

Implementing New Patient Safety Legislation through Bill C-17

Serena Small,
MA Candidate, Simon Fraser University

I) Background

New legislation designed to modernize the *Food and Drugs Act* in Canada (titled *An Act to Amend the Food and Drugs Act*, also known as *Vanessa's Law*) has established a series of important amendments that will impact health care delivery and the pharmaceutical industry. It is named after Vanessa Young, daughter of Terence Young, who passed away on March 19, 2000 at 17 years of age, following complications that arose in an interaction between a prescription drug that she was taking and an underlying disease state.

The Act applies to over-the-counter and prescription drugs, vaccines, gene therapies, cells, tissues and organs, and medical devices. It will not apply to natural health products (which are defined in the *Natural Health Products Regulations*). The amendments are intended to facilitate post-market research as well as regulatory changes, in the event that a risk to health as a result of a drug is suspected, therefore increasing patient safety.

The following is a review of the legislation and the path to its development using evidence from Hansard records of Government debates and committee meetings, relevant publications from Government and from other organizations, and media sources.

II) Mandating Adverse Reaction Reporting and Attempts to Modernize Legislation Since 2000

Post-market surveillance of pharmaceuticals became a prominent topic following Vanessa Young's passing, as the prescription drug she had been taking had been deemed unsafe by the regulator prior to the events leading to her death. Much of the media attention surrounding her case arose as a result of

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

the inquest into her death, in which a coroner's jury heard witnesses over the course of 16 days in April, 2001. The coroner's jury was not tasked with placing blame; rather, it focused on understanding the circumstances surrounding Vanessa's death and making recommendations to ensure that this would not recur in the future. Even before the inquest had begun, however, evidence was revealed that showed that Health Canada had been concerned with the side effects of cisapride as early as 1998, shedding light upon the inadequacies of Canada's post-market surveillance of pharmaceuticals (Foss, 2000). During the inquest, the jury heard from Dr. Brian Gillespie, Health Canada's senior medical advisor on pharmaceutical assessment, that Health Canada had received information that cisapride caused cardiac abnormalities and had initiated a review of the drug. Dr. Gillespie said that this review, which concluded in February 2000, found evidence that cisapride could cause serious harm, yet its sale continued until May, 2000 (Owens, 2001, Mar. 27). In fact, the United States Federal Drug Administration (FDA) had already issued a warning for the drug cisapride on January 24, 2000 (Canadian Medical Association Journal [CMAJ], 2001). It was recalled in the United States by July 14, 2000. In Canada, on the other hand, health care providers only received a Dear Health Care Professional letter from Health Canada on May 30, 2000, two months after Vanessa's death. The drug was recalled August 7, 2000 (ibid.). Indeed, the stark contrast between Health Canada's response to the drug and the FDA's was not ignored. As stated in an article published by the National Post:

While the Americans placed warning labels on the drug packaging and ordered the drug withdrawn by January, 2000, Canadian authorities allowed the drug company to issue its own letters to physicians (which many apparently did not receive), draft its own media advisory (which downplayed the caution so much that no media outlet picked it up), and allowed seven months to elapse between the time Health Canada was convinced of the drug's dangers until when it was finally pulled from the shelves. (Owens, 2001, Apr. 16)

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

The 16-day hearing concluded on April 24, 2001, and resulted in 59 recommendations, 14 of which were directly addressed to Health Canada, including the mandatory reporting of adverse drug reactions by health care professionals (Health Canada, 2002). Health Canada issued a response to the recommendations over a year later, on August 22, 2002. In reference to the recommended mandatory reporting of adverse drug reactions by health care professionals, Health Canada stated:

Based on a review of this issue, Health Canada does not yet have clear evidence that a mandatory reporting system would increase the number of adverse reaction reports or the quality of the information submitted. In fact, the results of a questionnaire sent to contacts in foreign jurisdictions showed no significant increase in quantity or quality of adverse reaction reporting under a scheme of mandatory reporting. (Health Canada, 2002)

They did, however, commit to bringing a stronger focus on post-market surveillance through the establishment of the Marketed Health Products Directorate (MHPD) within the Health Products and Food Branch of Health Canada to promote voluntary adverse reaction and medication incident reporting in partnership with other stakeholders. The recommendations also prompted Health Canada to negotiate with the US FDA to discuss the potential creation a combined US-Canada adverse event reporting system. This did not come to fruition.

Back in 2001, however, before Health Canada had responded to the coroner's jury recommendations, New Democratic Party (NDP) Member of Parliament (MP) and health critic Judy Wasylycia-Leis introduced a motion to the House of Commons to establish a mandatory adverse drug reaction reporting system. As debate ensued on September 18, 2001, opposing parties expressed support but requested a greater amount of detail. Although the time allocated for discussion expired and thus the motion was not designated as votable, an initial comment on implementation was produced by

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

Canadian Alliance (CA) MP Keith Martin, who spoke of the need to engage the provincial and territorial governments to successfully establish this system. This would be one of a number of ongoing themes in future deliberations and debates on the introduction of a mandatory adverse drug reaction reporting system.

On February 20, 2004, the establishment of a mandatory adverse drug reaction reporting system was reintroduced to the House of Commons by Conservative MP Rob Merrifield. Unlike Ms. Wasylycia-Leis' motion from three years prior, Mr. Merrifield provided some indication of how this would be undertaken:

We have to give [practitioners] some of the tools. Maybe we do not have to use a long form. Perhaps we could use Blackberry technology or another reporting system that could give them the ability to report in a way that is not cumbersome, that is streamlined so they can do it. We have to engage them in that process. We have to ask them how they would like to be able to come forward with mandatory reporting and how we can work collaboratively with them. (Merrifield, 2004, Feb. 20)

Mr. Merrifield also notes that lessons could be taken from other countries who had already implemented mandatory reporting, such as France, in addition to noting the importance of collaborating with provinces and territories. All parties expressed support for the motion during the debate, aside from the Bloc Quebecois (BQ). BQ MP Paul Crête noted that the federal government has no business trying to control the practice of provincially regulated health care professionals. Despite the positive support from other parties and the approval of Mr. Merrifield's motion, no action was taken and he was left to ask his fellow MP's why the government had done nothing after a month (Merrifield, 2004, Mar. 25).

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

The same year, Mr. Merrifield served as the vice-chair of the House of Commons Standing Committee on Health. During this time, the committee presented a report to the House of Commons titled *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*, which was based on hearings held during the fall of 2003. The recommendations in the report focused on the areas of clinical trials, post-market surveillance, and direct-to-consumer advertising. On the topic of post-market surveillance, a series of recommendations were directed at Health Canada, including increasing Health Canada's resources to ensure that their infrastructure has the capacity to receive, analyze, respond to, and disclose adverse drug reaction reports. It also recommended that the Department facilitate reporting by health care professionals through the use of simple formats and integrated computer technologies that permitted online reporting, as well as working with the provinces and territories to effectively implement mandatory reporting by health care professionals. Although a response from the government was requested by Liberal MP Bonnie Brown upon presentation of the report to the House of Commons, none was issued.

A year later (2005), Health Canada issued a discussion paper titled *Designing a Mandatory System for Reporting Adverse Drug Reactions*, which was intended to promote a discussion among health professionals, provincial and territorial governments, and other stakeholders on the objectives, limitations, considerations, and design principles concerning the development of a mandatory reporting system. . In response, the Canadian Medical Association (CMA) published a short paper that argued that Health Canada should not mandate adverse event reporting and that they should, instead, focus on building a post-market surveillance system that encourages and facilitates voluntary reporting through an easy and efficient process (CMA, 2005). The CMA's position was echoed and confirmed eight years later in an interview with the Toronto Star, in which Dr. Anna Reid, President of the CMA, suggested that Health Canada focus first and foremost on refining the current system to make it more user-friendly and

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

responsive by allocating a sufficient amount of resources to address the current reporting schema (Smith, 2013).

Aside from the items noted above, the topic of reporting adverse drug reactions was sparsely addressed between 2004 and 2007. On December 11, 2007, it was agreed that the House of Commons Standing Committee on Health would undertake a study on post-market surveillance of pharmaceuticals beginning in the following year. The study began on January 31, 2008, and the witness testimony was completed on May 1, 2008. The committee report was submitted to the House of Commons on July 3, 2008. Many of the witnesses argued that mandating an adverse drug reaction reporting system was problematic for a number of reasons. Some of the reasons included: the precedent from other countries who have unsuccessfully mandated a similar system; the added burden on health care providers who are already in short supply; the problematic nature of enforcement due to insufficient resources and jurisdictional issues; the lack of training that health care professionals receive to recognize adverse reactions; and, the lack of time and familiarity with existing reporting processes. In the opinion of Conservative MP Patricia Davidson:

If you start making it a mandatory requirement for physicians and health care professionals to report everything, how are you going to balance the increased red tape and bureaucracy, and everything else that's required, with the fact that our physicians and health care professionals are overloaded today with that type of requirement from governments? (Canada. Parliament, 2008, Jan. 31)

Some health care professionals that served as witnesses for this study also argued that mandating reporting would produce a new level of administrative redundancy because many known and familiar adverse reactions would be reported, which would not produce any new knowledge or improve patient treatment. The study concluded by arguing that Health Canada should instead focus on optimizing the

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

current reporting system through a variety of measures, including the mobilization of teams of trained health care professionals who could identify, assess, report, and analyze adverse reactions in the health care setting; the provision of training on reporting processes; the provision of feedback on the reports that are submitted; the standardization of definitions, reporting criteria, reporting forms, and timeframes; the provision of ongoing technological support for electronic reporting; and, the enhancement of citizen engagement so that consumers will have an active interest in submitting their own reports. An important point addressed by David Skinner, the President of NDMAC, related to motivating health care professionals to engage in the reporting process:

As I mentioned, my good old uncle, B.F. Skinner, said that the behavior that gets rewarded gets done. And I think that's part of the problem. Is it a responsibility? Most certainly it is. Is it part of common everyday practice? No it's not. It becomes part of common everyday practice when there is mutual benefit to everybody participating in it. So I think a lot of the behavioural aspects of doing good reporting relate a lot to some of the rewards that are available. (Canada. Parliament, 2008, Feb. 5)

Another recommendation of note was that Health Canada begin by mandating reporting within Health Canada's First Nations on-reserve health centres and nursing stations, which would allow the Department to remain within its jurisdictional authority while experimenting with a new mandate among a smaller sample. The committee report requested an official government response, however none was given.

At the same time that the House of Commons Standing Committee on Health was undertaking their study on the post-market surveillance of pharmaceuticals, a new bill was introduced into the House of Commons in an attempt to update the *Food and Drugs Act*. Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, was introduced by the then-Minister of

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

Health, Tony Clement, on April 8, 2008. A number of the proposed amendments in Bill C-51 reflected those to come in Bill C-17: it aimed to strengthen the oversight of therapeutic products by taking a 'life-cycle' approach to monitoring; to increase penalties for non-compliance and strengthen enforcement abilities; and, to enhance openness and transparency in the regulatory system. Of note, the definition of a therapeutic product as outlined in Bill C-51 included natural health products, which was an area of contention for many. The Bill proceeded through the first and second readings in the House of Commons, but was not passed prior to the conclusion of the 2nd session of the 39th Parliament in September, 2008. Subsequent mentions of the Bill between September, 2008, and February, 2009, in House of Commons debate pertained to the submission of petitions by Canadians against the reintroduction of Bill C-51, generally on the grounds of its inclusion of natural health products.

During this time period, the implementation of Bill C-51 was addressed twice during House debate. On April 30, 2008, BQ MP Christine Gagnon asked the Minister of Health how he believed that Health Canada would meet the required demands of increased human resources and training to properly implement the Bill. Mr. Clement responded by emphasizing the importance of investing in these areas. This question was reiterated on May 1, 2008, yet little more insight was provided in response.

Between late 2010 and early 2011, Health Canada hosted three sessions (October 27-28, 2010; November 30-December 1, 2010; January 19-21, 2011) of technical discussions to advance and inform the modernization of the regulations in the *Food and Drugs Act*. The potential amendments that were discussed during these sessions were based, in part, on the former Bill C-51. While the sessions were held behind closed doors, Health Canada attempted to ensure that the participants in the sessions were representative of all the stakeholders involved (e.g.: regulators, industries, health professionals, patients, academia, international groups, etc.). In an opinion piece written for The Hill Times, Michael McBane, Executive Director of the Canadian Health Coalition, criticized Health Canada for working

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

behind the scenes in closed door meetings with members of the drug industry, leaving Canadians in the dark regarding the “profound implications” on health policy and drug approval processes that were at stake (McBane, 2011).

In late 2011, the Office of the Auditor General published the Fall Report, including a chapter titled “Regulating Pharmaceutical Drugs – Health Canada” that detailed the results of the audit conducted between January 1, 2009, and December 31, 2010. This section of the report examined Health Canada’s regulation of clinical trials, safety monitoring and communication, and enforcement of industry requirements. Many of the main findings were critical of Health Canada, including its lack of timely action in regulatory activities, the lack of disclosure of information related to rejected drug submissions or drugs approved with conditions, and the Department’s inactivity on its commitment to increase the disclosure of information related to authorized clinical trials. Health Canada agreed with the recommendations and provided detailed responses throughout the report (Canada. Parliament, 2011). In addition to the responses in the report, then-Minister of Health Leona Aglukkaq stated in the House of Commons on November 22, 2011, that the Department was in agreement with the report and that they had already begun to implement changes in response to the recommendations. Ms. Aglukkaq stated that they intended to implement new procedures to improve transparency and monitoring, leading the opposition to comment on the ambiguity of her statements.

More recommendations were directed toward Health Canada in March, 2013, as the Senate Standing Committee on Social Affairs, Science and Technology concluded the second phase of their four-phase study on pharmaceuticals. The second phase focused on Health Canada’s capacity for post-marketing surveillance in the pharmaceutical industry. Eight meetings were held between October 3 and November 21, 2012, which heard witness testimony from a variety of stakeholders in the health care industry. The report addressed a number of issues facing Health Canada, as well as the health care

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

industry more broadly, which had been widely discussed in the past. It also addressed newer issues that reflected the changing health care landscape. As in the past, Health Canada's general lack of resources was noted, specifically questioning whether its current resources were sufficient to ensure the long-term sustainability and efficiency in the post-approval stages of the pharmaceutical life cycle. Calls for the modernization of legislation and regulatory frameworks were echoed as well. The report also addressed the issue of electronic health records (EHRs) and electronic medical records (EMRs), and their potential role in the collection of adverse drug reaction (ADR) reports. As key points for the collection of important patient data, it was recommended that a representative from Health Canada attend all discussions on the topic of EHRs in order to promote the inclusion of an ADR reporting form. EHRs and EMRs were perceived to have the power to facilitate the reporting process, thereby increasing the quality and quantity of ADR reports being produced; however, it was acknowledged that implementation would be a challenge due to Health Canada's insufficient resources. While the importance of encouraging and facilitating ADR reporting was noted in the report, it explicitly argued against mandatory reporting. The committee found that mandatory reporting would present issues in terms of enforceability and likely would not increase the number of reports submitted. Other recommendations targeted increasing the effectiveness of the Drug Safety and Effectiveness Network, enhancing communications to the public, and implementing post-approval strategies for at-risk population sub-groups (Canada. Parliament, 2013).

In the first of a series of advancements in modernizing the *Food and Drugs Act*, the then-Minister of Health, Leona Aglukkaq, announced on June 14, 2013, with Terence Young by her side, the beginning of Health Canada's Plain Language Labelling Initiative. The Initiative was targeted at improving the comprehensiveness of drug labeling and safety information. The regulatory proposal was published in the Canada Gazette (Part I) on June 22, outlining the background and providing a description of the issue, objectives, and proposed regulatory options, as well as a cost-benefit analysis of each. This

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

publication launched a 75-day public consultation surrounding the Initiative, which closed on September 6, 2013. Almost a year later, on July 2, 2014, the *Regulations Amending the Food and Drugs Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)* in support of the Plain Language Labelling Initiative was finalized. Further modernization of the *Food and Drugs Act* was mentioned in the Speech from the Throne, delivered October 16, 2013, upon the reelection of Stephen Harper and the Conservative Government. The Speech made a number of promises that would come to fruition through the amendments to the *Food and Drugs Act* that would be implemented the following year under *Vanessa's Law*. This included mentions of a greater power to recall unsafe drugs and increasing the number of adverse drug reaction reports being submitted to Health Canada.

III) Terence Young's Battle for Prescription Drug Reform

Terence Young, father of Vanessa Young, is a former Ontario MPP, current federal MP, and has been a vocal advocate for reform in the pharmaceutical industry since he lost his daughter in 2000. He successfully pushed for an inquest (which has been detailed above) in addition to launching a \$100 million class-action law suit against Janssen-Ortho Inc. (the manufacturer of Prepulsid), Johnson & Johnson (Janssen-Ortho's parent company), and Health Canada ("Health Canada, drug firm", 2001). Mr. Young's claims against Health Canada focused on their failure to ensure the safety of cisapride, their failure to ensure physicians were prescribing it safely, and their failure to act upon the concern that was expressed by their own experts years earlier (Foss, 2001, Oct. 14). The lawsuits, however, were not commented on until 2007, when Superior Court Justice Ellen MacDonald certified the lawsuit against Johnson & Johnson Corporation and Janssen-Ortho Inc. In response, Mr. Young was quoted in the Edmonton Journal as saying he felt both joy and frustration:

Joy that the judge made the right decision, because this will be great for patients; and it will help protect patients because the pharmaceutical companies will have to face

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

victims working together. Frustration because it took six years and four months to get permission for the victims to even present their case (“Class action drug lawsuit”, 2007).

The proposed settlement of \$8.7 million for persons injured by the drug cisapride was approved on October 28, 2009. The eligibility of claimants was to be determined by a six member medical specialist panel. It is unclear whether Mr. Young received a portion of this settlement.

During this time period, Mr. Young was elected as Conservative MP for Oakville at the beginning of the 40th session of Parliament in 2008. He also founded the patient safety advocacy group Drug Safety Canada and published a book titled *Death by Prescription: A father takes on his daughter’s killer – the multi-billion dollar pharmaceutical companies* on April 14, 2009.

Two days after his book was published, Terence Young tabled a Private Member’s Motion calling for the creation of an independent drug monitoring agency in Canada, thus marking the beginning of his active involvement in enhancing patient safety in Canada as an MP. The Motion was placed on notice in June, 2011, and reinstated for the following session as of October, 2013. In addition to being an important advocate for drug safety outside of the government, he has made a number of impacts since joining the Conservative caucus, from his support in the development of the Plain Language Labelling Initiative to the introduction of Bill C-17 at the end of 2013.

IV) Bill C-17 (Vanessa’s Law)

Vanessa’s Law was introduced in the House of Commons on December 6, 2013, by Minister of Health Rona Ambrose and Conservative MP Terence Young. The legislation will require mandatory reporting of serious adverse drug reactions and medical device incidents directly to Health Canada. As stated in Section 21.8 of the amendment:

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with the prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product (“Bill C-17”, 2013).

It has not yet been specified what the prescribed scope of time, the manner, or the required information will be, nor does it indicate which health care institutions fall within this legislation. Additionally, this amendment does not define the terms ‘serious adverse drug reaction’ or ‘medical device incident.’ As stated in Section 30 (1.2), the specific regulations related to this amendment will be determined by the Governor in Council for the purposes of this Act. It is also stated, in Section 30 (1.3), that the Minister will not make recommendations to the Governor in Council concerning the above without first taking into account existing information management systems, in order to avoid unnecessary administrative burdens.

Beyond mandating the reporting of adverse drug reactions from health care institutions, the following amendments are also included in Bill C-17:

- i. *The power to require information, tests, or studies:* if the Minister of Health suspects that a therapeutic product presents a serious risk of injury to human health, then the Minister can order that the relevant information is provided to him/her to determine whether it is a serious risk. The Minister may also disclose confidential business information (as defined in the amended Section 2) about a product without the consent of or notification to the person to whom it belongs or business with which it relates. Confidential business information may also be released if it is related to the protection or promotion of human health or safety of the public, as long as it is disclosed to a government, a person from whom the Minister is seeking advice, or someone who

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

carries out functions that are related to the protection and promotion of human health or the safety of the public.

- ii. *The power to require a label change:* the Minister can order that the label or packaging of a therapeutic product be modified or replaced if it is believed that this adjustment is necessary to prevent injury.
- iii. *The power to recall unsafe therapeutic products:* if the Minister believes that a therapeutic product presents a serious or imminent risk of injury to health, it may be recalled or sent to a place specified in the order.
- iv. *Increased fines and penalties for non-compliance.*
- v. *The ability to incorporate by reference:* the Minister holds the authority to reference documents, such as lists and technical standards, in regulations without requiring a regulatory amendment each time a change to a document is made. This is expected to reduce red tape and allow science-based decisions to be made more quickly.

The second reading in the House began on March 28, 2014, and resumed on May 27. During the debate that ensued on May 27, various MPs questioned the amount of time it had taken to have this type of legislation introduced, noting that it should have been updated following the thalidomide incident of the 1960s. In a similar vein, the failure of Bill C-51 in 2008 and Health Canada's inactivity following the series of recommendations made by the Auditor General in 2011 were noted. Regardless, all parties acknowledged that this legislation was a positive step for enhancing patient safety. Both Liberal MP Hedy Fry and NDP MP Libby Davis questioned Health Canada's capacity to implement the Bill during its second reading, particularly in light of budget cuts. As stated by Ms. Davis:

We have seen cuts in Health Canada; however, we need the tools and resources to provide the transparency, improve the timeline of reporting on adverse reactions, and

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

acknowledge the concerns that the Auditor General made in 2011. Those all require human resources. I do not know how much we will get into that at committee, but it is certainly something we would like to raise to make sure that the bill, when it is finally approved and implemented, would actually work and that the resources would be there (Davis, 2014).

The cuts that Ms. Davis is referring to were the Conservative Government's planned reduction of Health Canada's budget by \$310 million per year by 2014-2015 in the 2012 Federal Budget ("Canada Budget 2012", 2012).

Later in the May 27 debate, the issue of enforcement was addressed. As stated by NDP MP Alain Giguère:

Mr. Speaker, the text of this proposed legislation is important, but so is enforcement. Unfortunately, Canada has one great weakness: it passes bills but does nothing to enforce them...There is no real oversight, just a smokescreen. (Giguère, 2014)

Despite concerns, Bill C-17 was passed on to the House of Commons Standing Committee on Health for a clause-by-clause reading. The committee meetings were held June 5, 10, and 12, 2014, and raised a number of issues with the proposed legislation from the perspectives of many different stakeholders. Several issues were directly related to the implementation of a mandatory adverse drug reaction reporting system, in addition to concerns with the legislation more broadly. As in previous discussions, the issue of Health Canada's resources was cited as a barrier to the successful implementation and uptake of the legislation, particularly in terms of coordinating the information that would be received through an adverse drug reaction reporting schema and in light of budget cuts to Health Canada. Anne Lamar, Acting Assistant Deputy Minister of the Health Products and Food Branch of Health Canada,

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

assured the Members that the Department had been continually investing in IT infrastructure that would increase the efficiency of reporting, thereby reducing the burden on those who would be required to report, in addition to increasing the ability of the Department itself to review and analyze the data. In the words of Ms. Lamar, “we’ll be moving to a more efficient system.” (Canada. Parliament, 2014, Jun. 5) In reference to the development of regulations, both Ms. Lamar and Ms. Ambrose stated that the regulations would be developed in consultation with provinces, territories, and institutions to ensure that current systems are leveraged while attempting to maintain consistent reporting across the country.

Following the committee review of Bill C-17, the committee presented the House with amendments to the Bill. It was then read for a third time and passed on to the Senate. The Senate completed its Second Reading of Bill C-17 on September 18, 2014, and passed it on to the Senate Standing Committee on Social Affairs, Science and Technology for review. Although the Standing Committee presented no amendments to the Bill, these committee sessions heard the greatest number of individuals (either witnesses or senators) who questioned the practical implications of implementing the legislation.

Janet Currie, a witness representing the Psychiatric Medication Awareness Group, supported the idea of mandating adverse drug reaction reporting, but acknowledged that this type of legislative action has, historically, been unsuccessful. Ms. Currie emphasized the need for Health Canada to incentivize it and to actively support the process at each institution, although she expressed concern for Health Canada’s capacity to engage in these activities in light of their limited resources. Dr. Joel Lexchin echoed the concern that Health Canada’s resources were insufficient to successfully mandate the reporting of adverse drug reactions, pointing to the fact that Health Canada’s drug approval branch, the Therapeutic Products Directorate, received over three times the financial and human resources than what was allocated to post-market surveillance through the Marketed Health Products Directorate. This concern

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

was reiterated by Dr. Robert Peterson of the Drug Safety and Effectiveness Network on October 2, 2014. Additionally, Dr. Lexchin mentioned that the relative lack of resources would negatively impact the type of response one would receive upon submission of an adverse drug reaction report. Comparing Canada to the system in New Zealand, he argued that receiving feedback on submitted reports would enhance the process.

Dr. Stuart MacLeod argued that Health Canada needs more resources to provide training opportunities on evaluation and implementation sciences due to the complexity involved in studying adverse reactions. Both Drs. MacLeod and Lexchin were asked by Senator Chaput whether this initiative would be possible under circumstances in which Health Canada was not allocated additional resources or funding. They agreed that simply shuffling the deck of existing resources would not be sufficient.

Bill Tholl, the President and Chief Executive Officer of HealthCareCAN, noted his concern for the likelihood of an increased administrative burden that would result from mandated reporting. In order to fully understand this potential issue, Mr. Tholl suggested that the Department conduct a cost-benefit analysis to ensure that benefits will be realized as a result of this initiative relative to the direct and indirect costs, particularly if it is the expectation that health care facilities will need to invest in new infrastructure to report efficiently.

On October 8, 2014, when Minister of Health Rona Ambrose attended the meeting as a witness, many of the Senators reiterated questions concerning Health Canada's capacity to implement this legislation. Senator Seidman began the questioning by expressing concern over the Department's capacity to effectively implement and enforce the proposed legislation. This was then addressed by Senator Eggleton, who provided evidence from the Auditor General's 2011 report, as well as noting that 275 jobs were cut from Health Canada in 2012. Senator Cordy asked Ms. Ambrose about this as well. To all three, she stated that the negotiations that are currently undertaken with pharmaceutical companies consume

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

a significant portion of the Department's time and resources. She argued that this new legislation would free up resources as a result of reduced time required for negotiations. She also added, in response to Senator Eggleton, that the statement that Health Canada had experience 275 job cuts was false information (although the following day, October 9, Senator Eggleton provided evidence to support the fact that Health Canada had 275 fewer positions as a result of the 2012 Federal budget). Ms. Ambrose also mentioned that the need for resources would be reviewed and assessed on an ongoing basis, although they are under the impression that it is presently sufficient. Senator Cordy then followed up by asking Ms. Ambrose about the technological capacity of the health care institutions to ensure that they meet Health Canada's requirements for reporting adverse reactions, to which Ms. Ambrose replied that the provinces and territories were aware of their roles and responsibilities in terms of reporting to Health Canada. She added: "There isn't a great deal of advance technology needed to fill out a form and send it to Health Canada." (Ibid.) She also noted that Health Canada's experts would be able to analyze the information to identify trends. Senator Olsen was the last to ask Ms. Ambrose about Health Canada's resources, particularly requesting reassurance that ongoing assessment would be undertaken. She assured him that the reduced negotiation time would free up considerable resources and that assessments of resources would be ongoing as the regulations are phased in.

The development of the regulations was the second area in which Ms. Ambrose received a number of questions. Senator Eggleton addressed the timing of the regulations and whether the committee would be permitted to review them prior to finalization. Ms. Ambrose explained that the Prime Minister had requested that the regulations be established as soon as possible. Senator Seidman later asked about the process for developing the regulations related to adverse drug reaction reporting, particularly whether stakeholders and provincial/territorial governments would be consulted. Ms. Ambrose stated that the stakeholders and provincial/territorial governments have been supportive and consulted throughout the process and that Health Canada has committed to continuing to speak to them as

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

regulations are developed. She also noted that the regulations would go through the consultative Gazette process, and therefore be open for public consideration.

The following day, the Senate Committee completed a clause-by-clause reading of the Bill. Senator Eggleton proposed four amendments, including a provision whereby the Government ensures adequate funding to support the successful implementation of the Bill. The majority of the committee members, however, voted against all four proposed amendments. The Bill was thus returned to the Senate without amendments for the third reading. During the third reading on October 23, 2014, Senator Eggleton reiterated his position that Health Canada lacks sufficient resources to proceed with this, again addressing the shortcomings that were noted in the Auditor General's Fall Report of 2011. Regardless, the Bill was passed by the Senate and received Royal Assent on November 6, 2014. It is now law.

V) Coming Into Force

As noted above, certain elements of this legislation became law upon receipt of Royal Assent, while others will be phased in as they require the development of specific regulations. As stated in the Government's Question/Answer legislation and guideline release that was issued on October 31, 2014, the powers that have come into effect since the legislation received Royal Assent are: the ability to recall unsafe therapeutic products; the ability to impose tougher fines and penalties; the ability to direct label changes and modifications; and, the ability to seek an injunction (Health Canada, 2014). Meanwhile, the other changes that require the establishment of supporting regulations will come into force on a date to be determined in the future. This release notes that Canadians will have the opportunity to contribute to the regulatory development process by commenting on supporting regulations, which includes the regulations related to the reporting of adverse drug reactions. It is likely that the regulations will be open to comments from Canadians through the Canada Gazette Part I: Notices and Proposed Regulations, which is published weekly on Saturday and is a cornerstone of the

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

public consultative process in Canada. In a recent Health Committee meeting on November 20, 2014, Ms. Ambrose stated her belief that the regulatory change that has come into effect immediately are those that impact consumers the most, as well as having the greatest potential for optimizing the Department's efficiency. Ms. Ambrose repeated an argument she had made to the Senate concerning the amount of time and resources that Health Canada allocates to negotiations, stating that: "our officials spent literally hundreds of hours negotiating with pharmaceutical companies to change their labels, to pull unsafe products off the shelves," and that eliminating this will allow the Department to act more quickly in the public interest (Ambrose, 2014). This point was reinforced by Eve Adams, the Parliamentary Secretary to the Minister of Health, during House debate on November 27, 2014. She added that regulations related to the reporting of adverse drug reactions are being developed, "which will allow the regulator to reach into the health care system and extract data to provide a better window on what is happening in the real world with patients." (Adams, 2014) Deputy Minister in the Ministry of Health, George Da Pont, attended a recent meeting for the Health Committee as well, stating that the Department will be engaging with the provinces, local hospital authorities, and other authorities who will be responsible for reporting to work out the specific elements of the reporting process: "the timing, the mechanism, and the frequency of reporting." (Da Pont, 2014) Mr. Da Pont emphasized that they are trying to move the process along as quickly as possible.

While several media outlets have published articles notifying the public of the passage of this law, none have called into question how it will come into force. Indeed throughout the legislative process, the question of implementation was raised, but never adequately answered, largely due to the fact that the regulations that are yet to be established will be a determining factor of the implementation process. As noted above, the preliminary readings of the Bill in the House of Commons and at the Health Committee raised questions related to Health Canada's capacity to implement and enforce these changes; however, a definitive response was not provided. Similar concerns were raised during the Senate deliberations

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

regarding Health Canada's human and financial resources. The Senate Standing Committee on Social Affairs, Science and Technology heard the most concern over the successful implementation of this legislation from both witnesses and senators. Furthermore, representatives from Health Canada, including the Minister of Health, attended a committee meeting, therefore providing an opportunity for the Senators to directly address the issue of resources that was brought up so frequently. As discussed above, little insight was provided. Other issues related to the successful implementation of this legislation addressed the increased administrative burden and how to encourage people to report, in terms of incentivizing it and creating behavioural changes among health care providers to establish a culture of reporting and patient safety. The committee also heard a number of recommendations on how to ensure successful implementation, which included the enhancement technologies to facilitate reporting and the need to consult the provincial and territorial governments, health care practitioners, and other countries that have succeeded or failed at implementing a mandatory adverse drug reaction reporting schema.

Interestingly, the question of enforcing the mandatory adverse drug reaction reporting requirement was not addressed during Parliamentary debate. In addition to issues related to federal versus provincial/territorial jurisdictional authority, this raises the question of how they will know whether or not an adverse reaction has indeed been reported, unless they assign a representative at each health care site to monitor the reporting. While it is assumed that physicians and other health care service providers will be inclined to report in the name of patient safety, it cannot be guaranteed that this will occur if it is a cumbersome activity that takes away from the effective delivery of patient care. This, among many other unknown questions related to the legislation, will only be uncovered through the development and implementation of relevant regulations.

Recommended Citation:

Small, S. (2015). Implementing New Patient Safety Legislation through Bill C-17. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

Sources

Adams, E. (2014, Nov. 27). “Opposition Motion – Survivors of thalidomide”. Canada. Parliament. House of Commons. *Edited Hansard 150*. 41st Parliament, 2nd Session. Retrieved from:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6801944&Language=E&Mode=1>

Building a comprehensive post-market surveillance system: Canadian Medical Association response to Health Canada’s discussion paper “Designing a mandatory system for reporting serious adverse drug reactions.” (2005, Jul. 28). *Canadian Medical Association*, pp. 1-7.

Canada Budget 2012: Highlights of the federal government’s plans for spending and cuts. (2012, Mar. 29). *The Huffington Post Canada*. Retrieved from: http://www.huffingtonpost.ca/2012/03/29/canada-budget-2012-highlights-cuts_n_1384089.html

Canada. Parliament. House of Commons. Standing Committee on Health. (2008). *Minutes of Proceedings*. 39th Parliament, 2nd session, meeting no. 9. Retrieved from the Parliament Canada website:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=3238905&Language=E&Mode=1>

Canada. Parliament. House of Commons. Standing Committee on Health. (2008). *Minutes of Proceedings*. 39th Parliament, 2nd session, meeting no. 10. Retrieved from the Parliament Canada website:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&Parl=39&Ses=2&DocId=3250642&File=0>

Canada. Parliament. House of Commons. Standing Committee on Health. (2014). *Minutes of Proceedings*. 41st Parliament, 2nd session, meeting no. 32. Retrieved from the Parliament Canada website:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6648558&Language=E&Mode=1>

Canada. Parliament. House of Commons. Standing Committee on Health. (2014). *Minutes of Proceedings*. 41st Parliament, 2nd session, meeting no. 42. Retrieved from the Parliament Canada website:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6783597&Language=E&Mode=1>

Class-action drug lawsuit approved. (2007, Jan. 23). *Edmonton Journal*, p. A.5.

Davis, L. (2014, May 27). “Protecting Canadians from Unsafe Drugs Act”. Canada. Parliament. House of Commons. *Edited Hansard 90*. 41st Parliament, 2nd session. Retrieved from:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6619517&Language=E&Mode=1>

Foss, K. (2000, May 31). Bereaved father wants answers. *The Globe and Mail*, p. A.2.

Foss, K. (2000, Oct. 14). When the cure does harm. *The Globe and Mail*, p. A13.

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>

Giguère, A. (2014, May 27). “Protecting Canadians from Unsafe Drugs Act”. Canada. Parliament. House of Commons. *Edited Hansard 90*. 41st Parliament, 2nd session. Retrieved from:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6619517&Language=E&Mode=1>

Health Canada, Drugs and Health Products. (2014). *Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law): Questions/Answers*. [Ottawa]. Retrieved from: <http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguessedangereuses-faq-eng.php>

Health Canada, drug firm face \$100 million lawsuit from father of dead teen. (2001, Jul. 10). *Canadian Press NewsWire*. Retrieved from:

<http://search.proquest.com.ezproxy.library.ubc.ca/docview/325654034?accountid=14656>

Health Canada, Health Products and Food Branch. (2002). *Response to the Recommendations to Health Canada of the Coroner’s Jury Investigation into the Death of Vanessa Young*. [Ottawa]. Retrieved from:

http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/death-deces_vanessa_young_sum-res-eng.php

Lessons from cisapride. (2001, May 1). *Canadian Medical Association Journal*. 164(9): p. 1269.

McBane, M. (2011, Jan. 17). Drug safety: Health Canada thanks you for not enquiring. *The Hill Times*. Retrieved from: <http://healthcoalition.ca/drug-safety-health-canada-thanks-you-for-not-enquiring/>.

Merrifield, R. (2004, Feb. 20). “Adverse Drug Reactions”. Canada. Parliament. House of Commons. *Edited Hansard 15*. 37th Parliament, 3rd session. Retrieved from:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=1207692&Language=E&Mode=1>

Merrifield, R. (2004, Mar. 25). “Adverse Drug Reactions”. Canada. Parliament. House of Commons. *Edited Hansard 29*. 37th Parliament, 3rd session. Retrieved from:

<http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=1265193&Language=E&Mode=1>

Office of the Auditor General of Canada. (2011). *2011 Fall Report of the Auditor General of Canada*. [Ottawa]. Retrieved from: [http://www.oag-](http://www.oag-bvg.gc.ca/internet/English/parl_oag_201111_04_e_35936.html#hd3a)

[bvg.gc.ca/internet/English/parl_oag_201111_04_e_35936.html#hd3a](http://www.oag-bvg.gc.ca/internet/English/parl_oag_201111_04_e_35936.html#hd3a)

Owens, A.M. (2001, Mar. 27). Deadly drug continued to be sold despite years of warnings. *National Post*, p. A.1.

Owens, A.M. (2001, Apr. 16). Spotlight turned on drug system: Coroner’s Inquest: Company study questioned drug’s effectiveness. *National Post*, p. A5.

Smith, J. (2013, Apr. 16). Health Canada considers mandatory reporting of adverse drug reactions. *Toronto Star*. Retrieved from:

http://www.thestar.com/news/canada/2013/04/16/conservative_government_aims_to_improve_safety_of_food_childrens_products_and_prescription_drugs.html

Recommended Citation:

Small, S. (2015). *Implementing New Patient Safety Legislation through Bill C-17*. Vancouver, BC: Action ADE. Retrieved from <http://actionade.org/wp-content/uploads/2016/02/Implementing-Patient-Safety-Legislation-Bill-C-17.pdf>