.

However, in the early 1980s, the GATT appeared out of step with contemporary realities of global trade and members sought to create a more comprehensive agreement that could govern the progression of economic globalization (Velásquez & Boulet, 1999). Thus, with the objective of strengthening and enlarging the scope of the multilateral trading system, the World Trade Organization was born on January 1, 2005, following the Uruguay Round of negotiations. The WTO is not simply an extension of GATT; it actually extends the scope and reach of trade rules and leaves no area of economic,
social or cultural life untouched (Shrybman, 1999). That broad sweep of the WTO is achieved through a rules-based system that applies to all signatory countries despite their level of economic development, institutional maturity or international negotiating power.

When the Uruguay round started, participating countries did not envision it would end up as the WTO. Rather they thought it would entail a further reduction of barriers to trade in goods, including non-tariff barriers and subsidies (J. Calvert, personal communication, January 2011). The round began in 1986, before the Soviet Union collapsed. However, the US wanted to expand the scope of the GATT to include a number of major new areas of economic activity where it felt it had a competitive advantage such as investment, government procurement, financial services, services and intellectual property. It achieved some of these objectives in the Canada-US Free Trade Agreement, which was implemented in 1989. Following the Soviet Union’s collapse in 1989, the US emerged as the sole global superpower. This put the US in a strong position to argue that neo-liberal policies were the only effective route to economic development, given the failure of socialism in the Eastern Bloc (J. Calvert, personal communication, January 2011; Graeber, 2010). In regions across Europe, Africa and the Americas dictatorships were being replaced by new regimes based loosely on a liberal democratic model. And while these governments were ostensibly democratic, in practice they were deeply influenced by neo-liberal ideas. They were also influenced by the economic policies being promoted by the IMF and the World Bank. In fact the restructuring of their
economies was often supervised by international advisors and technocrats raised in the neo-liberal school of thought. Since the late 1980s, a majority of countries have, to varying degrees, implemented neo-liberal reforms (Graeber, 2010).

Another major development that emerged during this time was an expansion of the role of international trade agreements over domestic economic matters and domestic public policies (Graeber, 2010). Canada played a significant role in this process. For instance, the Canada-US free trade agreement (FTA)—specifically article 2004, which committed Canada to negotiate intellectual property issues in the Uruguay round, and article 2006 which extended Canada’s copyright protections—opened the door to including intellectual property in the Uruguay round negotiations for the new WTO agreement. The Canada-US FTA was followed by the North America Free Trade Agreement (NAFTA), which included an entire chapter on Intellectual Property. NAFTA was concluded a year before the WTO agreements.

Arguably, the period immediately following the collapse of the Soviet Union created a unique window of opportunity for the US to push through a system of global neo-liberal governance, supported by corresponding commitments in international trade rules. Under the framework of the WTO, it was able to establish a new regime designed to open markets, facilitate foreign investment and conditions for capital accumulation and entrench neo-liberal public policies in the member governments participating in the new world economic order, often at the expense of the well-being of the local populations (J. Calvert, personal communication, 2011). As David Harvey (2005) has observed:
“The formation of the WTO was the high point of institutional reform on the world stage. Programmatically, the WTO set neo-liberal standards and rules for interaction in the global economy. Its primary objective, however, was to open up as much of the world as possible to unhindered capital flow (though always with the caveat clause of protection of key “national interests”), for this was the foundation of the capacity of the US financial power as well as that of Europe and Japan, to exact tribute from the rest of the world” (p.16)

3.2 The WTO Trade Related Aspects of Intellectual Property Rights Agreement and the neo-liberal agenda

In order to participate in the WTO, member countries have to agree to a package of treaties covering a broad range of economic activities, including the agreement governing intellectual property and patents known as TRIPS. That agreement aims to harmonize patent laws globally by forcing signatory countries to amend national laws to reflect international trade obligations. According to Shrybman (1999), the simple addition of the prefix “trade-related” requires all member states to alter domestic laws and policies to reflect restrictive WTO patent standards. Since the TRIPS agreement establishes minimum standards for the protection of intellectual property, the agreement essentially governs the way knowledge, technology and other intellectual assets are accessed globally (Deere, 2009).

Multinational corporations—which had long sought to raise IP standards and expand their reach to developing regions that had historically maintained more flexibility in their patent laws—viewed TRIPS as a significant achievement (Deere, 2009; Sampat, 2010). Critics, however, saw it as a symbol of a new global economic order that reflected corporate-influenced Western initiatives driven by a neo-liberal economic agenda (Deere, 2009). Indeed, when TRIPS
came into force in 1995, critics suggested that it was part of a larger US strategy to implement US-style patent laws globally (Hasson, 2002). Many also worried about the negative implications for developing countries. While some advocates of IP protection saw TRIPS as a potential development tool, many economists—including Joseph Stiglitz, the recipient of the Nobel Memorial Prize in Economic Sciences in 2001—questioned the use of TRIPS in the WTO. Stiglitz continues to argue that the human costs of this highly restrictive agreement are far greater than the perceived rewards of stimulating innovation (Stiglitz, 2006).

3.3 Provisions for developing countries, economies in transition, and least-developed countries

Prior to the establishment of the WTO and TRIPS, few developing countries offered extensive patent protection for pharmaceuticals. States determined the level of intellectual property protection largely according to domestic factors, such as their level of economic development and the particular medicines at issue (Deere, 2009; Orsia and d'Almeida, 2010). This occurred for two primary reasons. First, the use of patents to encourage innovation appeared to result in minimal benefit for poor countries since research and development was—and remains—largely driven by wealthy markets. Second, developing countries saw affordable and broad access to drugs to be a necessary component to reducing the prevalence of disease in their regions especially for drugs targeting “basic needs” (Lanjouw, 2001; Lewis, 2002; Orsi and d’Almeida 2010).
Prior to the implementation of TRIPS in 1995, many developing countries relied on India, Brazil, Egypt, Israel, Jordan and Argentina for an affordable supply of medicines. These regions did not enforce product patents or had shorter patent terms and were able to reverse engineer existing drugs into cheaper generic versions. This led to the development of a large generic industry that supplied many developing countries with affordable alternatives to patented brand name drugs (‘t Hoen, 2009). When TRIPS was negotiated, its authors established two different deadlines for southern regions to enable them to comply with TRIPS’ 20-year prohibition against the manufacture of on-patent drugs. The agreement gave developing countries and economies in transition, including India, one of the largest generic drug suppliers of the developing world until 2005 to align domestic laws with the new international patent standards outlined in TRIPS. The least developed countries—designated by the UN for exhibiting the lowest indicators of socioeconomic development and the lowest human development index rating of all countries in the world—were given until 2006. This deadline was later extended to 2016 following the Doha Declaration on the TRIPS Agreement and Public Health (WTO, 2006). However, since developing countries with pharmaceutical manufacturing capacity—and the ability to export to less developed countries—were forced to comply with TRIPS standards in 2005, poor countries can no longer rely on the cheap supply of drugs they once could.
3.4 Compulsory Licensing

In an attempt to strike a balance between promoting research and development into new drugs and ensuring access to existing drugs, the TRIPS agreement includes enshrined “flexibilities” that permit government use of a patent. Article 31 of the agreement permits, “other use without authorization of the right holder”, under conditions aimed at protecting the interests of the patent holder (WTO, 2006). Although the term is not explicitly stated in the TRIPS agreement, compulsory licensing permits all WTO member governments to grant licenses that allow a producer to make on-patent drugs for domestic purposes without the consent of the patent holder (WTO, 2006; Abbott 2005). Under normal circumstances, applicants are required to seek a voluntary license “on reasonable commercial terms” from the patent holder first, except in the event of national emergencies or other circumstances of extreme urgency, and except in cases of public non-commercial use (Abbott, 2005; WTO, 2006). The grounds on which it issues the licenses are not limited, but they do contain substantive and procedural obligations. For instance, the license must be “non-exclusive” and the patent holder must be paid adequate remuneration (Abbott, 2005).

One of the key issues with the original text in Article 31 was that the TRIPS agreement limited the use of compulsory licenses “predominantly” for the supply of the domestic market of the issuing country. The result was that countries that did not have domestic manufacturing capacity were unable to circumvent the restrictive rules of TRIPS even in the event of a significant public health need. Although TRIPS seeks to “strike a balance between the long term
social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations” (WTO, 2006), it became apparent that low- and middle-income countries without existing pharmaceutical capabilities were unable to exercise the flexibilities available to rich countries because they did not have the manufacturing capacity to produce these drugs.

3.5 The Doha Declaration and the Implementation of the Paragraph 6 Decision

In recognition of this systemic barrier, WTO member countries met in Doha, Qatar on November 14, 2001 to find a practical solution to compulsory licensing for countries without manufacturing capacity. The meeting concluded with the adoption of an unprecedented statement now referred to as the Doha Declaration (hereinafter, the “Declaration”) (Westerhaus & Castro, 2006; Correa 2002). Although the Declaration lacked legal teeth and did not commit member countries to taking action, the following two parts of the statement are particularly relevant:

1. “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (WTO, 2001 paragraph 4) and;

2. “We recognize that WTO Members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002” (WTO, 2001 paragraph 6).
As seen, the Declaration reaffirmed that the TRIPS Agreement must be interpreted and implemented in a manner that protects public health and promotes global access to essential medicines (WTO, 2001; Correa, 2002). Following the Declaration, TRIPS council members went back to the table and deliberated over a more formal solution to the problem. The US led efforts to limit the solution to specific diseases, such as HIV/AIDS, malaria, tuberculosis and other tropical diseases, and to limit which countries could use the mechanism. The US also aimed to use highly restrictive language in order to appease their domestic pharmaceutical industry. Many member countries—particularly in developing regions—considered these proposals unacceptable and with the support of non-governmental organizations, they were reasonably successful in their efforts to thwart the American proposals (Loff, 2002).

On August 30th, 2003 a formal consensus was reached, appropriately known as the August 30th Decision (as noted above, the full title is the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health). The Decision allows member countries with pharmaceutical manufacturing capabilities to make generic versions of on-patent drugs under a compulsory license for export to those countries without production capacity. Public health advocates celebrated the Decision, believing it to be a necessary step toward correcting the imbalance between humanitarian and commercial objectives created by TRIPS.
3.6 Canada’s Implementation of the Decision: Canada’s Access to Medicines Regime (CAMR)

Key public figures played an integral role in increasing awareness and political pressure in Canada to mobilize a call to action on the August 30th Decision. The most notable plea was delivered by Stephen Lewis—a former Ontario NDP leader and the United Nations Secretary General’s Special Envoy on HIV/AIDS—who called on the Government of Canada to amend its patent laws to increase access to affordable drugs in poor countries. He said, “It’s time for one of the major industrial countries, in particular, one of the G7 countries, to announce the manufacture and export of generic drugs to Africa (Lewis, 2005). Further, a key article published in Canada’s Globe and Mail newspaper, written by Richard Elliott of the Canadian HIV/AIDS Legal Network and the Global Treatment Action Group, called on the Government to remove patent and drug export barriers (Elliott, 2003). These efforts likely increased public momentum on the issue and persuaded Paul Martin, the Prime Minister at the time, to take up the challenge to implement a solution to the access to medicines crisis.

In 2003, Paul Martin announced his intention to pass a Bill—An Act to Amend the Patent Act and the Food and Drugs Act, SC 2004, c23—to implement the August 30th Decision. Parliament passed the Bill unanimously and enacted it as the Jean Chretien Pledge to Africa Act 2004 to honour Prime Minister Chretien’s work on this issue. The Bill received Royal Assent in May 2004 and Canada officially became the first country to implement the August 30th Decision when it came into force in 2005 (Rimmer, 2008).
Canada’s Access to Medicines Regime symbolized a Canadian commitment to the agreed-upon WTO solution to the global access to medicines crisis. Other countries, including the Netherlands, Switzerland, Norway, India, China and South Korea, have also implemented CAMR-like regimes. However, key wealthy nations such as the US, Australia and Japan have declined to do so (Rimmer, 2008).

3.7 Export of Drugs to Rwanda under the CAMR Scheme

Not only was Canada the first country to announce the use of the August 30th scheme, but it also became the first country to use it. In 2007—four years following the WTO Decision—Rwanda notified the WTO of its intention to import drugs under the WTO General Council Decision 2003. Rwanda announced its intention as follows:

"Based on Rwanda’s present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Neviraprine (herinafter referred to as the “Product”) manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country’s public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate. Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda’s territory with respect to the Product” (WTO, 2007).

Although this was an encouraging first step toward increasing affordable access to drugs, what followed was a lengthy course of bureaucratic and regulatory hurdles, as described below, that significantly delayed the shipment to
Rwanda. Following this shipment of drugs under the CAMR scheme, it became evident that the Canadian legislation was not practical and effective; indeed, it ended up being even more restrictive and inflexible than the rules outlined in the WTO General Council Decision 2003. The Canadian Government noted the following in a review of CAMR:

“[Canada’s Access to Medicines Regime] contains a number of measures that have not been emulated elsewhere. These include its reliance on preapproved lists of products eligible for export and countries eligible to import them and making the grant of an export licence contingent upon the health and safety review of the product by the exporting country’s regulatory authority. In addition, whereas many other regimes waive the requirement that a pharmaceutical manufacturer request a voluntary licence from the patent holder(s) prior to applying for a compulsory licence, in cases of a national emergency or circumstances of extreme urgency, [Canada’s Access to Medicines Regime] does not.” (Government of Canada, 2007: 29).

Overall, the review concluded that CAMR was less permissive than the August 30th Decision intended and was unlikely to be used again in its current form (Rimmer, 2008; Canadian HIV/AIDS Legal Network, 2007). The current law creates multiple hurdles. All parties wishing to import drugs under the regime must do so on a drug-by-drug, country-by-country and case-by-case basis. The importing country is also required to establish a predetermined estimation of the required volume of drugs. This means that if medical needs and the demand for drugs increase during the time it takes to overcome all the regulatory red tape, countries are required to begin the lengthy process all over again. It therefore became clear that the design of CAMR is impractical and does not reflect the practical realities of health system management in developing countries (MSF, 2006).
3.8 The Push for CAMR Reform

Following review of CAMR in 2007, the Minister of Industry indicated that the Government of Canada had no plans to reform CAMR but did intend to continue to publicize the regime and encourage its use (Canadian HIV/AIDS Legal Network, 2008). Canada’s stance on CAMR disappointed a number of health advocates and civil society organizations (Canadian HIV/AIDS Legal Network, 2007; MSF, 2008; UAEM, 2010; Oxfam, 2010). As a result of increased advocacy efforts, two Bills (S-232 and C-393) were introduced into Canadian Parliament proposing carefully considered reform objectives while preserving the positive aspects of the original law. The most significant item proposed by the Canadian HIV/AIDS Legal Network is a “one-licence solution”, which would lead to the issuance of a single licence for on a patented drug for use in multiple countries (Canadian HIV/AIDS Legal Network, 2007). According to Elliott (2009) the one license solution would allow for the following:

- The issuing of a compulsory licence before a specific importing country is identified
- Ensuring flexibility while regulating the quantity of product exported
- The issuing of one licence authorizing exports to more than one country
- Removing the prerequisite of attempting to negotiate a voluntary licence

In theory, the one-license solution would streamline the process and make it easier to navigate by removing unnecessary legal and technical hurdles not required by the August 30th Decision. Not only do these proposed reforms comply with WTO obligations, they also reflect the spirit of the Doha Declaration’s statement that the TRIPS Agreement “can and should be interpreted and
implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all” (Doha Declaration, 2001, paragraph 4). The Declaration also encourages WTO Member countries “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose” (Doha Declaration, 2001, paragraph 4). The proposals in the CAMR reform Bills aim to implement these provisions of TRIPS more fully.

In addition to maintaining the integrity of WTO requirements, the one-licence solution also contains conditions to satisfy industry stakeholders – including the requirement that generic companies make royalty payments to patent holders for the use of their product (Elliott, 2009). This means, the patent holder would now be receiving payments based on sales to countries that would not otherwise be purchasing its drugs since without such a mechanism, developing countries could not afford the price of the patented version of these drugs. All parties involved, therefore, could benefit from a streamlined approach: generic companies benefit by securing a contract to distribute generic-drugs in otherwise untapped markets, patent-holders benefit by receiving royalty payments from generic companies, and most importantly, patients benefit by obtaining access to needed medicines. Thus, it appears to be a win-win-win situation, and an opportunity for Canada to take a lead role in upholding the Doha Declaration and the August 30th Decision.
4: PURPOSE OF THE RESEARCH

The research examines Canada’s debate over patent law within the parameters of CAMR. The research explores this topic through an examination of transcripts from the 2009 Senate’s Standing Committee on Banking, Trade and Commerce (Issue 11-14), which considered Bill S-232, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act.

The aim of the research is to undertake a deeper, critical analysis of the debate—one incorporating the perspectives of the various stakeholders involved—in order to provide insight into the reasons for opposition to substantive CAMR reform. The research focuses particularly on the use of neo-liberal discourse in the Senate debates with a view to assessing whether that discourse favours commercial interests over public health concerns.

Although Bill S-232 died following prorogation of Parliament in 2009 its companion Bill—C-393—survived and has since passed third reading in the House of Commons. But in order to receive royal assent, the Senate must approve the Bill. Thus, a balanced and nuanced understanding of the arguments made against reform will give insight into the prognosis of Bill C-393 as it moves through the Senate for final approval.
4.1 Research Questions:

The following questions guided the research:

1. How is Bill S-232 conceptualized and debated in the Senate of Canada?

2. More specifically, what is the role of neo-liberal discourse in the debate and what effects does it have in shaping perceptions of reform?
5: THEORETICAL FRAMEWORK

The global economic trend toward ideas around market centrality and efficiency is rooted in normative neo-liberal principles. These have become the dominant political paradigm for contemporary global economic organization. The neo-liberal project has evolved to provide a powerful—often prescriptive—framework for how global economies ought to function (Becker, 2010). It has served to drive economic globalization and justify its commitment to allowing the market to determine how resources and wealth ought to be allocated (Coburn, 2000; Bryant, 2009). The term neo-liberalism denotes many meanings across various disciplines, as will be discussed further below. Broadly speaking, the term refers to the pursuit of individual liberty and freedom through an institutional structure composed of private property rights, free markets, and free trade. Neo-liberalism generally discourages state intervention in the market and embraces state protection of property rights and the structured institutions that govern them (Lilley, 2006).

Nowhere is the dominance and complexity of the neo-liberal project as obvious as it is within the existing WTO structure. One of its institutional aims is to harmonize international rules of trade grounded in neo-liberal principles that seek to limit the regulatory involvement of governments. Such trade rules limit the regulatory power of nation states by forcing governments to modify their public policies to reflect global corporate standards and enshrined trade rules.
(Shrybman, 1999; WTO, 2009). Indeed, according to Steven Shrybman, “In many ways, the WTO should be seen as the realization of an ambition that took almost five years to achieve: the establishment of a global trade institution with real authority” (Shrybman, 1999 p. 1).

Neo-liberalism, however, tends to function in messy and inconsistent ways, which can make it difficult to recognize its pervasive power. For instance, while most aspects of the WTO regime reflect the deregulation ethos common to neo-liberalism, the TRIPS Agreement is an exception. The regime imposes a “positive obligation to legislate” (Shrybman p. 112) and thereby promotes regulation, suggesting that neo-liberalism and the practical application of neo-liberal policies function in inconsistent ways. For instance, although government regulation is the antithesis of neo-liberal orthodoxy, proponents may support increased regulation on the grounds of protecting property rights so long as market ambitions are met. In the case of patents, a government-issued patent creates a monopoly by blocking competitors from entering the market. This maximizes the benefits and resulting profits of the invention, even at the expense of population health. What becomes clear, is that the consistent and primary rationale of most neo-liberal projects privileges economic growth and corporate profit well above concerns for human and environmental health (Shrybman, 1999).

In order to explore the role of neo-liberal discourse in the Senate debates for CAMR reform, I have adopted Wendy Larner’s interpretation of three dimensions of neo-liberalism. Larner’s view of neo-liberal governance moves
beyond the basic neo-liberal tenet of more market, deregulation and privatization to include a nuanced understanding of neo-liberalism as a more complex phenomenon (Larner, 2000). She distinguishes between the following three constructs:

1. Neo-liberalism as Policy
2. Neo-liberalism as Ideology
3. Neo-liberalism as Governmentality

Larner argues that each of these constructs has different implications for understanding how neo-liberalism shapes the scope and content of political interventions (Larner, 2000). The following sections describe each of these three interpretations of neo-liberalism.

5.1 Neo-liberalism as Policy

Neo-liberalism as a policy framework is best understood as a shift from Keynesian economics to an economic paradigm characterized by an erosion of the welfare state and a preference for limited government interference in the market. This conceptualization of neo-liberalism, which Larner views as the most common, rests on five values: the individual; freedom of choice; market security; laissez faire; and minimal government (Larner, 2000; Belsey, 1996). This system of ideas has been widely adopted and is often associated with key economists such as, Milton Friedman and Friedrich Hayek and key institutions including the IMF and the World Bank, that favour a free-market agenda often at the expense of the welfare state (Larner, 2000; Lilley 2006). Larner’s example conceptualizes
neo-liberalism as a policy reform agenda that is “initiated and rationalized through a relatively coherent theoretical and Ideological framework” (Larner, 2000 p. 7). Market-based ideology transfers power out of the hands of democratically elected public officials to the private sector, whereby capital and profit are the primary objectives (Larner, 2000). This shift from the public to the private limits the power of state-actors to intervene when the inadequacies of the market are exposed.

5.2 Neo-liberalism as Ideology

From Larner’s perspective, the conceptualization of neo-liberalism as ideology extends beyond people and institutions to include more complex social phenomena. Using the example of Margaret Thatcher—perhaps the Western leader most associated with neo-liberal politics—and British theorist Stuart Hall’s analysis of “Thatcherism” suggest that the uptake of this ideology was achieved not simply through the application of right-leaning ideas and state-exercised power. Rather, the phenomenon of Thatcherism was the result of a more complicated process of struggle that was able to articulate—through discourse—a particular worldview that resonated with people across socio-economic strata to garner broad public support for her political agenda. This process effectively re-shaped political discourse and resulted in a new ideological hegemony structured by a neo-liberal doctrine (as summarized in Larner, 2000). Hall’s analysis of Thatcherism does not underestimate the contradictions and complexities of this phenomenon that helped pave the way for the uncritical public support of market forces (as summarised in Larner, 2000). Larner’s argument is that neo-liberalism—and new political configurations influenced by neo-liberal tenets—
cannot be understood as a simple phenomenon. Instead, it must be viewed as a multi-dimensional struggle between more and less powerful players deeply embedded in history and shaped by various state and non-state actors that participate within a complex socio-political matrix.

5.3 Neo-liberalism as Governmentality

The third feature of Larner's analysis on neo-liberalism is significantly shaped by the work of Michael Foucault and neo-Foucault literature. This framework is characterized by the view that discourse is a social construction that cannot be simply understood as a form of rhetoric or a framework for understanding the lived experience of people. Her analysis of discourse is best conceptualized as a “system of meaning”—made up of institutions and practices—that function in divisive and inconsistent ways (Larner, 2000). Larner observes that the neo-Foucault literature distinguishes between government and governance and she suggests that, although neo-liberal agendas may aim to limit state intervention, such agendas do not necessarily decrease the scope of governance. Instead, she sees governance as a method to promote institutional and individual conformity to market norms (Larner, 2000).
6: METHODS

The research adopts a directed content analysis to understand the contextual meaning embedded in the transcripts of the Senate debates. This technique utilizes existing theory and literature to inform initial coding categories while also allowing for the emergence of new codes and themes to appear in the data (Hsieh & Shannon, 2005). These codes were used to categorize the text in order to interpret its meaning. Neuman (2006) refers to content as “words, meanings, pictures, symbols, ideas, themes or anything that can be communicated (p. 322), while text means “anything written, visual, or spoken that serves as a medium for communication” (p. 322). Content analysis is considered to be “nonreactive”, whereby the text is written or recorded without the intention of its content ever being analyzed in a methodological way (Neuman, 2006). The Senate transcripts analysed in this paper are similarly nonreactive, in that they were not recorded with the intention of its contents being analyzed for research. Content analysis allows the researcher to extract and probe the content in a way that reveals meaning beyond the text itself (Neuman, 2006). Content analysis does not attempt to uncover truth, nor can it interpret the significance of text. Instead, it provides a framework for researchers to examine the text directly in order to reveal meaning that may not be obvious through observation alone (Neuman 2006).
The use of content analysis in the research allowed for themes to be identified in the Senate debates. These themes in turn revealed the persistent dominance of neo-liberal discourse throughout the Senate debates, particularly in opposition to Bill S-232. The research identifies these recurring themes in the debates, observes the recurrence of neo-liberal discourse, and evaluates the strength of the claims opposing the Bill.

6.1 Content Analysis

The content was organized with a set of systematic codes, which were derived through a thorough reading of the background literature and a first reading of the Senate of Canada Proceedings of the Senate Committee on Banking, Trade and Commerce transcripts. During the first reading of the transcripts, I pulled quotations from the text that highlighted common themes identified in the literature. I then analyzed these quotes during a second reading and used them to generate the coding scheme (herein referred to as the “predetermined codes”). Transcripts were coded during a third reading of the text using a system of “Latent Coding” and “Manifest Coding”. Latent Coding is used when a researcher is seeking to uncover implicit meaning within a communication medium; Manifest Coding is used to count the number of times a phrase or word appears in the text (Neuman, 2006). Transcripts were assigned a predetermined code and counted. Passages that could not be categorized into the predetermined codes were assigned a new code (herein referred to as “emerging codes”). Words and phrases were assigned one code per paragraph to avoid over counting. Quotes of interest were once again recorded during the
third reading to highlight the thematic content of the code. A fourth reading included an analysis of the quotations of interest extracted from the third reading to ensure nothing new was emerging from the data. Codes were then organized into clusters with shared characteristics. Finally, major themes were derived from each cluster.
7: FINDINGS

7.1 Unit of Analysis and Frequency Count

Table 1: Defines the unit of analysis for each code and presents the frequency with which the codes fit the text. Codes were only counted once per paragraph.

<table>
<thead>
<tr>
<th>Code</th>
<th>Frequency</th>
<th>Unit of Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAMR success</td>
<td>17</td>
<td>What factors determined how stakeholders defined CAMR success?</td>
</tr>
<tr>
<td>CAMR failure</td>
<td>50</td>
<td>What factors determined how stakeholders defined CAMR failure?</td>
</tr>
<tr>
<td>WTO compliance</td>
<td>44</td>
<td>What factors shaped the way stakeholders viewed Bill S-232’s compliance with the WTO TRIPS agreement?</td>
</tr>
<tr>
<td>WTO non-compliance</td>
<td>21</td>
<td>What factors shaped the way stakeholders viewed Bill S-232’s non-compliance with the WTO TRIPS agreement?</td>
</tr>
<tr>
<td>WTO obligations</td>
<td>77</td>
<td>How do stakeholders conceptualize WTO obligations?</td>
</tr>
<tr>
<td>Practical barriers in developed countries</td>
<td>48</td>
<td>Do stakeholders believe that CAMR is flawed because of bureaucratic difficulties in developed countries (ie – Canada and the first application of CAMR). What examples are provided?</td>
</tr>
<tr>
<td>Practical barriers in developing countries</td>
<td>29</td>
<td>Do stakeholders believe that CAMR is flawed because it does not reflect the practical realities of medicine procurement in developed countries? What examples are provided?</td>
</tr>
<tr>
<td>Economies of Scale</td>
<td>13</td>
<td>Do stakeholders see economies of scale to be a value mechanism to drive drug costs down? Are their cost advantages? Disadvantages?</td>
</tr>
<tr>
<td>Anti-diversion mechanisms</td>
<td>41</td>
<td>Are stakeholders worried about drug diversion to unintended markets? Why/why not?</td>
</tr>
<tr>
<td>Generic competition</td>
<td>59</td>
<td>How do stakeholders conceptualize generic competition? Is it seen to be an important way to drive drug costs down?</td>
</tr>
<tr>
<td>Cost of drugs/international competition</td>
<td>134</td>
<td>Is Canada’s generic market seen to be internationally competitive? Was CAMR an effective mechanism to compete with other generic drug companies?</td>
</tr>
<tr>
<td>Innovation</td>
<td>6</td>
<td>Are arguments around increased patent protection to stimulate research and development leveraged? Do humanitarian objectives threaten R&amp;D?</td>
</tr>
<tr>
<td>Public Health Needs</td>
<td>73</td>
<td>Do stakeholders recognize the scale of the global disease burden? Do they recognize that these diseases disproportionately affect people living developing countries? Do they have a sense of urgency in the access to medicines crisis?</td>
</tr>
<tr>
<td>Bilateral/multilateral pressure: the politics of meds</td>
<td>25</td>
<td>Do stakeholders understand the geo-politics involved over access to medicines? Do they believe there are inequities between rich and poor countries in terms of leveraging power?</td>
</tr>
<tr>
<td>Topic</td>
<td>Page</td>
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<tr>
<td>Donated Products</td>
<td>32</td>
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<tr>
<td>Aug 30 Legislation in other countries</td>
<td>30</td>
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<td>Black Market/Counterfeit Drugs</td>
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<tr>
<td>Intellectual Property</td>
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<td>People’s health needs considered first</td>
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<tr>
<td>Market norms considered first</td>
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<td>Humanitarian Objectives of the Bill</td>
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<td>Litigation</td>
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<td>Patents</td>
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<td>Procedural Practices in Drug Procurement</td>
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<tr>
<td>Canada’s Role in the Access to Medicines Debate</td>
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<td>Support for CAMR Reform</td>
<td>72</td>
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<td>Not Supportive of CAMR Reform</td>
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<tr>
<td>CAMR is not the problem</td>
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<td>Bill Technicalities</td>
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<tr>
<td>Big Pharm Concerns</td>
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<tr>
<td>Middle Income Country Concerns</td>
<td>53</td>
<td></td>
</tr>
</tbody>
</table>

7.2 Qualitative Themes

Four major themes emerged from the Senate of Canada Proceedings of the Senate Committee on Banking, Trade and Commerce transcripts. The order
of appearance does not indicate the scale of significance or relevance, and the
codes that emerged most often in the data did not necessarily reflect the weight
of the theme discussed. For instance, some codes were mentioned more often
than others, but did not necessarily appear to leverage more influence in the
debate. Therefore, each code was organized for relevance and “fit” with other
codes to create clusters of codes. After the codes were organized into clusters,
each code was assigned a “weight” that represented the leverage it had in
shaping the debates. Not all codes were used. But most, with the exception of
two, were included in a cluster. Some codes joined two clusters. The clusters
were then analyzed as a whole to draw out the larger narrative.

This section presents each theme in a visual graph. Each graph illustrates
the assessed “weight” of the code and how these codes fit with the theme. Each
illustration is followed by a brief synopsis of how the codes fit together. Themes
are expanded and discussed in depth in the “Discussion” section.
Figure 1: THEME 1 - Canada’s conservative interpretation and implementation of the August 30th Decision

Figure 1: Illustrates the factors that led to Canada’s conservative implementation of the August 30th decision. Even though Humanitarian concerns were raised often, issues of WTO compliance were raised more frequently and appeared to weigh more heavily in the debates.
Figure 2: Illustrates the contradictory arguments advanced in opposition to CAMR reform. Concerns over cost, international competitiveness and market ideology appear to overshadow the health needs of poor patients and mechanisms to harness low drug costs.
THEME 3: Circumventing the issue on the table for debate

Figure 3: Illustrates the arguments that were leveraged to circumvent the issue on the table. Opponents to CAMR reform focussed the debates on other access issues in developing countries, ie) infrastructure development and argued that Canada should be addressing those factors instead of reforming CAMR.
Figure 4: Illustrates how “chill factors” weighed heavily in the Senate debates and served to outweigh public health concerns.
8: DISCUSSION

As will be explained in this section of the paper, an examination of the Senate debates reveals a troubling lack of political will to reform CAMR to better ensure access to medicines for poor nations. Now that Bill C-393 has passed third reading in the House of Commons, the now Conservative-controlled Senate will have to approve the Bill before it is enacted into law. Given the Harper government’s general opposition to the Bill—including efforts to cut the core “one-license” solution out of it in November 2010—there is cause for concern that the decision will be overturned. Members of Parliament (MPs) voted to pass Bill C-393 on March 9, 2010 (172 yays to 111 nays). Of the 111 nays, Conservative MPs represented 109, and Liberal MPs spoke for two. The outspoken Liberal opponent Keith Martin, and his Liberal colleague Bernard Patry, joined the Conservatives in voting against Bill C-393. In the lead up to the third reading the Industry, Science and Technology Liberal critic Marc Garneau, also expressed opposition to the Bill but abstained from the formal vote.

Considering the general opposition to substantive CAMR reform in the Senate, the potential for overturning the will of the House of Commons is high. A personal email I received from James S. Cowen, the Leader of the Opposition in the Senate echoed this sentiment. In response to a letter I addressed to him urging the Senate to pass the Bill quickly, he stated, “With Conservative senators now holding a majority position in the Senate, I am not optimistic we will succeed
in moving this bill through the various stages of the legislative process. But please be assured that it has my personal support” (J.S. Cowen, Personal Communication, March 10, 2011).

The discussion below identifies four themes that emerged in the debates, which in combination appear to have persuaded Parliament to oppose substantive reform of CAMR. The discussion proceeds by setting out each theme and illustrating it with quotations from the debates, as well as evaluating the merits of the arguments raised in connection with each theme.

Underlying this analysis, however, is the persistent question of why Parliament appears so reluctant to reform CAMR. Why is Canada backing away from a humanitarian cause it once championed? Why would Parliament not wish to improve this mechanism for access to medicines so needed by poor patients in poor nations? When there is so much acceptance of the basic proposition that these patients deserve access to life-saving medicines, why is there so much resistance to reforming CAMR and seeing that an improved mechanism will work?

Larner’s analysis of neo-liberalism can provide some insight into these questions. Larner focuses on neo-liberalism as governmentality—that is, the notion that neo-liberalism must be viewed as a system of meaning—and indeed that phenomenon is reflected in the Senate debates. On the one hand, groups opposed to reform raise contradictory and inconsistent arguments against reform while advancing their market ideology. On the other, faced with the dominance of this neo-liberal system of meaning, advocates of reform themselves turn from
focusing on the moral and humanitarian dimension of the issue and instead adopt – and hence validate – neo-liberal discourse in order to support the Bill. The power of neo-liberal norms is obvious when even civil society stakeholders adopt discourse that privileges market-based logic over rights-based arguments.

In this sense, the debates over the reform Bill were often characterized by ideological assertions, as opposed to focusing more closely on how to improve CAMR from a more technical perspective. The dominant ideology in the debates appeared not to be a moral, humanitarian perspective primarily concerned with human health, but rather a neo-liberal set of assumptions oriented toward maintaining the health of markets. Throughout the debates, neo-liberal assumptions of what is possible appeared to shape how Canadian parliamentarians conceived of the potential to make CAMR workable. The debates demonstrate well Larner’s assertion that neo-liberalism ought to be viewed as governmentality – as a shared system of meaning, which itself shapes how an issue is conceived and discussed. In the Senate debates over the reform of CAMR, the assumption underlying a majority of the submissions and comments was that market-based solutions and market-based logic have a preferential place over humanitarian perspectives and human health.

The four themes set out below describe four “themes” or areas in which this preference for neo-liberal discourse appear to have affected the debate over the reform of CAMR. Together, these themes dominated the debates, to the point of overwhelming other perspectives that focused more on the human health needs that are the impetus for CAMR in the first place. The result is that the
Senate debates did not fully reflect the range of interests surrounding compulsory licensing and the access to medicines issue. The discussion of the four themes below therefore also sets out some of the logical errors in the four themes, and some of the counterpoints that were not given full treatment in the debates.

8.1 Theme 1: Canada’s conservative interpretation and implementation of the August 30th Decision.

Canada has consistently taken a conservative view of its international obligations under the August 30th Decision. Instead of focusing on what can be done to best improve access to medicine, Canada has tried to interpret its international commitments narrowly. Canada has also appeared more concerned with WTO compliance than with improving access to medicine.

Canada’s focus on limiting its obligations to achieve the access to medicine goal of the August 30th Decision likely reflects the fundamental problem with the use of market mechanisms to deliver public goods. When the market fails to adequately supply goods like medicine, it is up to governments to step in (The North-South Institute, 2007). When WTO member countries agreed to the August 30th Decision, they unanimously agreed to finding an “expeditious solution” that would allow developing countries to make “effective use” of compulsory licensing. Member countries also acknowledged that TRIPS “can and should be implemented in ways that support WTO members in protecting public health, including in promoting access to medicines for all” (Canadian HIV/AIDS Legal Network, 20 Q&A, 2010 p. 8). Yet these commitments have not been met. Despite acknowledging that the market was not delivering affordable medicines
to those who need them most, and despite seeking to be a leader in promoting access to medicine, Canada’s intervention into the market through CAMR has fallen far short of the “expeditious” solution that Canada promised. This criticism of Canada’s conservative approach to implementing the August 30th Decision is illustrated by a statement delivered by Jim Keon, the President of the Canadian Generic Pharmaceutical Association:

“Our view is that the central problem with CAMR is that many aspects relating to intellectual property go beyond what is needed for our country’s compliance with the WTO and the TRIPS Agreement.” (issue 11, p. 60)

By “go beyond”, Mr. Keon was criticizing the additional regulatory burdens imposed by CAMR, as opposed to a more streamlined approach envisioned in the August 30th Decision. Indeed, many participants voiced this criticism. According to the Executive Director of the Canadian HIV/AIDS Legal Network, Richard Elliott, “In fact, the August 30, 2003 agreement from the WTO is much broader than what the Canadian legislation covers.” (issue 11, p. 34) Here, Mr. Elliott is saying that the August 30th Decision contemplates more liberal access to on-patent drugs than CAMR actually provides. Why did Canada go beyond what was required while simultaneously celebrating an empty promise?

The preamble to the August 30th Decision may provide some insight into this question. In the lead up to the Decision, the US made efforts to distinguish between infectious and non-infectious diseases in order to limit the technologies that would be subject to compulsory licensing. Possibly this was a strategy to protect the interests of the US-based market for non-infectious diseases, such as heart disease, even though the highest burden of chronic disease is in
developing countries (Outterson, 2008). Was Canada influenced by US-led efforts that advocated for patent holder rights to limit the scope of diseases covered by the Decision?

Professor Frederick Abbott, an international law scholar at Florida State University, provided legal advice to developing countries during the round of negotiations that lead to the Decision. He notes that, “Canada’s initial response to the 2003 WTO Decision was highly ambiguous” (The North-South Institute, 2007, p. 4). He goes on to explain that a senior Canada government official advised the Canadian government to be “cautious in interpreting the Decision because there was uncertainty concerning the scope of diseases” (The North-South Institution, p.4). This advice may have informed Canada’s decision to implement a list of products subject to compulsory licensing for export, even though such a list was not required under the Decision. This approach has been criticized for being too narrowly focused on AIDS-related and off-patent drugs (Outterson, 2008).

All of this raises questions: Did Canada design CAMR to appease American interests? Was CAMR mere political symbolism designed to fail from the start?

Canada’s role in global public health is frequently addressed in the Senate debates. Advocates of CAMR reform suggest that Canada has failed to live up to its commitments. As Rachell Kiddell-Monroe, Advisor to the MSF Campaign for Access to Essential Medicines, articulates, “Canada was to provide leadership
and an example to the rest of the world” (issue 11, p. 16). The reality, however, has turned out very differently.

This lack of leadership from Canada is particularly unfortunate considering Canada is in a good position to provide strategic advice on the issue. In fact, Canada has a long history with compulsory licensing, dating back to 1923. Canada adopted compulsory licensing originally as a strategy to encourage competition among Canadian manufacturers by allowing a compulsory license to be issued to make drugs domestically. At the time, however, the pharmaceutical industry in Canada was underdeveloped and the market was too small to fully utilize the mechanism (Lexchin, 1997).

In the 1960s, three reports indicated that the cost of medicines in Canada was among the highest in the world and that patents were a primary cause (Restrictive Trade Practices Commission, 1963; Royal Commission on Health Services; Canada, House of Commons, 1967; {Lexchin, 1997}). One of the solutions to the problem was a 1969 decision by the Liberals to extend compulsory licensing provisions to allow for the import of cheaper medicines into the Canadian market. This decision helped lower health care costs for patients and insurers. Some commentators have argued that the legislation also helped to stimulate the development of the generic pharmaceutical industry in Canada (Lexchin, 2007; Canadian HIV/AIDS Legal Network, 2009). Despite the apparent success of compulsory licensing, however, the practice was subsequently abolished in two stages. First, in parallel with the Canada US Free Trade Agreement, the Federal Government significantly extended patent protection and
reduced the scope for compulsory licensing by passing Bill C-22 in 1987. Second, five years later, in 1993 it effectively abolished Canada’s compulsory licensing system by enacting Bill C-91. That Bill ensured that Canada could meet its new obligations as set forth in Chapter 17 of the North American Free Trade Agreement (NAFTA). The end of compulsory licensing was also a casualty of the general trend toward more restrictive global intellectual property rules that crystallized in the WTO’s TRIPS agreement (Lexchin, 1997).

Larner’s interpretation of neo-liberalism as ideology provides insight into these inherent contradictions in Canada’s conservative interpretation and implementation of CAMR. The design of CAMR as a policy tool can be seen as reflecting the struggle between more powerful groups (such as the US and Canada) and less powerful groups (such as developing nations). Although in the August 30th Decision the international community outlined a workable solution for developing countries, it nonetheless appears that, when it comes to actual domestic implementation of that solution, market ideology is preferred over the welfare of the poor. Although Canadian parliamentarians do not disagree with the humanitarian objectives of the bill, they are still unwilling to step up to provide the mechanism to achieve those objectives. This lack of leadership is particularly disappointing given Canada’s historical use of compulsory licensing for public health purposes. Canada is leaving developing countries behind by choosing not to acknowledge the flaws in CAMR and by choosing not to legislate a workable solution. Canada is in a position to amend CAMR that will both honour WTO
obligations and provide a more liberal interpretation of the law for developing countries to use.

8.2 Theme 2: Contradictory Arguments Against Reform

The Senate transcripts reveal a consistent focus on protecting pharmaceutical industry interests at the expense of humanitarian goals, even when the arguments voiced against reform defied economic logic. Liberal Senator Pierrette Ringuette observed this theme with frustration:

On one hand, some colleagues seem to be arguing about the free market. It seems that if one wants to promote free markets, then we should remove complexities and rules. Basically, this is what Bill S-232 is trying to achieve. (issue 11, p. 73)

Senator Ringuette is referring here to the various mechanisms built into the reform Bill that aim to reduce bureaucratic red tape to allow for increased competition between manufacturers. For instance, Bill S-232 would allow multiple countries to apply for medicines at one time, allowing for higher volume orders, and thereby making it more attractive to generic companies to supply the drugs.

This focus by some Senators on market interests parallels a kind of defeatism that emerged in the debates. Here the argument is that Canada’s generic pharmaceutical industry is too “uncompetitive” with other markets to provide a workable means for poor countries to access needed medicines. The assertion was made, for example, in a 2007 Government of Canada report on CAMR prepared by the Conservative Minister of Industry, Jim Prentice. The report states that, during the negotiations with Rwanda, the Clinton Foundation
website listed five major Indian generic companies with prices lower than what the Canadian generic company Apotex was able to offer (Government of Canada, 2007). According to Matthew Rimmer (2008), however, this report largely underestimates the competitiveness of the Canadian generic industry. Rimmer has demonstrated that the price differential between generics in Canada and other regions such as China and India is much smaller than suggested by critics of CAMR.

In the Senate debates, various Senators echoed the claim in the 2007 report that the original CAMR mechanism was not competitive enough to compete with large generic markets in India, China and South Africa. This argument is problematic on two levels. On the one hand, if the original mechanism is not competitive enough, why is Canada hesitant to make it more competitive by reforming it and allowing for larger-scale orders? On the other hand, the assertion that the Canadian generic industry is “uncompetitive” cannot be reconciled with Rwanda’s choice to use CAMR as the means to access a low cost generic drug. Indeed, the negotiated price of the drugs exported to Rwanda was one of the best on the market at the time at 19.5 cents (US) per pill (Rimmer, 2008, p. 96; Canadian HIV/AIDS Legal 20 Q&A, 2010). As stated by Richard Elliott:

You specifically mentioned the question of whether Canadian generic suppliers will compete with generic suppliers in other countries, such as India. That issue has been raised repeatedly. It is important to note that the one piece of evidence we have is that when CAMR was, after four-plus years, successfully used, it was a Canadian generic company who successfully competed against a number of Indian generic manufacturers in submitting a bid to the Rwandan government (issue 11, p. 24).
Indeed, even if it were the case that Canada's generic industry is not internationally competitive, why would the government not be interested in making it more competitive? The intellectual property scholar, Frederick Abbott, raised that apparent contradiction in the Senate debates:

It is strange to me to hear as an argument for not providing an opportunity under Canadian legislation that Canadian producers are inefficient or not competent to compete on the international market. If that was the situation, we might as well suggest that the Canadian generic producers shut up shop now, because they will not be able to compete on the international market. There is no good answer to that, other than to making your generic producers more competitive (issue 14, p. 57).

It is well accepted that generic competition is one way of making medicine affordable for more people. MSF notes that generic competition in the business of medicine is “the most significant factor in lowering prices” (Kapczynski et al., 2005). Oxfam echoes this point and considers generic competition to be “the single most important tool to remedy the access gap” (ibid).

One way to make CAMR more competitive is through leveraging economies of scale. Economies of scale lower the average cost per unit of a product as a function of increased production of the good (Encyclopedia Britannica, 2010). The proposed reform Bills attempt to create economies of scale—in the Bills “one license solution”—by pooling the purchasing power between developing countries faced with similar public health challenges (Government of Canada, 2007). The Bill harnesses generic production as means to lower production costs in Canada, while allowing generic companies to access
new markets. In fact, economies of scale were considered when devising the August 30th Decision as a way to create further incentives for generic companies to participate in the scheme and as a means to drive down costs, as observed by Richard Elliott in the debate in support of CAMR reform: “In fact, the WTO members, when they agreed on this August 30, 2003 decision, made explicit reference in that decision to the need to harness economies of scale” (issue 11, p. 25).

The proposed reform in Bill S-232 (and in its companion, Bill C-393) would allow for multi-country and larger-volume contracts in order to reduce the costs of medicine for purchasers in developing countries (Canadian HIV/AIDS Legal Network, 2008). The original Bill, on the other hand, allows only one country to make use of CAMR at a time, making it impossible to achieve high-volume orders. Efforts to make CAMR more economically competitive make sense from a neo-liberal perspective, and yet Canada is not making this possible. Richard Elliott put the point this way in the Senate debates:

Therefore, we have seen the potential to compete. The potential to offer even more competitive prices would be even greater if the process of getting to the point of having a license to supply multiple developing countries could be put in place. You would achieve economies of scale (issue 11, p. 25).

Critics of the Bill, however, insist it is not guaranteed that reform will make CAMR more efficient and the generic industry more competitive. Liberal Senator Mac Harb was raising this doubt, as seen below:

“I am not confident, as Senator Massicotte also said, that if we approve Bill S-232 tomorrow, which I wanted to support, that it will
change anything in the supply because of what you just told me and
my colleagues about India and Brazil, who already have the capacity
to produce that” (issue 11, p. 53).

The concern about the Canadian generic industry’s lack of
competitiveness contains an inherent contradiction, however. Either a reformed
CAMR will work better, or it will not. If it works better, then poor countries will
have better access to essential medicines, and if a reformed CAMR cannot
compete with other markets then there is no loss to industry. Canada has an
opportunity to set a global precedent by reforming CAMR. Ultimately, if a
reformed CAMR works no better than the current legislation, then the position is
no worse than it is today. Reforming CAMR, however, does hold some possibility
of actually improving access to medicines desperately needed by millions of
patients suffering today. This human health interest was consistently lost in the
rhetoric around competitiveness and efficiency. If reforming CAMR has potential
to provide better access to essential medicines, is that possibility not worth
attempting reform?

The contradictions in the arguments opposing CAMR reform raises the
suspicion that critics of CAMR are less concerned with finding an effective means
to increase access to medicines than they are in ensuring that IP protections are
not weakened by allowing for compulsory licensing. There appears to be an
underlying fear of opening the door to any exceptions to patent protection. Yet,
through the Doha Declaration and the August 30th Decision, the international
community has recognized that the human health need for essential medicines is
too great to be ignored in favour of intellectual property rights.
Another line of argument adopted by opponents of CAMR reform in the Senate debates focuses on international development more broadly. Many Senators questioned whether the compulsory licensing regime is the most effective and efficient way to improve health outcomes in developing countries. For instance, some argued that CAMR is the wrong mechanism, and that rather what is needed is increased foreign aid allocated to infrastructural development. Senator Massicotte asked: “My immediate reaction is that if this is a world problem, why is it just a Canadian legislation problem? Maybe we are not addressing the right problem?” (issue 11, p. 23). The obvious problem with a focus on economic aid and infrastructure development is that people are dying now, while economic development will take decades, if indeed significant development can be achieved. The arguments focusing on economic development as a preferred alternative to compulsory licensing therefore appear to circumvent the real issue at hand. Would the counterfactual argument hold any weight? As in, Canada should not address issues of international development because there are existing barriers to accessing affordable medicines? I think not.

Senators raised these arguments regarding economic development in the debates even though Canada has not honoured its goal of allocating 0.7% of GDP to international development. Indeed, Canada falls considerably short of that goal, with only 0.34% of Canada’s GDP going toward bilateral aid (UN, 2007). The nation has also reneged on its commitment to many countries in
Africa. According to the Stephen Lewis Foundation, as of 2009, “80% of Canada's $1.5-billion in annual bilateral aid will go to Caribbean and Latin American countries and others on the new priority list” (Stephen Lewis Foundation, 2010). Nine African countries were cut from the priority list, including Malawi, a region particularly hard hit by the HIV/AIDS pandemic.

The suggestion that access to medicine can be better addressed through international development and enhancing aid efficiency is therefore inconsistent with Canada’s actual practices in providing aid for economic development. That practice of aid contribution reflects the current Conservative government’s view of Canada’s geo-political and commercial interests. Instead of the Canadian International Development Agency (CIDA) prioritizing aid for countries that need it most, the priorities have shifted to regions where Canada has more significant trade interests (Stephen Lewis Foundation, 2010). The aid budget tells the story well. CIDA’s new “aid effectiveness” action plan (2009-2012) aims to make aid more “effective, focused and accountable…and in line with international agreements” (CIDA, 2010). The focus has shifted toward increasing food security, securing the futures of children and youth and stimulating economic growth (CIDA, 2010). Global pandemics fail to make the list.

While the listed goals are all laudable, a quick search of the action plan reveals that the words “health, HIV/AIDS, medicine and or “disease” are entirely absent (CIDA, 2009). Indeed, during the announcement of CIDA’s action plan, Bev Oda, the Minister of International Cooperation, was quoted as saying, “What I will talk about is not something that aims to please Irish rock stars” (Georgia
Straight, 2009), referring to Bono, one of the best-known philanthropic celebrities participating in the fight against HIV/AIDS. Unfortunately, Canada is not the only country making cutbacks. In 2009, donor nations gave $4-billion less than the previous year to The Global Fund to Fight AIDS, Tuberculosis and Malaria (Stephen Lewis Foundation, 2010). Even the budget for the Presidents Emergency Plan for Aid Relief (PEPFAR)—arguably George W. Bush’s most important legacy—will no longer increase aid to HIV/AIDS programs globally despite great need (Globe and Mail, 2010).

The arguments raised against CAMR reform appear disconnected from the people the decisions affect – the people living in regions with real health needs. The opposition to CAMR reform seems removed from the suffering and illness that millions of people experience daily. Patients need medicine today. For a sick person, the need for medicine is highly “tangible”, contrary to the suggestion of Amir Attaran, an outspoken advocate opposed to reform: “in other words, there is an opportunity cost. Each time CAMR comes up for debate in the House or Senate it drives from discussion those more tangible things we could do” (issue 14, p. 22).

Arguments around international development serve to distract from the issue at hand and that strategy appears to be working. Turning the debate into a polarized, either/or proposition that pits international development against legislative solutions gives one the false impression that there need be only one solution to the multi-faceted and complex challenge of securing access to medicines. CAMR is only one policy tool among many, all of which must operate
in harmony if global medicine shortages are to be addressed in an expeditious manner. Canada is in a position to assume a more effective role globally by establishing a workable international precedent for other countries wishing to implement the August 30th Decision. Reforming CAMR is an appropriate step toward assuming that role and the Conservative government and key Senators should pass the Bill without any further delay.

**8.4 Theme 4: Policy Chill**

The fourth and final theme that emerged from the debate comprises issues that chill or prevent the potential for policy reform. Policy chill generally came in three forms: the threat of WTO litigation over non-compliance, the influence of lobby groups accessing government of Canada parliamentarians, and bilateral pressure from trading partners.

Central to the debate over CAMR reform is the question of WTO compliance. Some civil society groups, most notably the Canadian HIV/AIDS Legal Network, argue that Bill S-232 is compliant with TRIPS, the Doha Declaration and the August 30th Decision. During the Senate debates, Richard Elliott, the Executive Director of the Legal Network, took the Senators step-by-step through an explanation of the Bill’s compliance with international obligations. The Legal Network also submitted a formal legal opinion to the Senate that provides a technical analysis of each reform proposal and how it abides by WTO rules.
By contrast, Foreign Affairs and International Trade (DFAIT) Canada argued that the Bill is not compliant with international rules, yet it failed to present any detailed explanation of that position. When asked by Senators to submit a formal opinion, Edith St-Hilaire, a DFAIT representative replied: “we consulted our legal bureau, our trade law bureau. We do not have a formal legal opinion.” (issue 10, p. 30) Despite evidence that supports the Bills compliance, some Senators appeared to remain sceptical. Suggestions of WTO non-compliance were raised repeatedly, even though there was direct and detailed support of the contrary conclusion. According to Richard Elliott, “no one, other than Government of Canada representatives, took issue with the WTO compliance of the proposed reforms, including the other international trade and intellectual property lawyers who were in the room.” (issue 11, p. 34) Even the most outspoken advocate against CAMR reform, Professor Amir Attaran, suggests that a WTO challenge is highly unlikely:

Therefore, WTO compliant or not, I think it is fanciful to imagine another country bringing a WTO complaint against Canada for the law. It simply will not happen. The outcry against it would be so tremendous that no country would dare to take that step (issue 14, p. 32).

So why is so much of the debate centred on this question? And what impact does the threat of WTO litigation have on the potential for reform? Part of the answer may lie in the lobbying behaviour of various special interests groups. A search of the Office of the Commissioner of Lobbying of Canada—the office dedicated to registering individuals who are paid to carry out lobbying activities—reveals that, of the total 202 registered lobbyists on CAMR, approximately 118
are consultants paid to perform lobbying activities (many of which represent large pharmaceutical firms), 51 are registered employees of a corporation and only 22 represented NGOs (Office of the Commissioner of Lobbying Canada, 2011).

During the debates, Liberal Senator Yoine Goldstein noted the lobbying activity this way:

> I was lobbied by the pharmaceutical companies, as I think most of us were. I do not say that negatively, because lobbying is a fundamental aspect of legislation. We get to know our legislation better because of the explanations we get from lobbyists (issue 10, p. 16).

One can only make assumptions about what is said, or not said, in these meetings, since communication reports are unavailable. If lobbying is to provide an educational function, however, the results above indicate that the education Parliamentarians are receiving likely weighs far more heavily on the side of the pharmaceutical industry than it does in respect of civil society perspectives.

Much of the opposition to the reform Bill is articulated by the pharmaceutical industry, including the lobby group Rx&D—representing Canada's Research-based Pharmaceutical Companies—and big pharmaceutical corporations such as Bristol Myers Squibb, Merck and Pfizer. According to the Canadian HIV/AIDS Legal Network, many Parliamentarians have heard from the pharmaceutical industry inaccurate claims that the reforms are not in compliance with Canada's obligations as a WTO Member (HIV/AIDS Legal Network, 2009). In a letter written to the 2007 CAMR review committee (including Industry Canada and Health Canada), the Pfizer Director of Federal Relations & Policy - Jennifer Buttars, said this:
Since undermining IP rights creates a powerful disincentive to future innovation, the CAMR review must carefully consider whether any additional measures aimed at enhancing access to medicines at the expense of IP rights will have serious unintended consequences for essential research and development activities in Canada and other nations. (J. Buttars, January 24, 2007)

And it appears these claims were carefully considered in the Senate debates.

Liberal Senator Pierrette Ringuette expressed her concern over WTO compliance this way:

> At our previous meeting, we received a presentation from Industry Canada about the legislation. It says how this bill collapses Schedule 2 and 4. It significantly broadens the scope of eligible products for export. It significantly reduces information in the generic manufacturer’s application to the commissioner. It eliminates special marking, colouring, shaping et cetera. They mentioned that they have received legal opinion that this bill does not comply with the WTO. (issue 11, p. 32)

Although there are many stated claims that suggest the reform proposals in CAMR are not compliance with WTO rules there is plenty of evidence to suggest the contrary. In fact, one of the key international law experts, Professor Frederick Abbott J.D., LL.M., shared this testimony in the debate:

> Bill S-232’s core proposal of a straightforward mechanism for issuing a single license to supply eligible importing countries with needed pharmaceutical products is consistent with Canada’s obligations under the TRIPS Agreement and the August 30th, 2003 waiver decision. (issue 14, p. 55)

Furthermore, In February 2010, experts on international law and access to medicines met in New York at the United Nations Development Programme
UNDP headquarters to discuss Bill C-393’s compliance with WTO law. The following provisions were discussed:

- The TRIPS Agreement
- The Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”); and
- The WTO General Council Decision of 30 August 2003

The expert working group concluded that Bill C-393, including the proposed “one license” solution” is indeed compliant with Canada’s international obligations. This conclusion has been repeatedly confirmed by international law and access to medicines experts, yet some Canadian parliamentarians remain unmoved by the existing evidence (UNDP and The HIV AIDS Legal Network, 2010).

The final example of policy chill focuses on the bilateral pressure faced by developing countries when attempting to utilize legal flexibilities in the TRIPS Agreement. According to Rachel Kiddell-Monroe, an MSF representative:

In practice, countries were reluctant to do that because of the real possibility of repercussions from rich nations and the pharmaceutical industry itself. This is no empty fear. We only have to look at the case of Thailand, where we have seen how the US, the European Union and Abbott Laboratories retaliated against Thailand for using legitimate compulsory licensing to meet the health needs of its own people (issue 11, p. 17).

Rachel Kiddell-Monroe is referring to an example from 2007, when Thailand issued compulsory licenses for three overpriced drugs and experienced severe retaliation by the US and the pharmaceutical industry in return. The pharmaceutical industry increased its lobbying efforts in the US, and the US placed Thailand on the USTR 301 Special watch list (mentioned earlier) for not
having high enough intellectual property protections. According to James Love, the Director of Knowledge Ecology International, Thailand's decision to issue the license was endorsed by MSF, Oxfam, the Clinton Foundation, Health Gap, Essential Action, Knowledge Ecology International, Third World Network, and hundreds of other groups and experts (Love, 2007). When Thailand issued the license, Abbott was charging close to $4000 per year for an HIV/AIDS treatment. This price later dropped to $1000 after Thailand's action (Love, 2007).

This is not the first time the pharmaceutical industry has used political pressure to protect its interests. According to Ellen 't Hoen (2009), trade disputes over patent relaxation have been occurring for decades. One of the most significant examples occurred in the lead up to the Doha WTO Ministerial Conference, where 39 pharmaceutical companies legally challenged a South African medicines legislation. This legal challenge was later backed by the threat of US trade sanctions. At the time, the South African government was attempting to pass an Act that would increase affordable access to medicines that allegedly violated the TRIPS Agreement. The legal challenge and trade sanction threat resulted in an international public outcry and the companies' legal challenge was withdrawn in April 2001 ('t Hoen, 2009).

Another illustration of the contentious nature of compulsory licensing use for public health purposes is the case of the US dispute against Brazil in 2001. The US challenged an article contained within Brazil's intellectual property law, which allowed local manufactures to produce on-patent drugs in the absence of production by the patent-holder. The US claimed the law discriminated against
US owners of Brazilian patents, while Brazil insisted the law was within the boundaries of TRIPS requirements. The challenge was brought to the WTO Dispute Settlement Body but later withdrawn following international outcry ('t Hoen, 2009).

These examples highlight the real threats faced by countries when attempting to make practical use of compulsory licensing. The threat of US-based sanctions or WTO litigation can dissuade countries from utilizing legal flexibilities—and interpreting these flexibilities with practical considerations in mind—that are intended to offset the consequences of patents on the price of medicine. Governments have an important role to play in mitigating these threats and upholding the principles expressed in the Doha Declaration and the August 30th Decision. Doing so will provide more political leadership and commitment to public health than Canada has demonstrated so far.
9: LIMITATIONS

This research was limited by many factors. The biggest challenge in conducting the research stemmed from a limited understanding of Canadian Parliamentary procedure, as well as limited knowledge of intellectual property law and international trade law. Given the complexity of the topics, it was very challenging to develop a working understanding of these matters. The debates were also being analyzed while debate over Bill C-393 (the private members bill that survived prorogation) was still in progress. The Bill chosen as the basis of this analysis—Bill S-232—unfortunately did not survive. The Bill is identical to C-393, however, so it should not affect the value of the analysis of the various perspectives advanced regarding CAMR reform in general.

This research was further constrained by a limited experience with content analysis. This was the first time the author used this kind of methodological approach and had to learn the methodology throughout the research process. This paper has approached neo-liberalism primarily as governmentality – which is a challenging phenomenon to identify and analyze. The contextual and complex layers of this phenomenon could take a lifetime to understand, which is very far beyond the scope of this paper.

Finally, it should be noted that the author has an affiliation with Universities Allied for Access to Medicine, an organization that aims to enhance
the impact of university-based research on global public health and adapt the way university license technologies to ensure they are more globally accessible. That affiliation could lend some bias to the author’s perspective.
10: IMPLICATIONS FOR GLOBAL PUBLIC HEALTH AND RECOMMENDATIONS

The extent to which the August 30th Decision is used may depend on the success of CAMR in Canada. According to Antony Taubman, the Director of Intellectual Property Division at the WTO, “people learn from experience in the implementation of such mechanisms generally in intellectual property.” (issue 14, p. 48) Canada’s reluctance to make the law truly workable will not only have global public health implications, but may also influence the perceived legitimacy of compulsory licensing in the future.

The House of Commons has taken an important first step by passing Bill C-393. But while the Commons’ action is truly commendable, the Bill’s fate lies with the Conservative-controlled Senate. Although the Senate is not an elected body, it appears that it is willing on occasion to block private members Bills passed by the elected House of Commons: it did so late last year in respect of an NDP climate change Bill that had been approved by a majority in the House (Galloway, 2010). Moreover, despite having considered the near-identical Bill S-232 at length in the debates analysed in this research, the Senate appears to be stalling the progress of Bill C-393 (Taylor, 2011). That stalling poses a grave risk to Bill C-393, given the very high probability (at the time of writing) of a Federal election: if the Senate does not pass Bill C-393 prior to Parliament being dissolved, then it will die on the order paper.
If the Senate approves Bill C-393, and does so in time, not only will Canada keep its promise to developing countries but it will also show a deeper commitment to finding workable solutions to a larger systemic problem associated with patents and the global pharmaceutical industry. Fixing CAMR will not remove all the barriers that limit access to low-cost medicine, but a reformed CAMR has the potential to make a significant contribution. And while that contribution is not guaranteed, the only way to determine whether a reformed CAMR will work is by actually putting the reforms in place.

This research has examined four themes in the debate over the reform of CAMR that have so far dissuaded the Senate from implementing the reforms. These themes are grounded in a neo-liberal perspective that privileges the market over human health. The thesis of this research is that the neo-liberal discourse around these four themes has significantly exaggerated the barriers to implementing an effective CAMR and improving access to medicines for developing nations. Certainly there are challenges to improving access to medicines, but Canada can make an important contribution globally by committing to the spirit of the August 30th Decision and providing an example to other nations. Achieving real and substantial access to medicines will require a number of solutions. It is all too apparent that market-based solutions will not always address the gaping inequities in access to drugs globally. A more structural solution must aim at relaxing patent laws—through increased global support of the compulsory licensing mechanism—in order to dampen the effects of patents on price for those with an urgent need for drugs, and an inability to
pay. Effective, practical compulsory licensing is an important first step in this regard.

Putting a reformed CAMR in place cannot be the last step, however. This research has demonstrated the existence of a strong, persistent opposition to CAMR and the use of compulsory licensing more broadly, even in the face of the obvious global need for greater access to essential medicines. Even if Bill C-393 is passed by the Senate and enacted into law, advocacy efforts must continue to urge the use of CAMR so that essential medicines are available to all patients who require them, and not only to those who can afford them.

Based on the research set out above, the following steps and observations are suggested to Canadian Senators:

• Every day is critical. Canadian Senators must pass Bill C-393 quickly in order to ensure it does not die with the dissolution of Parliament if an election is called. If the Bill does indeed die, Parliamentarians are urged to introduce a new Bill upon commencement of Parliament.

• Interpret CAMR in the spirit of the Doha Declaration and the August 30th Decision. Frame CAMR in light of the objectives the Declaration and the Decision seek to achieve, instead of simply meeting the obligations which they impose.

• Increasing global access to affordable medicines will require multiple solutions. The fact that there are other existing barriers to accessing drugs does not justify inaction on CAMR reform. Access to affordable medicine is a fundamental and complementary component of all health care systems.

• Make a stronger effort to hear from underrepresented voices in the debate. Pharmaceutical companies and associated interests are able to out shout other perspectives through the use of lobbyists. Reach out to NGOs and civil society groups to ensure their arguments are fairly represented and understood.

• Provide leadership in the access to medicines crisis by providing strategic advice and technical assistance to developing countries.
seeking to utilize compulsory licensing. The historical use of compulsory licensing in Canada resulted in lowering the costs of drugs significantly and can serve as a model for routine use of compulsory licensing globally.

• Interpret CAMR with an emphasis on the lives of millions of people in need of drugs globally. Public health is an area where significant market failures do occur and where governments must be prepared to intervene.

• Reach out to developing countries in order to promote continued use of CAMR. Canada needs to inform developing countries on what CAMR offers and how to apply for a license. A first step would be to update the government of Canada website on CAMR, which has not been modified since 2007 (see CAMR Government of Canada website, 2007).
APPENDIX: PULLED QUOTES FOR ANALYSIS

THEME 1: Canada’s conservative interpretation and implementation of the August 30th Decision

a) WTO Compliance

As it stands, Canada's legislation fails already to take advantage of the flexibility that is explicitly set out in WTO law. At the very least, in those circumstances, there should be no question that if Canada gets rid of the requirement to negotiate, we are entirely in compliance with our WTO obligations. We have, so far, failed to take advantage of the flexibility available to us (issue 11, p. 13).

No one, other than Government of Canada representatives, took issue with the WTO compliance of the proposed reforms, including the other international trade and intellectual property lawyers who were in the room (issue 11, p. 34).

However, it is also my belief, based on reading Bill S232, that the bill does not, in its current form, violate the August 30 mechanism. For me, and again this might come from being the first country to pass legislation to operationalize the August 30 mechanism, CAMR was a noble attempt but a conservative interpretation of the August 30 mechanism. Bill S232 is a more liberal interpretation, but within the confines of the mechanism (issue 14, p. 32)

b) WTO Non-Compliance

*The Chair, The Honourable Michael A. Meighen, requested a formal legal opinion regarding statements by Industry Canada and Foreign Affairs and International Trade Canada suggesting Bill S-232 is not compliance with WTO obligations. To date, it has not been submitted.

We consulted our legal bureau, our trade law bureau. We do not have a formal legal opinion (issue 10, p. 30)

At our previous meeting, we received a presentation from Industry Canada about the legislation. It says how this bill collapses Schedule 2 and 4. It significantly broadens the scope of eligible products for export. It significantly reduces
information in the generic manufacturer's application to the commissioner. It eliminates special marking, colouring, shaping et cetera. They mentioned that they have received legal opinion that this bill does not comply with the WTO (issue 11, p. 32).

c) WTO obligations

Our view is that the central problem with CAMR is that many aspects relating to intellectual property go beyond what is needed for our country's compliance with the WTO and the TRIPs Agreement (issue 11, p. 60)

d) Bill Technicalities

We still think the August 30th decision is problematic, but let us at least take as much advantage of the flexibility it offers us to get the regime as good as we can get it (issue 11, p. 29).

e) Developed Country Barriers

The supplier, Apotex, who I understand will be a witness two weeks hence, has indicated that it will never do it again under the current regime because of the obstacles, the delays and the bureaucracy that accompanied the manufacture and shipment (issue 10, p. 7)

In fact, the August 30, 2003 agreement from the WTO is much broader than what the Canadian legislation covers (issue 11, p. 34)

f) Humanitarian Objectives of the Bill

No one here disagrees with the objective of the original bill. We all agree with the moral implications and the need to share resources with the world, especially the poor. That is not an issue for any of us (issue 11, p. 23).

Originally, this legislation went through both houses with unanimous support, on the humanitarian premise that there were lives being lost in our world due to a want of proper treatment medicines. We have the capacity to produce the drugs through brand names; through generics. Let us do it. It is the right thing to do. We can do it (issue 13, p. 15)
g) Canada’s Role in the Access to Medicines Debate

It is a policy tool Canada should use to get affordable medicines to developing countries. This is something to which clearly WTO members have already agreed. Canada should, as a matter of ethics, and can, as a matter of law, take advantage of this flexibility in the TRIPS Agreement of the WTO (issue 11, p. 14).

In doing so, Canada was to provide leadership and an example to the rest of the world (issue 11, p. 16)

THEME 2: Existing contradictions in the debate

a) August 30th Legislation in other Countries

I also understand that other countries, a number of other countries, including Belgium, France and others, are watching to see how successful we will be in amending it so that they can join us in this effort to save lives (issue 10, p. 12)

Canada has already taken an important step as a pioneer in breaking the drought, if I might say, and putting the system into operation. We found that people learn from experience in the implementation of such mechanisms generally in intellectual property. It is important in this particular area. I would not underestimate the importance of what Canada has done do far (issue 14, p. 48).

b) Generic Competition

It is strange to me to hear as an argument for not providing an opportunity under Canadian legislation that Canadian producers are inefficient or not competent to compete on the international market. If that was the situation, we might as well suggest that the Canadian generic producers shut up shop now, because they will not be able to compete on the international market. There is no good answer to that, other than to making your generic producers more competitive (issue 14, p. 57).

Traditionally, one of the key drivers for price reduction of ARVs has been generic competition (issue 11, p. 45).

The answer is that this will allow us to compete from Canada. We still have to compete on a worldwide basis. If, at the end of the day, they can buy these products from India, for example, for less than from a Canadian company, so be it. Without the amendments, you will not get a Canadian company to step up and take advantage of manufacturing the products in Canada (issue 11, p. 71).
The trouble is that through no fault of CAMR or those who worked for it, Canadian generics are possibly the most expensive generics in the world. Therefore, no poor country is eager to buy them (issue 14, p. 20).

c) Cost of Drugs/Affordability

I have learned that drugs are more expensive and that the generics in Canada are less expensive, but there are generics from other countries that are less expensive still. How can we use the dollars we want to spend? As a country, should we create jobs or save people’s lives? (issue 13, p. 14)

d) Economies of Scale

In fact, the WTO members, when they agreed on this August 30, 2003 decision, made explicit reference in that decision to the need to harness economies of scale (issue 11, p. 25).

The ability that this bill would give to develop regional provisions for structuring the patent terms and compulsory licenses for a region would allow us, just on the basis of economies of scale, to drive the prices down. That is one of the most important impacts when it comes to price (issue 11, p. 64).

Therefore, we have seen the potential to compete. The potential to offer even more competitive prices would be even greater if the process of getting to the point of having a license to supply multiple developing countries could be put in place. You would achieve economies of scale (issue 11, p. 25).

e) CAMR Success

Contrary to what you are saying, it seems to me that the program is not a failure. We have had a delivery, and the cost per pill, as you indicated, was a reasonable one (issue 10, p. 13).

CAMR is only one piece of a larger puzzle. That piece has proven to work effectively and efficiently to achieve its objectives when put to the test (issue 13, p. 25).
f) CAMR Failure

In a correct diagnosis, CAMR has failed for economic reasons, not for legal reasons. Where the causes of CAMR's failures are deeply economic, it stands to reason that amending the housekeeping provisions of the law is not likely to help (issue 14, p. 19).

g) Support for CAMR Reform

On one hand, some colleagues seem to be arguing about the free market. It seems that if one wants to promote free markets, then we should remove complexities and rules.Basically, this is what Bill S232 is trying to achieve (issue 11, p. 73).

We are here to comment on this Bill S232 and what it does rather than to talk about the broad issue of access to medicines and other things going on in the developing world (issue 10, p. 30).

For the moment, many developing countries - as you have heard - are relying on generic drugs coming from India. Those tend to be the first-line AIDS treatments. That window is closing. As new treatments come along, it will not be easy to get generic versions of those from India. That is all the more reason why the Canadian legislation should be made to work (issue 11, p. 28).

I think that the legislation creates serious impediments to its effective use, and with the types of modifications proposed in Bill S232, Canada really can step forward as a leading supplier to the developing world of medicines needed to address public health needs (issue 14, p. 60).

h) Not Supportive of CAMR Reform

I am not confident, as Senator Massicotte also said, that if we approve Bill S232 tomorrow, which I wanted to support, that it will change anything in the supply because of what you just told me and my colleagues about India and Brazil, who already have the capacity to produce that (issue 11, p. 53).

i) Anti-diversion Mechanisms

The same anti-diversion mechanisms that exist in the current legislation would continue to exist in exactly the same form in the proposed legislation. The
pharmaceutical companies and all members of the House of Commons were satisfied five years ago, with respect to anti-diversion mechanisms (issue 10, p. 15).

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CAMR includes a number of measures that prevent exported drugs from being diverted back to Canada, and other rich country markets, that unlike developing, or least-developed countries, do not need facilitated access to cheaper medicines. The private member's bill, Bill S232, proposes to remove a number of these measures (issue 10, p. 26).

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Brand name pharmaceutical companies already distribute their regular products into these regions. If they are not concerned about diversion of their own products in these regions, then I do not know why, under this legislation, we would be any more concerned about diversion of these products (issue 11, p. 75).

j) Black Market

It is clear more and more that major NGOs - Medecins sans frontières, UNICEF and so on - are the driving forces for purchase of drugs in developing countries. They work with the government of those countries. Their checks and balances are quite stringent (issue 13, p. 16).

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I can give you one concrete example. My colleague in Africa has stood on a runway and seen an airplane land. An envelope changes hands and the plane takes off and goes back to Europe. We have had to take extraordinary measures to ensure that this does not happen. We will continue to be concerned as we see these things happen (issue 13, p. 30).

k) People’s Health Needs Considered First

This bill is about people - people living primarily in sub Saharan Africa, people who live in adjunct poverty, people whose opportunities to get treatment from malaria, tuberculosis and HIV/AIDS is virtually impossible. It is about giving the chance of life to children, their moms and dads and their grandparents. It is about ensuring that a child receives treatment as soon as diagnosed, at a cost that is affordable (issue 10, p. 10).

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Consider Carol who lives in Meru, Kenya. She is a bright, grade 9 high school student who dreams of becoming a doctor. This dream is based on her childhood experiences. When she was seven years old, she tended to her mother as she
died of AIDS. Then Carol went to live with her grandmother. Carol was HIV positive and already experiencing painful sores and persistent infections (issue 13, p. 9).

I) Market Norms Considered First

I have learned that drugs are more expensive and that the generics in Canada are less expensive, but there are generics from other countries that are less expensive still. How can we use the dollars we want to spend? As a country, should we create jobs or save people's lives? (issue 13, p.14)

We must not lose sight of the needs of patients in the developing world. We must refrain from using CAMR as a means to reopen the intellectual property debate in Canada. This would create further instability and drive away crucial investment our country needs (issue 13, p. 25).

This legislation will have no effect, none at all, on high-profit markets (issue 10, p. 9).

m) Patents

One of the things we often hear coming from Canada's Research-Based Pharmaceutical Companies, Rx&D, is that the real issue here is infrastructure and resources, not patents (issue 11, p. 19).

Yes, changes should be made at the WTO level. That is clear. Do you know what it takes to get something negotiated between 150-plus members of the WTO on something as contentious as patent issues? If we are to wait for years for that to happen, millions of people will die. We could help prevent the deaths if we use the flexibility available to us already under WTO rules to get the Canadian legislation right (issue 11, p. 31).

n) Innovation

Obviously, we want to encourage innovation and protect and reward those who cause innovation. It is fundamental to the world because that is how we progress as a nation, through productivity improvements and innovation. Therefore, there is a real argument by the pharmaceutical companies, as with other inventors, to say, "Please protect our rights because that is our rewards system." what does this mean for other kinds of reward systems? Is this really the only way we can drive "innovation"? (issue 11, p. 50)
o) Middle Income Country Concerns

You specifically mentioned the question of whether Canadian generic suppliers will compete with generic suppliers in other countries, such as India. That issue has been raised repeatedly. It is important to note that the one piece of evidence we have is that when CAMR was, after four-plus years, successfully used, it was a Canadian generic company who successfully competed against a number of Indian generic manufacturers in submitting a bid to the Rwandan government (issue 11, p. 24).

Despite the fact that Apotex is said to be offering its products at cost, five major Indian generic pharmaceutical companies are listed in the Clinton Foundation Website as having lower-priced versions of the same product available for sale to African countries, the lowest of which is roughly half the price specified by Apotex in its application to the Commissioner (issue 11, p. 56).

The implementation or use of this mechanism is likely to take place over time as the situation in the international pharmaceutical market changes. India now grants pharmaceutical patents and product patent protection. For example, as second-generation antiretrovirals come under patent protection in India, it will become necessary for countries to take advantage of this mechanism (issue 14, p. 56).

THEME 3: Circumventing the issue

a) Developing Country Barriers

Most developing countries do not have the means or the luxury of time to navigate such a convoluted system (issue 11, p. 17)

b) CAMR not the Problem

Perhaps it is not the fault of the legislation. Why would Rwanda buy from Apotex if they can buy it at one-half of the price from an Indian supplier? (issue 10, p. 19)

We also know that we have to address a whole series of other problems that go to the actual problems of the spread of the types of diseases that drugs are treating (issue 10, p. 27).
There are other mechanisms that are available to developing countries to deal with the problems of these diseases (issue 10, p. 28).

My concern is whether we are repairing the right problem. We can talk about our legislation, but I find it odd that the world has not responded (issue 11, p. 25).

If there are 50 countries that make generics, I suppose nearly 50 are sympathetic to the problem. Why is it that the other 49 countries did not get there? It cannot all be due to legislative hurdles. There must be something more fundamental on the demand side; maybe it is the country side. I am trying to grapple with the issue (issue 13, p. 14).

Simply delivering medicines, whether brand name or generic, does not address the challenges developing countries face, such as poor sanitation and education, insufficient infrastructure and diversion of medicines from the intended patients (issue 13, p. 25).

My immediate reaction is that if this is a world problem, why is it just a Canadian legislation problem? Maybe we are not addressing the right problem? How do we find solution, and why has this problem not been satisfied by other countries (issue 11, p. 23).

In other words, there is an opportunity cost. Each time CAMR comes up for debate in the House or Senate it drives from discussion those more tangible things we could do....to put time toward CAMR when there is ample demonstration in other countries that it is an utterly futile exercise in terms of results detracts from discussing problems for which you may have ready solutions (issue 14, p. 22).

c) Donation

To the credit of Canadian pharmaceutical companies, of which there are about 50, over the years they have shipped millions of dollars worth of drugs without being paid for them, and that is perfectly noble (issue, 10, p. 16).

Clearly, current treatment efforts will not be sustained through donation programs alone. For a sustainable response, market mechanisms will need to be applied as well (issue 11, p. 43).
THEME 4: Policy chill

a) Litigation

*If Parliament passed the bill we would be exposed almost certainly to a challenge from one of our WTO partners. Is that your concern?* (issue 10, p. 30)

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*Should it be found that there is non-compliance in the bill in terms of the WTO, they have the right to sue the government under international law, which will delay further the transfer of drugs to those who need it* (issue 13, p. 19).

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*Therefore, WTO compliant or not, I think it is fanciful to imagine another country bringing a WTO complaint against Canada for the law. It simply will not happen. The outcry against it would be so tremendous that no country would dare to take that step* (issue 14, p. 32).

b) Bilateral and Multilateral Pressure: the politics of medicine

*In practice, countries were reluctant to do that because of the real possibility of repercussions from rich nations and the pharmaceutical industry itself. This is no empty fear. We only have to look at the case of Thailand, where we have seen how the US, the European Union and Abbott Laboratories retaliated against Thailand for using legitimate compulsory licensing to meet the health needs of its own people* (issue 11, p. 17).

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*I believe that countries, especially on an individual basis, are subjected to bilateral pressures by certain developed countries when they try to utilize flexibilities for public health purposes* (issue 11, p. 17).

c) Big Pharm Concerns

*I was lobbied by the pharmaceutical companies, as I think most of us were. I do not say that negatively, because lobbying is a fundamental aspect of legislation. We get to know our legislation better because of the explanations we get from lobbyists* (issue 10, p. 16).

d) Public Health Needs

*In reality, far more people in sub-Saharan Africa die of tuberculosis and malaria than they do of HIV/AIDS* (issue 10, p. 19)
e) Intellectual Property

We must refrain from using CAMR as a means to reopen the intellectual property debate in Canada. This would create further instability and drive away crucial investment our country needs (issue 13, p. 25).
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