A Gold Mine of Information: Using Pharmaceutical Data Mining to Ensure Long-Term Safety and Effectiveness of Pharmaceuticals

by

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Abstract

In an era of highly advertised blockbuster medicines, newly approved pharmaceuticals can pose a hazard to the public if not properly monitored following their approval. Drugs are only given to a limited number of healthy individuals during clinical trials, leaving significant questions as to the risks for the population at large. There are limited opportunities for assessment following the product’s introduction onto the market and adverse effects may not be detected. This paper argues that hurdles in tracking long-term safety and effectiveness can be partially remedied through the aggregation and analysis of information collected through pharmaceutical data mining. Pharmaceutical data mining is a process whereby private organizations compile extensive information on patients’ prescription histories, including: the drug prescribed, recommended dosage, and the patient’s subsequent history with the medication. The Canadian government should collect this information and analyze its meaning to better ensure the long-term safety and effectiveness of drugs.
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1 Introduction

Technological advances have led to a constant exchange and collection of electronic data.¹ To make credit card purchases, communicate efficiently, perform Internet searches, and undergo countless other daily tasks, individuals give out personal information that is often aggregated and analyzed for business purposes.² The Internet enables information to be collected quickly and easily.³ Additionally, computers can now amass dizzying amounts of data, enabling “ever more comprehensive records of individual attributes and activities”.⁴ Critics of such practices decry the “war on information privacy,”⁵ while supporters laud the benefits of effectively utilizing available data.⁶ This debate has taken on a new life in light of the recent revelations that the United States government is involved in extensive data collection and analysis processes.⁷

¹ Ontario, Information and Privacy Commissioner, Dispelling the Myths Surrounding De-identification:


³ See Cavoukian & El Emam, supra note 1, at 2 (explaining that the Internet has made it difficult to safeguard information privacy since even information that may seem to be anonymous on the Internet can be compared to other information available online to reveal the identity of the individual).

⁴ Julie E. Cohen, “Examined Lives: Informational Privacy and the Subject as Object” (2000) 52 Stan L Rev 1373 at 1374 [Cohen] (finding that “the rise of a networked society…has brought with it intense concern about the personal and social implications” of databases containing personal information which can be “rapidly searched, instantly distributed, and seamlessly combined with other data sources…”).


⁶ See e.g., “Brief for Amicus Chamber of Commerce of the United States of America in Support of Respondents”, (2011) Sorrell v. IMS Health, Inc., at 6-12, online: SCOTUSblog.com <http://www.scotusblog.com/case-files/cases/sorrell-v-ims-health-inc/> [US Chamber of Commerce] (arguing that targeting advertisements based on such information allows efficient spending and enables consumers to learn about the products most likely to be of interest).

⁷ See e.g., Ira Basen, “Big Data’s Got Your Number. Should You Care? Retailers, Political Parties, Government Spy Agencies All Collecting Personal Data”, CBC News (24 June 2013) online: CBC News: Technology and Science <www.cbc.ca/news> [Basen] (noting that the phenomenon of data collection is referred to as “big data” and that while it has been known since the mid-1990s, it has become better
health information is involved, both the privacy concerns and potential benefits of collecting data may be drastically heightened.⁸

Extensive, reliable data on health outcomes is crucial to improving the health care system.⁹ Among its myriad applications, the data enables officials to oversee public health concerns.¹⁰ It also allows researchers to pinpoint populations at risk, recognize health impediments, and identify effective disease prevention strategies and treatments.¹¹ Conclusions elucidated from aggregated health data have the potential to revolutionize the use of pharmaceuticals.¹²

Difficulties in tracking the long-term effects of licensed pharmaceuticals currently pose a significant challenge to the regulatory regime.¹³ There are limited opportunities for assessment following a product’s introduction onto the market.¹⁴ If regulators harness technology and data known in the past year and particularly since the news of government “spy agencies” collecting metadata became public knowledge).

⁸ See generally Sharona Hoffman & Andy Podgurski, “Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information” (2007) 48 BC L Rev 331 [Hoffman & Podgurski] (conceding that the electronic collection of health information presents a danger to privacy, but finding that it offers significant benefits if proper legal protections are implemented).

⁹ Canadian Institutes of Health Research, Secondary Use of Personal Information in Health Research: Case Studies, (Ottawa: CIHR, 2002) at 5 [Secondary Use of Personal Information] (commenting that health research to improve the system and formulate beneficial policies “critically depends on the ready availability of existing data about people” which is most effective when the information is collected en masse).

¹⁰ Cavoukian & El Emam, supra note 1, at 4.

¹¹ Secondary Use of Personal Information, supra note 9, at 5.


¹³ See e.g., Trudo Lemmens & Ron A. Bouchard, “Regulation of Pharmaceuticals in Canada” in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds, Canadian Health Law and Policy, 3d ed (Markham: LexisNexis, 2007) 311 at 335-337 [Lemmens & Bouchard] (concluding that the analysis of whether a drug is safe and effective occurs almost exclusively prior to its introduction to the market).

¹⁴ See Health Canada, Brief History of Drug Regulation in Canada—Progressive Licensing—Drugs and Health Products, (11 April 2007), online: Health Canada <http://www.hc-sc.gc.ca/> [Brief History of Drug Regulation] (noting that the Canadian system focuses on pre-market scrutiny and is classified as
that are currently directed towards commercial activities could enable the regulatory system to recognize and control health risks at the earliest signs, instead of responding to devastating tragedies.

This paper argues that hurdles to ensuring long-term safety and effectiveness can be partially remedied through the collection and analysis of information collected in a practice known as “pharmaceutical data mining” (PDM). Part I will provide a brief overview of the pharmaceutical regulatory framework in Canada and establish how information on safety and efficacy is currently obtained. The term “efficacy” refers to the drugs’ effects as demonstrated in the controlled conditions of a clinical trial. In contrast, “effectiveness” refers to the drug’s benefits as observed in the general population. The discussion in Part I will establish that the review process is disproportionately focused on scrutinizing pharmaceuticals prior to their introduction onto the market. Part I will also introduce arguments that post-market surveillance of drugs is insufficient and there are not proper mechanisms in place to identify problems that may become apparent once a drug is introduced to the population at large.

Part II will discuss the collection and use of health information in PDM. Through this process, companies collect extensive information relating to patients’ use of pharmaceuticals, including the doctor’s reason for prescribing the medication, how long an individual remains on a medication, and whether he or she switches to an alternative. Part II will also highlight the

“point in time” regulation, meaning oversight only occurs at specified periods); Federal/Provincial/Territorial Ministerial Task Force, National Pharmaceuticals Strategy Progress Report, (Ottawa: Health Canada, 2006) at 20 [Pharmaceuticals Strategy Progress Report] (“While there is an increasing recognition of, and reliance on, scientific evidence in treatment and reimbursement decision, currently the majority of this evidence is gathered through clinical trials in highly controlled environments in the pre-market phase.”).


16 Ibid.

17 See discussion infra Part II.A.
controversies raised in connection with the practice and the legal battles that have been fought about PDM in the United States and Canada.

Part III will conclude that the government should obtain health information by requiring pharmaceutical companies to provide copies of all data mining reports they purchase, or by collaborating with the companies that compile it. The government should combine this information with data it already holds to create a comprehensive database. It should then utilize data mining techniques to identify safety and effectiveness concerns. To make this argument, Part III will detail how this proposal could be effected and how it would benefit the current system. As an illustration of the potential for data mining in post-market drug surveillance, Part III will discuss the Sentinel Initiative in the United States. Finally, the paper will respond to the criticisms against prescription data mining and why they should not be a deterrent to establishing the proposed system.

Data mining practices are controversial, but given that they are already occurring, the information obtained should be utilized to ensure patient safety. This paper does not take a position as to whether the laws allowing pharmaceutical data mining should be modified, but argues that unless and until they are, the fruits of data mining should be put to use to benefit the public. The health information prescription data miners collect could provide pharmaceutical regulators with insight into patients’ prescription history as well as drugs’ long-term benefits and harms. If effectively integrated into the existing regulatory framework and combined with information the government already has access to, this knowledge could facilitate efficient and informed decisions regarding medications’ safety, effectiveness, and quality. In particular, mechanisms to track harmful reactions to medications could improve health care and save lives.

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18 See discussion infra Part III.
19 See discussion infra Part III.
20 See discussion infra Part III.
2 Background

2.1 Regulation of Pharmaceuticals in Canada

Medications are integral to maintaining and improving the health of the population. In Canada alone, hundreds of millions of prescriptions are filled annually. These medications can only provide their intended benefit if they are effective for the purposes for which they are used and safe to the individuals ingesting them.

After a history fraught with deception and abuse, the marketing and sale of medicines is now closely monitored. Long before a medication can be prescribed, it enters a regulatory process to be evaluated and approved. Under the Food and Drugs Act and related regulations, Health Canada oversees “therapeutic products,” monitoring their safety, efficacy, and quality. Health Canada’s mandate includes “drugs.” The Act defines drugs as any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

22 Ibid at 5
23 See Ariel Katz, “Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry” (2007) 14 Mich Telecomm & Techn L Rev 1 at 2-4 [Katz] (outlining a history of quackery in the late 1800’s through early 1900’s in which products presented as medications were often ineffective while others had deleterious consequences to health).
24 See e.g., ibid at 4 (describing the path from a drug’s development to approval as “costly and lengthy”).
27 Health Canada, How Drugs are Reviewed in Canada, (2001), online: Health Canada <http://www.hc-sc.gc.ca/> [How Drugs are Reviewed in Canada].
(b) restoring, correcting or modifying organic functions in human beings or animals... 28

To evaluate safety, efficacy, and quality, Health Canada requires all new drugs to go through specified stages of assessment.29 The drug review is conducted under Health Canada’s Health Products and Food Branch’s (HPFB) oversight through the Therapeutic Products Directorate (TPD).30 The earliest phase of analysis is referred to as “pre-market.”31 The drug evolves through research in laboratories and is then tested and refined through clinical trials.32 At the next stage, the HPFB decides whether to authorize the drug to be sold.33 The regulatory process then continues with measures to monitor the drug after it becomes available to Canadian patients.34

2.1.1 Pre-Market Review

The current pharmaceutical regulatory system primarily focuses on analyzing new drugs prior to their introduction to the market.35 This type of model, which focuses on a specific time frame of a drug’s life cycle is known as “point-in-time.”36 Prior to the introduction of a new medication, the manufacturer first conducts pre-clinical studies and clinical studies, and the HPFB evaluates the scientific evidence.37

28 Food and Drug Act, RSC 1985, c. F-27 sect. 2 [Food and Drug Act].
29 Access to Therapeutic Products, supra note 26, at 3.
30 Ibid at 19.
31 Ibid at 5.
32 Ibid at 6.
33 Ibid at 5.
34 Brief History of Drug Regulation, supra note 14,
35 Ibid.
37 Patricia A. Carter, “Federal Regulation of Pharmaceuticals in the United States and Canada” (1999) 21(2) Loy LA Int’l & Comp LJ 215 at 230 [Carter] (classifying the process into four phases: the pre-
The first step for a manufacturer introducing a new drug is pre-clinical studies. During this time, researchers refine the chemical entity based on in vitro testing, applying the chemical to cells in test tubes. The manufacturer will then conduct in vivo tests, administering the drug to animals. These studies provide evidence of the product’s potential use and demonstrate whether it will have a lethal effect. The Canadian government does not regulate pre-clinical studies but requires the manufacturer to provide the results. Based on their outcomes, the HPFB will determine whether to authorize a clinical study involving human subjects.

To progress to clinical trials, the manufacturer must first submit a Clinical Trial Application. This must be done prior to beginning the clinical trial. The application includes study protocols, details on the site where the trials would be conducted, any research ethic boards in Canada that rejected the proposed study, and whether regulatory bodies outside Canada refused to authorize the clinical trial. The application will also detail any available findings on the

38 Access to Therapeutic Products, supra note 26, at 6.
40 Access to Therapeutic Products, supra note 26, at 6.
41 Ibid (noting that these studies are referred to as either in vitro, involving “test tube testing”, or in vivo, utilizing animals).
42 Lemmens & Bouchard, supra note 13, at 321.
44 Health Canada, Guidance for Clinical Trial Sponsors: Clinical Trial Applications, at 14, online: <http://www.nc-sc.gc.ca/> [Guidance for Clinical Trial Sponsors].
46 How Drugs are Reviewed in Canada, supra note 27, at 10-13.
drug’s quality. HPFB evaluates Clinical Trial Applications and assesses the protocols to prevent participants from facing undue risk. HFPB must notify the drug manufacturer of the decision within thirty days.

Clinical studies provide information on therapeutic benefits, optimal dosing, and possible side effects. Trials are then generally conducted in three pre-market phases in carefully controlled environments. HPFB has the authority to investigate and inspect clinical trials to assure compliance with the regulatory requirements.

Each phase gradually progresses from a minimal number of participants, minimizing the reach of any deleterious effects. In the first phase, researchers dispense the drug to approximately 20-80 healthy participants to observe its effects. From these studies, the manufacturers approximate the doses at which the drug is safe. The second phase consists of around 100-300 individuals afflicted with the condition the drug is intended to treat. This allows scientists to evaluate whether the drug is effective and provides further evidence of whether side effects exist. Finally, the product is administered through double-blind controlled trials in phase three, where neither the participants nor those conducting the study are aware who receives the drug

48 Access to Therapeutic Products, supra note 26, at 6 (commenting that clinical trials must comply with international good practices as established by the Good Clinical Practices and detailed in the Food and Drugs Act and regulations).
49 Guidance for Clinical Trial Sponsors, supra note 44, at 12.
50 How Drugs are Reviewed in Canada, supra note 27, at 2.
51 Carter, supra note 37, at 231-32; Pharmaceuticals Strategy Progress Report, supra note 14, at 7.
53 Carter, supra note 37, at 232.
54 Lemmens & Bouchard, supra note 13, at 322 (explaining that the studies particularly focus on whether the drug is safe, serious side effects, and the rate at which the participants’ systems absorb, break down, and purge the chemicals).
55 Carter, supra note 37, at 231-32.
56 Lemmens & Bouchard, supra note 13, at 322.
57 Ibid.
and who receives a placebo. These studies generally include anywhere from 1,000 to 5,000 subjects. The objective is to establish the drug’s efficacy and safety, further monitoring any possible side effects. The results may also refine the expected proper dosages.

Once phase three is complete, the drug manufacturer can file a “New Drug Submission”. HPFB scientists evaluate the submissions and will approve the application if they determine sufficient evidence demonstrates the therapeutic benefits outweigh any potential side effects. The HPFB will consider whether risks can be moderated or controlled. If the HPFB concludes that the benefits are greater than the risks, it will issue a Notice of Compliance and provide the product with a Drug Identification Number. This signifies that the HPFB approves the drug for sale in Canada.

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58 Ibid.
59 Ibid.
60 Ron A. Bouchard & Monica Sawicka, “The Mud and the Blood and the Beer: Canada’s Progressive Licensing Framework for Drug Approval” (2009) 3 McGill JL & Health 49 at 55 [Bouchard & Sawicka]. See Lemmens & Bouchard, supra note 13, at 322 (adding that the studies may involve “specific patient-populations” and are sometimes assessed alongside medications that have already been approved to determine comparative effectiveness).
61 Carter, supra note 37, at 232.
62 How Drugs are Reviewed in Canada, supra note 27, at 2.
64 Access to Therapeutic Products, supra note 26, at 9, 13.
65 Ibid at 13.
66 Ibid.
Alternatively, Health Canada can issue a Notice of Compliance with Conditions (NOC/c), which allows the product on the market pending additional studies to confirm the drug’s benefits.\(^67\) An NOC/c is issued to allow “promising new drug therapies” to reach patients on an expedited timeframe where there is no similar medication currently available.\(^68\) However, the *Food and Drug Act* and its regulations do not enable Health Canada to enforce the conditions attached to the drug’s approval.\(^69\)

### 2.1.2 Post-Market Monitoring and Surveillance

Health Canada continues to regulate drugs after they are approved for sale.\(^70\) The Marketed Health Products Directorate (MHPD) of the HPFB conducts oversight of drugs after they enter the market.\(^71\) To enable informed supervision, MHPD runs the Canadian Adverse Drug Reaction Monitoring Program.\(^72\) MHPD also bears responsibility for monitoring reports of significant drug safety issues internationally.\(^73\)

The *Food and Drugs Act* places the onus on the manufacturers of new drugs to inform the government about reports of serious side effects.\(^74\) These side effects are called “adverse reactions.”\(^75\) The regulations define an adverse reaction as “a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or


\(^{68}\) *Ibid.*

\(^{69}\) Taylor, *supra* note 39, at 190.


\(^{71}\) *Ibid.*

\(^{72}\) *Ibid.*

\(^{73}\) Taylor, *supra* note 39, at 40.

\(^{74}\) Access to Therapeutic Products, *supra* note 26, at 19.

\(^{75}\) *Ibid* at 20.
prevention of a disease...”. Thus, a health condition is considered an “adverse reaction” only where there is reason to suspect the medication has caused the harm. This can include reactions resulting from the drug’s interaction with another medication. A “serious adverse drug reaction” is one that “requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malfunction, results in persistent or significant disability or incapacity, is life-threatening or results in death”.

Under *Food and Drug Regulation C.01.017*, a drug manufacturer must notify the government about serious adverse drug reactions within fifteen days of “receiving or becoming aware of the information.” The manufacturer must report the reaction regardless of whether it occurs in Canada or abroad. However, the regulations impose no requirement for pharmaceutical manufacturers to obtain information about possible adverse drug reactions through safety or effectiveness studies following approval. The agency predominantly receives notifications about suspected health risks from health professionals and affected patients. “MedEffect Canada” is an online database through which any individual can report adverse reactions or

76 *Food and Drug Regulations*, Part C, Division 1, CRC, c 80 [*Food and Drug Regulations*].


78 *Ibid*.

79 *Ibid*.

80 *Ibid*.

81 *Ibid*.


83 Health Canada, *Authority to Require Post-market Studies- Post-Market Authorization*, (19 January 2011), online: Health Canada Drugs and Health Products <http://www.hc-sc.gc.ca/dhp-mps/index-eng.php> [Authority to Require Post-Market Studies] (acknowledging that information obtained from third parties is “often limited in scope and of restricted availability, and…may be of limited usefulness” as the studies from which it is obtained may have divergent goals from Health Canada’s needs).
search for information on drug safety. MHPD’s regional offices collect and review reports and send them to the National Office, where they are further analyzed.

This reporting process is predicated on the drug manufacturers receiving information on serious adverse events. They are not required to conduct any post-market studies to uncover potential problems. Yet undertaking efforts to discover problems with their own products requires a financial investment that may be adverse to their corporate interests. In fact, the Food and Drug Administration in the United States noted that, “substantial underreporting of adverse events is widely acknowledged.”

Health Canada asserts that the agency has “no authority to request new efficacy, therapeutic effectiveness, or safety data from marketing authorization holders (MAHS) beyond their initial pre-marketing drug submission data.” Additionally, Health Canada cannot require MAHS to actively monitor consumers’ experiences. The agency therefore depends on third parties to supply such information. Most often, health care providers and patients provide the information that the drug has caused adverse reactions. Health Canada reports obtaining additional adverse reaction information from scientific publications, through collaborating with

86 Ferris & Lemmens, supra note 82, at E 123.
87 Lemmens & Bouchard, supra note 13, at 337.
89 Authority to Require Post-market Studies, supra note 83.
91 Authority to Require Post-market Studies, supra note 83.
92 Adverse Reaction Information, supra note 85.
“patient groups, academic institutions, professional associations in Canada and internationally”, and from “risk communications” from international regulatory agencies.  

2.1.3 Issues with Long-Term Surveillance

Even though Health Canada has stringent requirements for pre-market testing, introducing the drug to the population reveals unidentified risks. The true scope of a medication’s effects is only discernable outside the structured confines of clinical studies. A study investigating the prevalence of adverse effects found that safety concerns often do not manifest for years after a drug is approved. Clinical trial results are inherently limited based on the restricted number of participants. Individuals in vulnerable health are excluded from trials, leaving questions as to how they will respond. Additionally, the results of interactions with other medications are unknown and the time span of studies fails to account for long-term effects.

Despite the inherent risks once a drug is approved, the regulatory process in Canada focuses on the period prior to approval. As Ron Bouchard and Monica Sawicka explain, the current regulatory regime is strongly front-loaded in that the vast majority of regulatory resources are spent before initial market authorization, when very little information is known, and almost none following market entry when the vast

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93 Ibid.
94 Authority to Require Post-Market Studies, supra note 83.
97 Access to Therapeutic Products, supra note 26, at 20.
98 Authority to Require Post-market Studies, supra note 83.
100 Bouchard & Sawicka, supra note 60, at 72.
majority of information pertaining to drug safety and efficacy becomes available.\textsuperscript{101}

Although new medications may therefore pose the highest health risks, they are heavily promoted and ingested.\textsuperscript{102} Indeed, the number of individuals that take new, unsafe drugs is increasing.\textsuperscript{103} Drugs’ post-market safety concerns have been exacerbated by the growing number of long-term medications that patient take and the advent of “blockbuster” drugs, prescribed for a vast number of patients.\textsuperscript{104}

Concerns with the safety and effectiveness of medications have been identified as a “serious public health concern” that signal the need for improved long-term oversight.\textsuperscript{105} An assessment conducted by the Auditor General of Canada in 2011 found that Health Canada was slow to evaluate and respond to potential safety issues.\textsuperscript{106} The Health Council of Canada estimated in 2010 that Health Canada only identified 1-10\% of adverse reactions.\textsuperscript{107} Furthermore, harmful reactions from drug interactions are likely to become more prevalent, since “more potent drugs” are becoming increasingly available.\textsuperscript{108}

\textsuperscript{101} Ibid.

\textsuperscript{102} Lasser et al, supra note 96, at 2219.

\textsuperscript{103} Wiktorowicz et al, supra note 90, at 9 (attributing the increase to the fact that people trust a drug is safe once it is approved by Health Canada and that newer drugs are heavily marketed, but likely to present a greater health risk).

\textsuperscript{104} Mary Wiktorowicz, Joel Lexchin & Kathy Moscou, “Pharmacovigilance in Europe and North America: Divergent Approaches” (2012) 75 Social Sciences & Medicine 165 at 165 [Pharmacovigilance in Europe and North America].

\textsuperscript{105} Lemmens & Bouchard, supra note 13, at 335, 337.

\textsuperscript{106} Office of the Auditor General, supra note 21, at 22.

\textsuperscript{107} Wiktorowicz et al, supra note 90, at 4.

\textsuperscript{108} National Committee on Vital and Health Statistics, Report to the Secretary of the US Department of Health and Human Services on Protections for Uses of Health Data: A Stewardship for ‘Secondary Uses’ of Electronically Collected and Transmitted Health Data (19 Dec 2007) at 3, online: <www.ncvhs.hhs.gov>. 
The federal government introduced Bill C-51 in 2008 in an unsuccessful bid to end the point-in-time system and thereby address the safety and effectiveness concerns. The bill did not pass, but the government intended to implement “progressive licensing” instead of focusing on pre-market evaluation. Under progressive licensing, Heath Canada would have continued to collect and assess information about the drug continuously. The regulatory process would actively supervise the drug throughout its “life cycle,” from inception until it is withdrawn from the market.

The focus of progressive licensing is risk management, detecting and responding to health risks. The model would have incorporated pharmacovigilance, meaning “the process of detecting, assessing, understanding, and preventing adverse reactions or any other problems with drugs.” By continually collecting information about the drug throughout its life cycle, Health Canada would reassess the drugs’ risks and benefits and whether it should maintain its approval. Observers note that Health Canada still seems to be interested in implementing progressive licensing measures despite Bill C-51’s defeat. Yet until life cycle regulation is imposed, significant risks remain.

109 Wiktorowitz et al, supra note 90, at 5.
110 Ibid.
111 Life-Cycle Management, supra note 36.
113 Ibid.
114 Life-Cycle Management, supra note 36.
115 Bouchard & Sawicka, supra note 60, at 75.
116 Wiktorowitz et al, supra note 90, at 5.
2.1.4 The Drug Safety and Efficacy Network

The Canadian government has recognized that there is limited information available on the long-term effects of pharmaceuticals and is beginning to respond. In 2009, the Canadian Institutes of Health Research (CIHR) in the federal government launched an initiative to ameliorate the gap in post-market information. The Drug Safety and Efficacy Network (DSEN) will fund research into drug’s safety and efficacy in the “real world”. DSEN will provide up to $10 million annually. Additionally, DSEN created a virtual network to link the research once it is conducted.

This initiative represents “a significant step forward” in ensuring proper monitoring of pharmaceuticals. However, it will undoubtedly take time for scientists to apply for funding, conduct research, and achieve meaningful findings. Their efforts could be augmented through the use of information collected by pharmaceutical data miners.

2.2 Pharmaceutical Data Mining

2.2.1 What is Pharmaceutical Data Mining?

Ann Cavoukian, the Information and Privacy Commissioner for Ontario, describes “data mining” as “a set of automated techniques used to extract buried or previously unknown pieces of information to make proactive knowledge-driven business decisions.” Thus, data mining

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118 About DSEN, *supra* note 117; *see also* Ferris & Lemmens, *supra* note 82, at E 123 (noting that, if proven effective, the initiative could be essential to restoring the public’s confidence in the safety of Canadian drugs).
120 Pharmacovigilance in Europe and North America, *supra* note 104, at 168.
121 About DSEN, *supra* note 117.
122 Wiktorowitz et al, *supra* note 90, at 5.
123 Cavoukian, *supra* note 1, at 4.
involves collecting and analyzing extensive sets of information to deduce correlations and
trends. Generally, the information is gathered from electronic sources holding abundant
data. The aggregated data is referred to as “big data”, meaning “datasets whose size is beyond
the ability of typical database software tools to capture, store, manage, and analyze.” The
analysis often includes “metadata”, which is secondary information linked to a file, such as the
date and time a file was created. The data is evaluated “for what it may reveal about large
patterns and trends and, in the particular, for what it may reveal about specific actors or
enterprises.”

Data mining practices are not unique to the pharmaceutical field. Analyzing consumer data is
now a common commercial enterprise encompassing a $12 billion sector of the economy.
Public awareness of the practice has recently heightened as the result of the revelation that the
United States government engages in data mining practices for security surveillance. Through
the “PRISM” intelligence program, the government collects information about users’ Internet

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124 Ibid at 1-4.

125 Andrew M. Wilson, Lehana Thabane & Anne Holbrook, “Application of Data Mining Techniques in
Pharmacovigilance” (2003) 57:2 British Journal of Clinical Pharmacology 127 at 128-29 [Wilson,
Thabane & Holbrook].

126 James Manyika et al, “Big Data: The Next Frontier for Innovation, Competition, and Productivity”

127 Ibid at 32.

IMS Health Inc., et al at 2, online: SCOTUSblog.com <http://www.scotusblog.com/case-
files/cases/sorrell-v-ims-health-inc/> [Brief of Academic Research Scientists].

129 See Cavoukian, supra note 1, at 1 concluding that it is now essential for businesses to collect and
analyze consumer information due to the “sharpening of the competitive edge to improve products and
services”).

130 Basen, supra note 7.

131 Ibid.
activities from Google, Facebook, Apple, and other companies.\textsuperscript{132} Thus, myriad organizations employ data mining processes for a variety of purposes.

With pharmaceutical data mining (PDM), the data being utilized entails abundant information on patients’ prescription histories and doctors’ prescribing practices.\textsuperscript{133} Sources including “[p]hysicians, pharmacists, veterinarians, drugstores, hospitals, distributors and retailers”\textsuperscript{134} sell records to private organizations known as pharmaceutical/prescription data miners or “prescription drug intermediaries”.\textsuperscript{135} Pharmacies are the predominant source from which the companies obtain information.\textsuperscript{136}

When a patient fills a prescription, the pharmacy collects certain information, as is required to conduct the transaction and pursuant to legal obligations.\textsuperscript{137} With the pharmacy’s permission, data mining companies place software on the pharmacies’ computers that automatically transmits information collected from each transaction.\textsuperscript{138} Any patient identifiable information is encrypted.\textsuperscript{139} The program transmits the date a prescription is filled, the store number of the pharmacy, whether the prescription has been filled before or can be in the future, the reasons for

\begin{thebibliography}{99}
\footnotesize
\bibitem{Orentlicher} \textit{E.g.}, David Orentlicher, “Prescription Data Mining and the Protection of Patients’ Interests” (2010) JL Med & Ethics 74 at 74-75 [Orentlicher].
\bibitem{KallukaranKagan} Paul Kallukaran & Jerry Kagan, “Data Mining at IMS Health How We Turned a Mountain of Data into a Few Information-rich Molehills” at 2, online: <http://130.203.133.150/viewdoc/summary?doi=10.1.1.121.2705> [Kallukaran & Kagan].
\bibitem{Klocke} Jennifer L. Klocke, “Prescription Records for Sale: Privacy and Free Speech Issues Arising from the Sale of De-Identified Medical Data” 44 Idaho L Rev 511 at 512 [Klocke].
\bibitem{Sorrell2} \textit{Sorrell, supra} note 135, at 2660.
\bibitem{Ayotte} \textit{IMS Health Inc v Ayotte} 490 FSupp2d 163 at 166 (DNH 2007) [Ayotte].
\bibitem{Ibid} \textit{Ibid}.
\end{thebibliography}
prescribing the medication, and the details of the medication including its manufacturer, name, quantity, and strength.\textsuperscript{140} It records the prescribing physician’s full name, identification number, telephone number and specialty.\textsuperscript{141} Further, the program sends data mining companies sales information, particularly the price of the medication, the patient’s insurance carrier, and the form of payment utilized.\textsuperscript{142} The data mining companies combine this information with the data they collect from other sources.\textsuperscript{143} Privacy laws prohibit the transmission of certain patient identifiable information.\textsuperscript{144} The patient’s name and address, for example, are excluded from the records.\textsuperscript{145} However, data mining companies collect details such as a patient’s gender and birth date.\textsuperscript{146} The firms assign each patient a unique number used to distinguish his or her prescription history.\textsuperscript{147} Prescription data mining companies then compile and analyze the information into commercial databases.\textsuperscript{148} They sell reports primarily to pharmaceutical companies.\textsuperscript{149} In Canada, companies

\textsuperscript{140} Orentlicher, supra note 133, at 75; Klocke, supra note 136, at 515.


\textsuperscript{142} Office of the Privacy Commissioner of Canada, Privacy Commissioner Releases his Finding on the Prescribing Patterns of Doctors (News Release- Archived- PIPEDA Case Summary # 15) by George Radwanski, (2 October 2001) at 1, online: OPCC <http://www.privcom.gc.ca/media/an/wn_011002_e.asp> [Privacy Commissioner Releases his Finding on Prescribing Patterns].

\textsuperscript{143} Ayotte, supra note 138, at 166.

\textsuperscript{144} Klocke, supra note 136, at 511-12.


\textsuperscript{146} Privacy Commissioner Releases his Finding on Prescribing Patterns, supra note 143, at 1..

\textsuperscript{147} Ayotte, supra note 138, at 166..

can purchase summaries outlining physician prescribing histories and can pay to access a database containing the names, specialty, contact information, sex, language, and “special interest” of Canadian physicians.\textsuperscript{150} Papers rank the doctors based on the frequency of prescribing specific medications.\textsuperscript{151} However, physicians in Quebec have the choice to opt-out of allowing pharmacies to sell their prescribing information.\textsuperscript{152}

\subsection*{2.2.2 Controversy Surrounding Pharmaceutical Data Mining}

The collection and sale of prescription information is highly controversial.\textsuperscript{153} The primary objection relates to its potential use to influence doctors’ prescribing practices.\textsuperscript{154} In a practice known as “detailing,” pharmaceutical representatives meet with doctors to provide information on the medications they sell.\textsuperscript{155} They may furnish promotional and/or educational handouts, as well as free samples of their drugs.\textsuperscript{156} Knowing how frequently physicians prescribe a manufacturer’s drug or their competitors’ could allow detailers to target sales pitches.\textsuperscript{157}

\begin{itemize}
    \item \textsuperscript{150} Dick E Zoutman, B Douglas Ford & Assil R Bassili, “A Call for the Regulation of Prescription Data Mining” (2000) 163(9) Can Med Assoc J 1146 at 1146 [Zoutman, Ford & Bassili]. \textit{But see discussion infra Part II.C.2. (discussing limitations on PDM practices in some Canadian provinces).}
    \item \textsuperscript{151} Finding on Prescribing Patterns of Doctors, \textit{supra} note 143, at 1.
    \item \textsuperscript{152} Ann Silversides, “Canada Pension Plan Buys IMS Health” (2010) 182.1 Can Med Assoc J E48 at E48 [Silversides].
    \item \textsuperscript{153} \textit{See e.g.}, Cal Woodward, “Data-Mining Tests Boundaries of Medical Privacy” 183:9 CMAJ E509 at E509 [Woodward] (discussing a lawsuit challenging the sale of pharmaceutical data mining information and noting, “[i]f the scales of justice were tipped by the sheer number of parties on one side of the case, it would be a slam dunk against data miners and the drug industry”).
    \item \textsuperscript{154} Mello & Messing, \textit{supra} note 135, at 1248.
    \item \textsuperscript{155} Ayotte, \textit{supra} note 138, at 167.
    \item \textsuperscript{156} \textit{Ibid}.
    \item \textsuperscript{157} \textit{See e.g.}, Klocke, \textit{supra} note 136, at 515.
\end{itemize}
Critics of data mining argue that the use of the mined information enables manufacturers to improperly induce doctors to prescribe their most profitable drugs. Former sales representatives describe targeting “high prescribers” of certain drugs. The pharmaceutical companies may also look for “early adopters”, doctors that have a history of prescribing newly approved medications. Critics fear the possibility that sales representatives may use “perks” to sway doctors to prescribe their medications. Furthermore, opponents suggest the information presented during the detailing visit may be biased or inaccurate. Tracking the physicians’ subsequent prescriptions allows the representative to determine which methods of persuasion were most effective.

As David Orentlicher explains, “[c]ritics have argued that drug detailing results in sub-optimal prescribing decisions by physicians, compromising patient health and driving up spending on medical care.” Sales representatives are more likely to promote new drugs that are under patent protection and therefore provide a greater financial benefit to the company when

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158 See e.g., Vt Stat, Ann Tit 18 sect 4631 (finding that sales calls increase health care costs because representatives focus on promoting “high-margin, high-profit drugs”).


160 Orentlicher, supra note 133, at 75.

161 E.g., Nancy Robb, “Sale of Prescribing Data by Pharmacists Causes Growing Concern Among Physicians” (1996) 154(11) Can Med Assoc J 1747 at 1748 [Robb] (concluding that “[f]or some doctors, such ‘gifts’ may seem ‘very tempting’ ” when salaries are seen as unsubstantial). For an account of how sales representatives use the information to persuade doctors’ prescribing practices see Big Brother Pharma, supra note 160.

162 Aaron S Kesselheim & Jerry Avorn, “Pharmaceutical Promotion to Physicians and First Amendment Rights” (2008) 358(16) New Eng J Med 1727 at 1727 [Kesselheim & Avorn] (“Studies have highlighted the substantial effect of promotional statements on the prescribing behavior of physicians, and litigation has revealed that some manufacturers have depicted the risks and benefits of their products inaccurately.”); see also Orentlicher, supra note 133, at 75 (highlighting concerns that detailers may stress the benefits of the drug they are selling without depicting a “balanced assessment of the place for their products among a physician’s options for treatment.”).

163 Big Brother Pharma, supra note 160.

prescribed. However, these drugs may cost more and present greater safety concerns than alternatives. Commentators worry that doctors may be convinced to prescribe a medication that is not truly the patient’s best option. Doctors Aaron Kesselheim and Jerry Avorn contend that

[m]eetings with detailers have been shown to influence physicians’ prescribing practices, as well as spark requests by physicians to add a drug to their hospitals’ formularies. Such contact predicts early adoption by physicians of pharmaceutical products whether or not they are the most cost-effective choices.

Flawed treatment decisions could be detrimental to the patient’s health and could lead to more serious and costly health care requirements in the future. Opponents also raise concerns that the sales representatives’ influence could weaken patients’ trust in their health care providers.

Others stress that there are potential benefits of utilizing prescriber identifiable information for detailing. Proponents of PDM assert that it facilitates an exchange of truthful and beneficial information. Indeed, drug manufacturers are the primary source from which doctors receive information about available medications. As will be discussed below, arguments in favour of

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165 Kesselheim & Avorn, supra note 163, at 1730; see also Sorrell, supra note 135, at 2660 (“Detailing is an expensive undertaking, so pharmaceutical companies most often use it to promote high-profit brand-name drugs protected by patent.”).

166 Kesselheim & Avorn, supra note 163, at 1729-30.

167 Orentlicher, supra note 133, at 75.

168 Kesselheim & Avorn, supra note 163, at 1729.

169 Orentlicher, supra note 133, at 75.

170 See Sorrell, supra note 135, at 2670 (describing Vermont’s justification for legislation limiting prescription data mining, voicing concern that it “undermines the doctor-patient relationship” and “makes people ‘anxious’ about whether doctors have their patients’ best interests at heart”).


172 Ibid at 17-18.
facilitating free speech were influential in the United States Supreme Court’s rulings on PDM and set national precedent.173

While opponents criticize the process of singling out high prescribers, supporters point out that doing so identifies physicians that will receive the most benefit from information on any particular drug.174 This targeted marketing permits pharmaceutical manufacturers to conserve money by spending more efficiently, which could reduce the cost of their products.175 Furthermore, obtaining the prescribers’ identities allows the drug manufacturers to contact pertinent doctors when they learn about a safety concern relating to the drug’s use.176

Advocates of PDM and one-on-one drug marketing emphasize the benefits an open exchange between pharmaceutical companies and physicians can facilitate.177 The detailing process provides an opportunity for the doctor to learn about the drug being promoted without financial cost or a significant time investment.178 Sales representatives can provide valuable information relating to the drug’s performance in scientific studies, potential safety concerns, indicated use, and known interactions with other drugs.179 The detailer can inform doctors about all available varieties of their drug, including whether there is a form specific to children.180 Supporters point out that, contrary to the popular criticisms, the sales representatives may be endorsing a drug that

173 See infra Part II.C.1.
174 Brief of IMS Health, Verispan and Source Healthcare Analytics, supra note 175, at 2.
175 E.g., US Chamber of Commerce, supra note 6, at 6-12.
177 See e.g., Brief of IMS Health, Verispan and Source Healthcare Analytics, supra note 175, at 17 (condemning an attempt to limit detailing as an attempt to make it more difficult for drug companies and prescribers to have an intelligent conversation.”).
178 See Orentlicher, supra note 133, at 77 (arguing that it is, however, “very easy” for physicians to obtain alternative sources of education, such as through newsletter subscriptions or Internet searches).
179 Brief of IMS Health, Verispan and Source Healthcare Analytics, supra note 175, at 18.
180 Ibid.
is the optimal choice for a patient and that the doctor may not otherwise know to prescribe it. The pharmaceutical representatives could therefore inform the doctors on prescribing practices that benefit their patients. Furthermore, the meeting can allow drug manufacturers to obtain feedback from physicians on their patients’ experiences to be incorporated into the drug’s future development.

2.2.3 Legal Challenges

2.2.3.1 The United States

In the United States, efforts to limit pharmaceutical data mining practices culminated in a legal battle before the country’s Supreme Court. A New Hampshire state representative led the charge against selling prescriber information after learning that sales representatives used the data to target her husband. New Hampshire, Vermont, and Maine subsequently passed legislation restricting the dissemination of “physician-identifiable” prescribing information to varying degrees. Data miners and pharmaceutical manufacturers challenged each statute in court under the First Amendment.

In April 2011, the U.S. Supreme Court heard arguments over Vermont’s statute in the case of Sorrell v. IMS Health Inc. (Sorrell). The legislation prohibited health insurers, pharmacies, organizations transmitting electronic health information, and “other similar entit[ies]” from selling or licensing records where the prescribing physician was identified absent the prescriber’s

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181 Pharmaceutical Research and Manufacturers of America Brief, supra note 175, at 19-20.
182 Robb, supra note 162, at 1749.
183 Brief of IMS Health, Verispan and Source Healthcare Analytics, supra note 175, at 20.
184 See generally Sorrell, supra note 135.
185 Big (Brother) Pharma, supra note 160.
186 Mello & Messing, supra note 135, at 1248.
187 Ibid.
188 See generally Sorrell, supra note 136.
consent. Additionally, the parties listed could not provide records containing prescriber-identifiable information to be used for marketing. However, the statute carved out exceptions for selling or licensing the records to facilitate dispensing medication and insurance payments, research, informing the patient, law enforcement, and where the prescribing doctor is not identified.

The Court found that the Vermont statute impermissibly infringed upon the targeted companies’ free speech and thereby violated the First Amendment. Justice Anthony Kennedy, writing for the majority, held that the “creation and dissemination of information are speech within the meaning of the First Amendment.” By limiting the “availability and use of prescriber-identifying information,” the Vermont statute restricted free speech.

After finding that the statute limited free speech, the Court analyzed the state’s justifications for implementing the limitations. Justice Kennedy classified the justifications into two types of arguments. The first category included claims that the statute protected medical privacy, “including physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship.” The second group of arguments related to protecting “policy objectives—namely, improved public health and reduced healthcare costs.”

Justice Kennedy’s opinion emphasized that the state sculpted the law’s provisions to permit the sale and use of information in contexts it view favorably, while prohibiting it in others. Under

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189 Vt Stat, Ann Tit 18 sect 4631(d).
190 Ibid.
191 Vt Stat, Ann Tit 18 sect 4631(e).
192 See generally Sorell, supra note 135, at 2662-65.
193 Ibid at 2667.
194 Ibid.
195 Ibid at 2667-72.
196 Ibid at 2668.
197 Ibid.
198 See generally Sorell, supra note 135.
American jurisprudence, a statute is subject to higher judicial scrutiny where it imposes limitations based on the speaker and content of the speech.\textsuperscript{199} In this case, the statute did not truly protect physician privacy, Justice Kennedy reasoned, because it allowed pharmacies to share their prescribing histories “with anyone for any reason” except for marketing purposes.\textsuperscript{200} Additionally, the objective of preventing detailers from influencing doctors’ prescribing patterns could not justify the statute’s restrictions because any influence derived from the fact that doctors found the information to be convincing.\textsuperscript{201} Justice Kennedy noted that “[t]he fear that speech might persuade provides no lawful basis for quieting it.”\textsuperscript{202} He concluded that

\begin{quote}
[t]he State seeks to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers’ ability to influence prescription decisions. ... But the ‘fear that people would make bad decisions if given truthful information’ cannot justify content-based burdens on speech.\textsuperscript{203}
\end{quote}

Popular response to the Court’s ruling has been mixed. Some public health and privacy advocates are wary of the Supreme Court’s emphasis on protecting free speech at the expense of data control.\textsuperscript{204} Other commentators applaud the Court’s decision, noting that researchers

\begin{footnotes}
\item[199] \textit{Ibid} at 2664.
\item[200] \textit{Ibid} at 2668 (commenting that the analysis may have been different if the statute presented “a more coherent audience” but the numerous exceptions to the prohibition against sharing prescriber-identifiable information poked too many holes in the State’s justification).
\item[201] \textit{Ibid} at 2670.
\item[202] \textit{Ibid}.
\item[203] \textit{Ibid} at 2670-71 (2011).
\item[204] \textit{See} Mark Greenwold, “Evolving First Amendment Protections of Commercial Speech: Health Law Implications”, (Symposium delivered at the American University Washington College of Law 21 March 2013), [unpublished] (describing the \textit{Sorrell} holding as “very ominous” for public health regulations); Woodward, \textit{supra} note 154, at E510 (containing a discussion of the views of Marc Rotenberg, the executive director of the Electronic Privacy Information Center, who believes patients’ privacy is not respected by PDM). \textit{See also} Mello & Messing, \textit{supra} note 135, at 1251 (commenting that the justices that dissented in the \textit{Sorrell} decision feared that it would impugn officials’ ability to implement public health protections in the future).
\end{footnotes}
benefit from PDM companies having a financial incentive to collect the potentially useful data.\textsuperscript{205}

Yet the Sorrell ruling left room for the possibility that a more narrowly crafted law could successfully limit PDM practices.\textsuperscript{206} Meanwhile, drug regulators have focused their efforts on policing the products themselves, instead of their promotion.\textsuperscript{207}

\subsection*{2.2.3.2 Canada}

In Canada, legal challenges have questioned the privacy implications of selling prescriber information.\textsuperscript{208} In 2001, the Privacy Commissioner for Canada was prompted to investigate.\textsuperscript{209} Two individuals submitted complaints arguing that prescription data mining companies improperly utilized person information.\textsuperscript{210} However, the Privacy Commissioner announced that the practice was permissible under the \textit{Personal Information Protection and Electronic Documents Act (PIPEDA)}.\textsuperscript{211}

\begin{itemize}
\item \textsuperscript{205} Mello \& Messing, \textsl{supra} note 135, at 1251 (“These databases are used for purposes that benefit public health...[and PDM companies] might not invest in building prescription databases at all if their primary market evaporated.”).
\item \textsuperscript{206} See e.g., Christopher R. Smith, “Somebody’s Watching Me” (2012) Constitutional Constraints on State Health Care \& Privacy Regulation After Sorrell v. IMS Health Symposium, 36 Vermont L Rev 931, at 989-93.
\item \textsuperscript{207} Lindsay Wiley, “Evolving First Amendment Protections of Commercial Speech: Health Law Implications”, (Symposium delivered at the American University Washington College of Law 21 March 2013), [unpublished]
\item \textsuperscript{208} See e.g., Silversides, \textsl{supra} note 153, at E48 (detailing the Canadian Medical Association’s attempts to challenge the practice based on doctor’s privacy).
\item \textsuperscript{209} Privacy Commissioner Releases his Finding on the Prescribing Patterns of Doctors, \textsl{supra} note 143, at 1.
\item \textsuperscript{211} See generally Privacy Commissioner Releases his Finding on the Prescribing Patterns of Doctors, \textsl{supra} note 143.
\end{itemize}
**PIPEDA** is a federal statute that regulates the collection, use, and disclosure of personal information for commercial endeavors.\(^{212}\) Pursuant to **PIPEDA**, an organization cannot collect, use, or disclose personal information for purposes other than those reasonably related to the why the individual provided the information to the company, without the individual’s consent or other specific exceptions.\(^{213}\) **PIPEDA** defines personal information as, “information about an identifiable individual” other than his or her “name, title or business address” or the “telephone number of an employee of an organization”.\(^{214}\) Any province can implement its own information privacy legislation, as long as it is determined to be “substantially similar” to **PIPEDA**.\(^{215}\) Thus, even where **PIPEDA** does not apply, similar rules are imposed. In Ontario, the *Personal Health Information Protection Act, 2004*\(^{216}\) (PHIPA) governs health information.\(^{217}\) However, PHIPA is limited in scope to the protection of “identifying information”.\(^{218}\) The PDM data, with identifying information removed, would not be within its purview.

The Privacy Commissioner concluded that the prescribing practices of doctors does not constitute “personal information” and is therefore outside **PIPEDA**’s scope.\(^{219}\) He reasoned that the information disclosed “little or nothing about the physician as an individual” and therefore was beyond the purview of **PIPEDA**.\(^{220}\) Additionally, he cautioned that ruling otherwise would

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\(^{212}\) Office of the Privacy Commissioner of Canada, *Legal Information Related to PIPEDA- The Personal Information Protection and Electronic Documents Act (PIPEDA)*, online: <http://www.priv.gc.ca/leg_c/leg_c_p_e.asp.>.

\(^{213}\) *Personal Health Information Protection Act, 2004*, SO 2004, c 3 Sch A, at paras 5-7 [PIPEDA].

\(^{214}\) Ibid at sect 2.


\(^{216}\) PIPEDA, *supra* note 219.

\(^{217}\) Public Health Information Privacy and Confidentiality, *supra* note 221, at 98.

\(^{218}\) PIPEDA, *supra* note 219, at sec 4 (emphasis added).

\(^{219}\) See generally Privacy Commissioner Releases his Finding on the Prescribing Patterns of Doctors, *supra* note 143.

\(^{220}\) Ibid at 2.
chill consumer reporting on patterns discernable from “work products”. Opponents unsuccessfully sought judicial review to appeal the decision.

PDM is legal under federal law although there are limitations on the practices in some provinces. In 1996, the British Columbia Health Minister directed the College of Pharmacists, who regulate pharmaceutical practice in the province, to prohibit pharmacists from transmitting prescriber information. In 2003, the province of Alberta similarly barred the sale of doctors’ prescribing practices, calling it a violation of the province’s Health Information Act. Additionally, in Quebec, doctors are given the opportunity to opt-out of having their information collected by PDM companies.

Thus, despite some limitations imposed by provincial governments, PDM practices have been upheld in both United States and Canadian court challenges. Although it is possible that the legal stance may change in the future, for now PDM remains a strong industry. Therefore, policy makers should seek to use the information collected to the benefit of the public at large.

221 Ibid at 3-4.
222 Silversides, supra note 153, at E48.
225 Silversides, supra note 153, at E48.
226 See e.g., ibid (discussing the fact that Canada Pension Fund and the TPG Capital Investment Fund purchased IMS in 2010 for $5.2 billion and quoting Professor Khaled El Emam that the purchase “shows that the secondary use of health information is worth a lot of money...”).
3. Using Prescription Data Mining Information for Long-Term Post-Market Surveillance

As the discussion in the previous sections demonstrates, there is a booming market of health information, while the government lacks the necessary data to quickly identify and respond to the existence of unsafe or ineffective medicines. Additionally, government agencies have insufficient knowledge about the comparative cost-effectiveness of different medications. The information sold by prescription data mining companies has the potential to provide the Canadian government with the information it needs to effectively monitor pharmaceuticals if combined effectively with the government’s pre-existing resources.

3.1 Proposed Framework

The Canadian government should utilize the information compiled and analyzed by prescription data miners for post-market monitoring. Canada could require companies to supply a copy of all information and reports they purchase from pharmaceutical data mining companies. Alternatively, the government could collaborate directly with the PDM companies and acquire the results from the companies that compile the information. The two options are discussed in turn below followed by a discussion of some of their potential advantages and disadvantages.

Once the government obtains the information, it should analyze the data and systematically integrate the findings into the existing regulatory framework overseeing drug approvals and licensing. Computer programming should be put in place to employ effective data mining techniques on an ongoing basis to obtain the optimal benefit from the health information it holds. Properly structured systems may be able to reveal the true long-term effects of medications and their comparative cost-effectiveness.

A centralized database could be implemented using the infrastructure that has been created by the DSEN in collaboration with Health Canada. As discussed in Part II, the DSEN established “a

\[227\] Flood & Dyke, supra note 15, at 300.

\[228\] See infra Part III.A.3.
virtual network of linked Collaborating Centres in post-market pharmaceutical research”. 229 Combining the DSEN’s research with PDM reports would create an invaluable database with extensive health information. As will be discussed below, additional sources of information could further strengthen such a system.

The results elucidated from the proposed system could be used in a progressive licensing scheme. Although Health Canada has not yet implemented an ongoing drug monitoring system, the agency may do so in the future. 230 If a progressive licensing scheme is created, the proposed database could provide invaluable insight to inform continued analysis of drugs’ post-market performance and risks.

3.1.2 Options for the Government to Obtain PDM Data

3.1.2.1 Requiring Pharmaceutical Companies to Submit Data

One method for the Canadian government to acquire the PDM data would be to implement regulatory requirements obligating pharmaceutical manufacturers to provide the government with a copy of all reports, databases, or any other information the companies purchase from pharmaceutical data miners. To do so, Parliament could amend the Food and Drug Act to either grant a government agency, such as Health Canada, the requisite power to compel companies to send the reports, or could directly require it through the Act. This model would avoid any potential arguments that the government’s actions would expand PDM practices, since the information would be gathered exclusively from reports that were already created and disseminated.

Further, it is possible that such a requirement would discourage companies from ordering information from PDM companies. If a drug manufacturer sought to conceal information about their products’ risk or ineffectiveness, the company would not want to turn over PDM data to

229 About DSEN, supra note 115.

230 See e.g., Wiktorowitz et al, supra note 90, at 5 (“Although [Bill C-51] was ultimately withdrawn, Health Canada still appears to be committed to a system of progressive licensing.”).
Health Canada. This result would be deleterious to compiling a fully informed system. However, it would be seen as a boon to critics of PDM.

3.2.2.2 Collaborating with PDM Companies

A second option for acquiring health data would be for the regulatory agency Health to enter into a collaborative relationship with a PDM company. IMS Health, the predominant company involved in pharmaceutical data mining, boasts that it “regularly [collaborates] with leading health authorities, regulatory bodies, HTAs and government institutions to advance the use of health technologies.”231 Through these collaborations, IMS provides regulatory bodies with pertinent patient data and analytical assistance with health economics and outcomes research.232

3.2.2.3 Advantages and Disadvantages of the Two Options

There are advantages and disadvantages to the government from choosing either course of action to obtain PDM data. Purchasing the data from PDM companies is advantageous in avoiding legislative action. This option would also eschew any potential legal pitfalls. Critics could raise questions about the proper ownership of the health information contained in PDM companies’ databases and the records analyzing the data. Some may dispute the government’s ability to compel PDM companies to provide its data without compensation. A full analysis of these potential arguments is beyond the purview of this paper. These issues could likely be mitigated through the provisions of the legislation enacting the requirement. Yet collaborating with the companies and providing compensation would avoid this issue altogether.

Collaborating with PDM companies could potentially be a more expensive route. However, the cost may be offset by the fact that such a collaboration would supply the government with

232 Ibid.
assistance in monitoring and analyzing the relevant data. Additionally, some PDM providers offer reduced prices to access their information for research purposes.\(^{233}\)

If a collaboration is considered, the government should be cognizant of the potential that it could potentially expand pharmaceutical data mining practices instead of optimizing information that has already been aggregated. Opponents of the data mining practices would likely object to collaborating with the companies for this reason.

### 3.2.3 Additional Sources of Health Information

All information collected from the data mining companies should be tied to the MedEffect and DSEN systems. As discussed above, MedEffect allows patients and doctors to report adverse events.\(^{234}\) These reports contain “relevant information about the patient characteristics and details about the reaction(s) suspected to be associated with the health products(s), the general finding(s), the treatment and final outcomes.”\(^{235}\) However, the patient’s identity remains confidential.\(^{236}\) The database could therefore augment the information collected by PDM companies by highlighting drugs that cause adverse drug events more frequently and would provide more insight into the individual characteristics of affected patients.

The research promulgated through the DSEN should also be incorporated into the system to monitor drugs post-market approval. As discussed above, the DSEN funds $10 million of post-market drug research annually and established a virtual network to connect research results.\(^{237}\) Although the DSEN is run through the CIHR and not Health Canada, both agencies would benefit from working together to further research on pharmaceuticals’ post-market safety and

\(^{233}\) See e.g., IMS Health, *About IMS Health-Corporation Responsibility* (2013), online, IMSHealth.com: <www.imshealth.com> [About IMS Health Corporation Responsibility] (describing IMS Health’s commitment to providing lowered prices to researchers and commenting that the company also offers pro bono services at times).

\(^{234}\) Adverse Reaction Information, *supra* note 85,

\(^{235}\) *Ibid.*

\(^{236}\) *Ibid.*

\(^{237}\) Pharmacovigilance in Europe and North America, *supra* note 104, at 165.
efficacy. Health Canada could also engage DSEN researchers to provide any studies needed to make the database more effective.

Additional sources of health information could be added to enhance the system’s capabilities. Logically, the greater the amount of data included, the higher the likelihood of identifying drugs with adverse effects and evaluating effectiveness. Although this paper focuses on the long-term safety and effectiveness of pharmaceuticals, the data mining system could be structured for numerous purposes. Sources should therefore be identified based on the system’s goals.

**3.2.4 Identifying Safety and Effectiveness Concerns**

A computer database containing PDM results and DSEN research could allow the government to more quickly and effectively identify safety concerns with drugs currently on the market. The aggregated PDM data includes patients’ prescription histories, which indicates when a patient is taken off of a prescribed drug and given an alternative, and contains prescriber codes for the reason the medication was prescribed. Thus, it may be possible to discern trends such as which medication is prescribed the most frequently, which drugs patients are often switched off of and after how long, and whether physicians terminate the patient’s prescription for one consistent reason. Combined with insights obtained from research input to the DSEN network and MedEffect, it may be possible to identify which drugs are most effective and to highlight safety concerns as early as possible. Even where the system lacks sufficient data to provide conclusive answers, it could highlight areas of concern and help to direct future research.

According to IMS Health and Verispan, the information within their databases is already being utilized to identify drug interactions, by tracking reported adverse events and assessing prescriber-identifiable data. The information is also used to analyze long-term effects of drugs, particularly for patients with chronic diseases. Furthermore, it has helped in studies to

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238 *See e.g.*, Rodwin, *supra* note 12, at 587 (arguing that “[n]ational longitudinal patient data could be used to monitor and respond to public health problems” including “adverse effects from drug use.”).

239 *See* note 141 and accompanying text.

240 Opposition to HB 1346, *supra* note 149, at p.6.

determine safety concerns relating to withdrawal from the medication. One company specializing in technological analyses explains

[in pharmacovigilance applications, the [data mining techniques are] sometimes used to compensate for the disproportionate reporting patterns in spontaneous adverse reporting systems. Data mining tools were developed to enhance...signal detection procedures in large databases. They have been successful as methods for hypotheses generation; analyses of potential signals, and detection of complex dependencies... .

Thus, proper analysis techniques can highlight potential concerns with pharmaceuticals and direct future studies towards more conclusive results.

Computer programs to track adverse events have shown promise in fostering better detection. A study conducted using electronic patient records found that a properly structured computer program could accurately identify incidences of adverse drug reactions. The researchers found the computer programs only displayed “moderate sensitivity” in detecting health problems caused by prescribed drugs. However, they concluded that tailoring the search parameters could improve the identification rate. Additionally, the program could help to direct further inquiries into drug’s safety. As pharmacovigilance is becoming a staple of pharmaceutical

242 Ibid.
244 See generally Benjamin Honigman et al, “Using Computerized Data to Identify Adverse Drug Events in Outpatients” (2001) 8:3 JAMIA 254 (comparing computer-generated results with the findings of medical professionals with expertise in “adverse drug events” to find that the computer programs were able to pinpoint some of the adverse drug events) [Honigman].
245 Ibid at 263.
246 Ibid at 265.
247 Ibid at 254.
policies worldwide, programs to detect safety and efficacy concerns are evolving and improving.

### 3.2.5 Benefits of Proposed System

Obtaining information from PDM companies would provide the Canadian government with extensive data while respecting patient privacy. As CIHR explains, “[l]arge volumes of [health] data are generally needed in order to assemble unbiased samples from which health researchers can draw meaningful conclusions that are representative of populations.” Extensive sources of health information are therefore needed to draw accurate conclusions regarding a drug’s safety and effectiveness. The information collected through PDM can meet that need.

IMS Health is the leading PDM company in Canada. IMS reports that it gathers information from more than 40 billion health “transactions” annually from approximately 700,000 sites worldwide. IMS Health receives information from 100,000 data suppliers. The company’s information base contains data going back to 1958.

Access to such records could provide more reliable analysis than is possible from any data that could be collected in Canada alone. Additionally, since the patient identifying information

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248 Wiktorowitz et al, supra note 90, at 19-34 (providing an overview of the pharmacovigilance programs in the EU, US, UK, New Zealand, and France, and arguing that Canada needs strong post-market surveillance).

249 Chaterjee, Pannala & Chakraborty, supra note 251, at 3.

250 Zoutman, Ford & Bassili, supra note 151, at 1146.


253 About IMS Health, supra note 259.

254 Opposition to HB 1346, supra note 149, at 6.

255 See Adverse React Information, supra note 85 (noting that Canada must collaborate with other nations to identify drugs’ safety concerns, as “it is more difficult for a relatively small country” such as Canada to
has already been removed, PDM data respects patient privacy more than obtaining research information through alternative sources, such as patient records. Furthermore, the information would be obtained at low-cost to the federal government.

For these reasons, there are significant benefits to using PDM data to structure a system for health information analysis. There is also the possibility for the Canadian government to engage in PDM practices itself and collect health data from medical records and government reports. Further analysis of the potential benefits and issues may be warranted.

“generate and evaluate signals for rare adverse reactions” than the United States, which has a population “ten times higher than that of Canada”).
4. **Existing Pharmacovigilance Systems Using Data Mining**

Regulators and private organizations are increasingly using health information and computerized data analysis in order to make more informed and tailored decisions. Governments in the European Union, United States, the United Kingdom, New Zealand, and France have all recognized that “passive monitoring”, such as waiting for adverse events to be reported, is insufficient to identify unsafe or ineffective drugs. These nations have therefore implemented pharmacovigilance programs to provide better drug monitoring. Canada should learn from those nations’ experiences and could benefit from a similar program.

The United States has created a comprehensive data mining system for effective pharmacovigilance. The US Food and Drug Administration (FDA) launched a national program to collect and evaluate health information from across the public and private sectors. This program is called the “Sentinel System”. Sentinel will draw upon information compiled through electronic health systems containing patient records in addition to research and reports submitted to the FDA. The FDA will obtain further data by recruiting research centres to fill informational gaps.

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256 See *e.g.*, Ragas, *supra* note 260, at 2.

257 Wiktorowicz et al, *supra* note 90, at 4; see also *ibid* at 19-34 (providing an overview of the pharmacovigilance programs in the EU, US, UK, New Zealand, and France, and arguing that Canada needs strong post-market surveillance).

258 *Ibid* at 7 (suggesting that Canada should look to “increase the available evidence on drug safety and effectiveness available to regulators, and patients; and to increase capacity within Canada to undertake high-quality post-market drug safety and effectiveness research”).


262 *See* The Sentinel Initiative, *supra* note 88, at 5 (indicating that Sentinel will incorporate data from clinical studies and post-market studies on pharmaceuticals).

The Sentinel System will engage in active post-market surveillance by identifying what the FDA refers to as “safety signals.”\textsuperscript{264} The US Department of Health and Human Services (HHS) and FDA define a “safety signal” as “a concern about an excess of adverse events compared to what is expected to be associated with a product’s use.”\textsuperscript{265} HHS and FDA describe the initiative, saying

\begin{quote}
[i]n the Sentinel System, active surveillance will involve the use of sophisticated statistical and epidemiological methods to actively search for patterns in defined patient populations, such as insurance claims databases or electronic health record systems, which might suggest the occurrence of an adverse event or safety signal related to use of a medical product.\textsuperscript{266}
\end{quote}

Sentinel will query “the product’s clinical development program, postmarket studies of a product, ... postmarket adverse event reports”, and administrative health claims to pinpoint and verify the existence of safety signals.\textsuperscript{267} The FDA is planning not to hold any personally identifiable information in a central location.\textsuperscript{268}

Before implementing Sentinel, the US government launched two pilot projects to fine tune how the system will operate.\textsuperscript{269} Through “Mini-Sentinel,” twenty collaborating led by the Harvard Pilgrim Health Care Institute will test the “feasibility and utility of methodologies” to engage in post-market drug surveillance.\textsuperscript{270} A second pilot, the “Federal Partners Collaboration,”\textsuperscript{271} will include the FDA and the Centers for Medicare & Medicaid

\begin{footnotes}
\textsuperscript{264} The Sentinel Initiative, supra note 88, at 5.
\textsuperscript{265} Ibid.
\textsuperscript{266} Ibid at 6.
\textsuperscript{267} Ibid at 5.
\textsuperscript{268} Ibid at 12. The Sentinel System will use a “distributed approach,” where the health data will be held at the locations where it is collected. Ibid at 5. The FDA will send queries to the individual partners to run and the partners will return their findings to the FDA. Ibid.
\textsuperscript{269} Wiktorowitz et al, supra note 90, at 26.
\textsuperscript{270} The Sentinel Initiative, supra note 88, at 8.
\textsuperscript{271} Ibid at 8.
\end{footnotes}
Services. The two agencies will use Medicare data to analyze drugs’ post-market safety.

The Sentinel Initiative illustrates that data mining systems can be used for effective post-market surveillance of pharmaceuticals. These types of programs show promise for the future of pharmaceutical regulation. Canada could implement a similar program following the recommendations listed in this paper.

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272 Wiktorowitz et al, supra note 90, at 27.

273 Ibid at 27.
5. **Addressing PDM Criticisms**

Critics that condemn the current pharmaceutical data mining practices may object to further disseminating the information collected. However, since the data mining processes have mostly withstood the legal and ethical challenges leveled at them, it does not appear the industry will disappear. Even if future data mining practices were to be limited, it is doubtful that laws or regulations would affect the information the PDM companies currently hold, or that the companies would cease to benefit from their pre-existing databases. Therefore, it is better to utilize the information for the public’s benefit than to ignore its existence.

5.1 **Privacy**

Since personal health information is encrypted, using PDM data safeguards patient privacy more than alternative sources of information. Individual voices concern over patient privacy in relation to pharmaceutical data mining may object to companies further distributing the information. However, allowing the information to be sold by PDM companies but not using it to the public’s benefit would not benefit patients or safeguard their privacy. Furthermore, studies have shown that patient information that is properly de-identified gives rise to a “very small” risk that the data could be tied to a particular patient.

5.1.1 **The Health Insurance Portability and Accountability Act of 1996 and De-Identification Standards**

The dominant PDM companies are based in the United States and therefore must comply with health privacy standards established by the federal statute, the *Health Insurance Portability and

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274 See Secondary Use of Personal Information in Health Research, *supra* note 9, at 6 (listing potential sources of collecting health information including “personal interviews, analyses of tissue samples, results of scientific tests, physician, hospital and laboratory records, birth and death records, billing claims and employee records”, all of which would be connected to personally identifying information about the patient).


Accountability Act of 1996\textsuperscript{276} (HIPAA).\textsuperscript{277} Under HIPAA, “covered entities” cannot disclose personal health information about an individual without his or her consent.\textsuperscript{278} The HHS Office of Civil Rights explains that HIPAA

Protects all “individually identifiable health information” held or transmitted by a covered entity or its business associate... . “Individually identifiable health information” is information, including demographic data that relates to: the individual’s past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.\textsuperscript{279}

“Covered entities” include health plans, health care clearinghouses, health care providers that conduct electronic transactions.\textsuperscript{280} However, if health information is de-identified, it may be used and disclosed freely.\textsuperscript{281}

\begin{footnotesize}
\footnote{277}{As mentioned previously, the main company providing PDM services is IMS Health. Zoutman, Ford & Basili, \textit{supra} note 151, at 1146. IMS Health lists its “global headquarters” as Danbury, Connecticut. About IMS Health Corporation Responsibility, \textit{supra} note 240.}
\footnote{279}{United States Department of Health and Human Services Office of Civil Rights, “OCR Privacy Brief Summary of the HIPAA Privacy Rule” at 3, online: HHS.gov <www.hhs.gov/ocr/> [HIPAA Summary] (citing 45 CFR sect 160.103) (providing examples of “individually identifiable health information”, including a patient’s name, address, birth date, and Social Security Number).}
\footnote{280}{HIPAA, \textit{supra} note 287, at sects 160-164.}
\footnote{281}{HIPAA Summary, \textit{supra} note 288, at 4.}
\end{footnotesize}
HIPAA provides two possible methods to de-identify information. Pursuant to sect 164.514(b)(1), the “Statistical Standard”, the entity can properly de-identify information where

A person with appropriate knowledge of an experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable: (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and (ii) Documents the methods and results of the analysis that justify such determination.

Alternatively, under section 164.514(b)(2), an entity can use the “Safe Harbor” method. The Safe Harbor method entails removing eighteen specific personal identifiers and requires that the covered entity does not have actual knowledge that the information could be used to identify the individual it relates to. This Safe Harbor method was reviewed in 2010 to ensure that its protections covered modern technological advances. The

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283 E.g., Cavoukian & El Emam, supra note 3, at 2.

284 HIPAA, supra note 287, at sect 164.514(b)(1).


286 Ibid.

Statistical Standard outlined in section 164.514(b)(1) is usually used in relation to PDM information.\textsuperscript{288}

### 5.1.2 Security of De-Identified Information

The plain wording of section 164.514(b)(1) requires proof that the information presents a “very small” risk that the subject could be re-identified.\textsuperscript{289} The Safe Harbor Standard was similarly devised to provide stringent protections.\textsuperscript{290} Dr. Khaled El Emam, a specialist in personal health information privacy, and Jane Yakowitz, a professor of information privacy, point out that there is no known instance of anyone re-identifying HIPAA de-identified information in the “real world”\textsuperscript{291}

Opponents criticizing HIPAA de-identification standards as insufficient seem to base their arguments on hypotheticals or comparisons to privacy breaches in significantly different contexts.\textsuperscript{292} Researchers have conducted several studies to test the security of information that

\textsuperscript{288} See ibid at 6 (establishing that the “statistician method” is most commonly used in the pharmaceutical industry).

\textsuperscript{289} HIPAA, supra note 287, at sect 164.514(b)(1).

\textsuperscript{290} Guidance Regarding Methods for De-Identification, supra note 291 (acknowledging that it is possible to re-identify health information under the Safe Harbor Standard, but stating that the risk is “very small”).

\textsuperscript{291} Brief for El Emam & Yakowitz, supra note 284, at 4.

\textsuperscript{292} See e.g. generally, C. Christine Porter, “De-Identified Data and Third Party Data Mining: The Risk of Re-identification of Personal Information” (2008) 5 Shidler JL Com & Tech 3, at paras 7 & 8, online: \texttt{<http://digital.law.washington.edu/dspace-law/bitstream/handle/1773.1/417/vol5_nol_art3.pdf>} (citing “anecdotal evidence” as a basis for claiming that it may be possible to re-identify patient information, while conceding that a federal court opinion determined that the risks to patient privacy were “illusive); Brief for El Emam & Yakowitz, supra note 284, at 11 (discussing the \textit{amicus curiae} briefs filed in \textit{Sorell v. IMS} and finding that “virtually all of the citations have no relevance whatsoever to the immediate situation, because they do not address how the use or disclosure of Prescriber Data specifically compromises patient re-identification protections) (emphasis in original); “Brief for Genetic Alliance and the National Organization for Rare Disorders as \textit{Amici Curiae} in Support of Respondents”, (2011) \textit{Sorrell v. IMS Health, Inc.}, at 15-16, online: SCOTUSblog.com \texttt{<http://www.scotusblog.com/case-files/cases/sorell-v-ims-health-inc/>} (criticizing the articles cited by opponents of HIPAA de-identification, noting that the “only successful re-identification attack discussed” in an article against the respondents in \textit{Sorrell v. IMS} involved “a pre-HIPAA data set” that “could not have even approached compliance with the HIPAA de-identification standards” since birth dates and zip codes were left in the information, in breach of HIPAA rules).
had been de-identified under HIPAA’s standards. In one instance, the United States’ Health and Human Services Office of the National Coordinator for Health Information Technology assembled experts to attempt to re-identify HIPAA compliant patient records.\(^{293}\) The research team used records from only one health center and further narrowed the test by singling out one ethnic minority.\(^{294}\) By focusing on a specific minority group, the team sought to “increase the likelihood of an ‘easy’ match”.\(^{295}\) Yet, they were only able to accurately identify two individuals out of the 15,000 records canvassed.\(^{296}\) This amounts to a success rate of 0.013%.\(^{297}\) Similarly, a different expert estimated that there may be approximately a 0.04% chance of re-identification under HIPAA’s Safe Harbor Standard.\(^{298}\)

The Privacy Commissioner of Ontario notes that it is not possible to guarantee one hundred percent protection against potential privacy threats.\(^{299}\) However, she argues that, “under appropriate circumstances, it is also important to provide access to this information for vital secondary purposes that are strongly in the public interest.”\(^{300}\) She concludes that

[while de-identification may not be a perfect tool in preventing the disclosure of identifiable information, in all circumstances, de-identification will certainly prevent countless third parties, who in the vast majority of cases have neither the

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\(^{293}\) Brief for Dr. Khaled El Emam & Yakowitz, \textit{supra} note 284, at 8.

\(^{294}\) \textit{Ibid.}


\(^{296}\) \textit{Ibid}.

\(^{297}\) \textit{Ibid}.


\(^{299}\) \textit{Ibid} at 4.

\(^{300}\) \textit{Ibid.}
motivation, nor the technical expertise, nor the resources necessary to re-identify individuals, from knowing information about identifiable information.\textsuperscript{301}

HIPAA de-identification standards provide strong protections. However, if opponents feel that the privacy protections are not enough, more can be put in place. The Ontario or federal government could impose statutory protections above those required by \textit{PIPEDA}. For these reasons, concerns over patient privacy should not curtail beneficial uses of PDM information.

\textbf{5.2 Detailing}

As discussed in Part II of this paper, PDM practices have also been criticized for the information’s use in connection to detailing. Opponents are concerned that the information may be used to persuade doctors’ prescribing practices.\textsuperscript{302} However, if measures to limit PDM practices are truly targeted toward detailing, proponents should look to a more direct approach. Laws should be leveled at detailing itself, instead of the data informing it. Alternatively, regulations could place more stringent limitations on pharmaceutical companies’ tactics for persuading physicians.

Furthermore, the proposal contained in this paper would work to counteract the negative effects of detailing. The system could identify medications that are unsafe, allowing regulators to place restrictions on their use.\textsuperscript{303} Even if the medications remain on the market, the system’s discoveries could be disseminated to doctors to better inform their prescribing practices. Better educating physicians could neutralize any misleading or incorrect information that pharmaceutical representatives could provide. Additionally, where detailers are emphasizing new, blockbuster drugs, the potential harm that those drugs could bring about would be decreased by the added post-market surveillance.

\textsuperscript{301} \textit{Ibid} at 5.
\textsuperscript{302} \textit{See supra} notes 156-170 and accompanying text.
\textsuperscript{303} \textit{See supra} Part III.A.3.
6. **Conclusion**

As technology evolves, it brings opportunities to advance and protect our society. This paper envisions utilizing cutting-edge tools and techniques to better regulate Canadian pharmaceuticals. The Canadian government should acquire the health data currently held by companies involved in pharmaceutical data mining. Although PDM is controversial, the practice is ongoing and the information obtained should therefore be used to further national goals.

Collecting and analyzing health information could propel the pharmaceutical regulatory system forward and help to save countless lives.