Whose Data?
The Public Interest in Clinical Trial Information in Canada

by

Elizabeth May Stalker Rafferty

A thesis submitted in conformity with the requirements
for the degree of Master of Laws

Faculty of Law
University of Toronto

© Copyright by Elizabeth Rafferty 2017
Whose Data?
The Public Interest in Clinical Trial Information in Canada

Elizabeth Rafferty

Masters of Law
Faculty of Law
University of Toronto

2017

Abstract

Traditionally, the conception of clinical trial information has only recognized the commercial interest of the trial sponsor. This understanding has gradually shifted as the public interest in clinical trial information, which is grounded in the public contributions to the production of the information, has been recognized. The public interest is supported by the public health harms that can result when clinical trial information is kept confidential, and those public health harms reinforce the argument that the government’s lack of transparency with respect to clinical trial information is an infringement of the freedom of expression and rights to life, liberty and security of the person. This paper will evaluate Health Canada’s current regime and argue that the public interest supports increased transparency of clinical trial information. It will also review the policies of the European Medicines Agency to demonstrate where there is room for improvement in the Canadian experience.
Acknowledgments

Thank you to my advisor, Professor Trudo Lemmens at the University of Toronto, Faculty of Law, whose support and expertise added considerably to my experience at the University of Toronto and whose guidance allowed me to not go too far astray (hopefully).

Thank you also to my mother, father and sister for their unfailing encouragement and support, and for always wanting what’s best for me. When I doubted, they were there.
# Table of Contents

Acknowledgments........................................................................................................... iii  
Table of Contents............................................................................................................ iv  
1 Introduction....................................................................................................................... 1  
2 Interests in Clinical Trial Information ............................................................................. 3  
  2.1 The Commercial Interest in Clinical Trial Information ............................................. 5  
  2.2 The Public Interest in Clinical Trial Information ..................................................... 11  
    2.2.1 Clinical Trial Information is a Public Good .................................................... 11  
    2.2.2 Transparency in the Interest of Public Health ................................................. 14  
    2.2.3 Transparency to Fulfill Human Rights ......................................................... 22  
3 Health Canada and Trial Data ......................................................................................... 33  
  3.1 Health Canada’s Role ................................................................................................. 33  
  3.2 The Access to Information Regime ............................................................................ 36  
  3.3 Vanessa’s Law ............................................................................................................ 41  
    3.3.1 Disclosure pursuant to Section 21.1 of the FDA ............................................. 42  
    3.3.2 Disclosure of Confidential Business Information ........................................... 48  
4 The European Medicines Agency as a Model ................................................................. 51  
5 Conclusion ....................................................................................................................... 61
1 Introduction

For years, advocates have called for greater transparency with respect to clinical trial information. Traditionally, clinical trial information has been treated as proprietary and deserving of protection because of the commercial interests of the pharmaceutical company that ran the clinical trial. Gradually, the understanding of clinical trial information has shifted, as other interests in the information have been recognized, and as the implications of the proprietary treatment have become clear. Based on this shift in understanding, there has been a growing recognition of a public interest in clinical trial information which favours its disclosure. The public interest is grounded in the fact that the public has also contributed to the production of the data and the knowledge generated by the trial, and is supported by the harms that can result when clinical trial information is treated as confidential. As a result of the public health harms, and given the government’s role in regulating pharmaceuticals, there is an argument that the government’s lack of transparency with respect to clinical trial information is also an infringement of human rights. In Canada, government action must be in compliance with the Canadian Charter of Rights and Freedoms, and it could be argued that rights and freedoms guaranteed by the Charter, specifically the freedom of expression protected by s. 2(b) and the rights to life, liberty and security of the person protected by s. 7, support clinical trial information transparency. The public interest in clinical trials data, as supported by the public health and human rights arguments, supports Canada’s pharmaceutical regulator adopting a more transparent approach to clinical trial information.

Although Health Canada’s rhetoric has suggested that it supports transparency policies, it remains hesitant to release clinical trial information to the public when that information is obtained from a pharmaceutical company for the purposes of demonstrating safety and efficacy in connection with an application for marketing authorization. Until 2014, clinical trial information could only be obtained through the federal access to information regime, which had established policies and jurisprudence that clinical trial information was the property of the third party pharmaceutical company that provided the information to Health Canada. Then in 2014,

---

section 21.1 of the *Food and Drugs Act*\(^2\), which authorizes disclosure of clinical trial information, was enacted pursuant to Bill C-17, known as “Vanessa’s Law”. Although Vanessa’s Law was intended to promote transparency, Health Canada was responsible for implementing s. 21.1, and it has required those who receive the information pursuant to s. 21.1 to execute a confidentiality agreement which restricts what they can do with that information. Health Canada’s strict confidentiality requirements suggests that its embrace of transparency is nothing more than empty rhetoric.

Although there remain issues with the transparency policies of Health Canada, there has been a general trend towards greater transparency. The transparency trend is further supported by Health Canada’s decision in the spring of 2017 to begin public consultations on regulations that will govern the disclosure of confidential business information, a power which was also enacted as part of Vanessa’s Law. Health Canada released a white paper\(^3\) which provides that, once Health Canada has provided its final regulatory approval of a pharmaceutical, the clinical trial information with respect to that pharmaceutical will no longer be considered confidential business information, and so could be disclosed. Although the White Paper is the most liberal of Health Canada’s disclosure policies, it is still limited, in that it is a policy of reactive disclosure which requires someone to request the information from Health Canada. Ideally, Health Canada would adopt a policy of proactive disclosure, where information would be automatically made public, through Health Canada’s website, for example.

In contrast to Health Canada, the European Medicines Agency (the “EMA”) has adopted, and is in the process of implementing, a policy of proactive disclosure of clinical trial information. Since 2010, the EMA has adopted two policies and the European Union has enacted one regulation all of which explicitly reframe the balancing of commercial interests and public interests in favour of the public interests, based on the potential benefits of transparency for public health. The EMA has a longer history of transparency than Health Canada, and its

\(^2\) RSC 1985, c F-27 [*FDA*].

increased transparency has been shown to be effective in achieving some of the public health benefits scholars claim will result from disclosure, even if its transparency policies are not yet fully implemented. Although there are undoubtedly some flaws in the EMA policies and regulations, the European Union and the EMA can provide a model for how greater transparency can be implemented in Canada.

In discussing the above in greater detail, this paper will be divided into three additional sections. Section 2 will examine the two interests in clinical trial information, being the commercial interest claimed by the drug developers and clinical trial sponsors, which forms the traditional understanding of clinical trial information, and the public interest, which is based on the conception of clinical trial information as a public good and is supported by public health considerations and human rights arguments under the Charter. Section 3 of this paper will examine Health Canada’s role regulating pharmaceuticals as well as the regimes that are available to request disclosure of clinical trial information, specifically the federal access to information regime and the regimes enacted pursuant to Vanessa’s Law. Finally, Section 4 will provide a brief overview of some of the transparency measures that apply to the EMA, and how those measures can help increase transparency in Canada.

2 Interests in Clinical Trial Information

In the 1960s, when regulatory agencies such as Health Canada started assuming greater responsibilities for approving the sale of drugs, a private system for approval developed, with the regulatory process pausing and restarting as pharmaceutical companies amended their applications in response to the requirements of the regulators. Since those beginnings, both the pharmaceutical industry and the regulators have continued to treat clinical trial information as the confidential property of the manufacturer that submitted the information to the regulator. As a result, since evidence of safety and efficacy was first required by regulators like Health

---

5 Ibid.
Canada, that evidence has been presumptively treated as confidential and proprietary in the commercial interests of the pharmaceutical sponsors, demonstrating that, in the view of regulators, the overriding interest in clinical trial information is the private interest of the sponsoring pharmaceutical company. The presumption of confidentiality which has been in place for 50 years is deeply ingrained in the system.

In recent years, however, the literature around the disclosure of clinical trial information has started to recognize that there is a public interest in the data, which exists alongside the private interest; this public interest arises out of the fact the public invested in the development of the data and in the potential public health harms that exist as a result of the data being withheld. In turn, the potential harms also inform the argument that human rights are implicated when the clinical trial information is withheld by the government regulators who rely on that information in determining that a drug is sufficiently safe and effective to be sold in Canada. This section will argue that the public interest in the clinical trial information, informed by the nature of the data as a public good and the potential public health harms from confidentiality, both of which also implicate human rights, outweigh the private interest of the pharmaceutical sponsor, which is grounded in its commercial investment in the development of the data and the manufacture of the drug in question.

The private, commercial interest, and the three overlapping dimensions of the public interest, which I will frame in terms of the nature of clinical trial information as a public good, the public health considerations in disclosure, and the human rights justifications for transparency, will each be discussed in turn, although a full discussion of each dimension is beyond the scope of this paper.
2.1 The Commercial Interest in Clinical Trial Information

Pharmaceutical industry members who oppose transparency of clinical trial information do so on the basis of their commercial interest in the data, which can manifest in one of two ways: the drug manufacturer’s intellectual property rights and its competitive advantage.

Many drug developers claim that the results of clinical trials cannot be disclosed because disclosure will impinge on their intellectual property rights. One concern of pharmaceutical companies is that they will have to obtain their patents earlier if trial information is disclosed, or that disclosing outcomes could prevent them patenting their medicine.

The concern that public disclosure of clinical trial data will undermine intellectual property is a weak one. With respect to patent applications, for example, as soon as there is an expectation that the product or use in question is patentable subject matter, a patent application will typically be filed; the patent application thus occurs long before the product or use begins to be tested via clinical trials. There is added incentive to file a patent application earlier rather than later in Canada because the process for undertaking a clinical trial involves disclosing the intentions of the pharmaceutical company and disclosing details about the trial in question to a number of people and entities, including trial participants and ethics review boards. The patent application

---

6 The pharmaceutical industry has also raised other objections to the release of clinical trial information, including that disclosure may endanger clinical trial participants’ privacy, may lead to groundless litigation, may impose additional costs on the pharmaceutical industry, and may increase the risk of health scares because clinical trial information requires interpretation to be properly understood. See D So, Y Joly & BM Knoppers, “Clinical Trial Transparency and Orphan Drug Development: Recent Trends in Data Sharing by the Pharmaceutical Industry” (2013) 16 Public Health Genomics 322, DOI: 10.1159/000355941 (re: privacy, litigation, costs and misinterpretation concerns) and Trudo Lemmens & Candice Telfer, “Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency” (2012) 38 JL & Medicine 63 (re: costs and misinterpretation concerns).


8 Lemmens & Telfer, supra note 6 at 79.

9 See Trudo Lemmens & Ron Bouchard, “Mandatory Clinical Trial Registration: Rebuilding Public Trust in Medical Research” in Global Forum Update on Research for Health, Vol. 4: Equitable Access: Research Challenges for Health in Developing Countries (London: Pro-Book Publishing, 2007) 40, available online at: <https://ssrn.com/abstract=1083565> at 41; and Lemmens & Telfer, supra note 6 at 80; and Gabriele Spina Ali,
itself contains a great deal of information about the development and potential new uses of the drug, all of which will be made public once the application is submitted. In fact, the patent application contains more information than would be disclosed as part of a transparency measure with respect to clinical trial information, because the intention of the patent system is to promote transparency of innovations in exchange for the market exclusivity provided by the patent.\(^\text{10}\) While a patent is a right which grants the holder the ability to exclude others from utilizing an innovation for commercial purposes, clinical trial information contains no additional information on the medicine in question.\(^\text{11}\)

Others argue that transparency, whether disclosing trial data or regulatory decision-making, would result in a loss of competitive advantage to drug developers, and weaken incentives to develop new therapies.\(^\text{12}\) Drug developers are concerned that competitors could use disclosed clinical trial information to accelerate their own drug development programmes,\(^\text{13}\) either using the data to obtain regulatory approval for a similar drug in another jurisdiction where the original developer has not yet obtained approval, or using the trial information more generally as a template for how to secure regulatory approval for a similar drug, cutting the cost and time required to put together a successful application.\(^\text{14}\) Any drug developer who enters the market after the initial approval has been obtained could thus free-ride on the research and development investment of the initial drug developer, permitting the second company to market their pharmaceutical for a lower price that does not take into account research and development costs.\(^\text{15}\) Nevertheless, according to Peter Gøtzsche, there is no evidence to suggest that

\(^\text{10}\) See Lemmens & Bouchard, “Mandatory”, supra note 9 at 41-42; and Lemmens & Telfer, supra note 6 at 80.

\(^\text{11}\) Andanda, supra note 7 at 146-147.

\(^\text{12}\) Herder, “Jurisprudence”, supra note 4 at 248.

\(^\text{13}\) So, Joly & Knoppers, supra note 6 at 323.

\(^\text{14}\) Ali, supra note 9 at 27.

\(^\text{15}\) Ibid.
transparency of clinical trial data will negatively impact drug profitability and development, so this concern may be overblown.\textsuperscript{16}

The fear that transparency would result in a loss of competitive advantage ignores the fact that competitors can obtain much of the information through other means. Pharmaceutical companies already gather intelligence on competitors, including on their strategic developments, through corporate espionage, their contacts with patient advocacy groups and individuals seeking trials for specific therapies, the review of informed consent forms which must legally and ethically ensure that trial participants have a reasonably detailed understanding of the trial they are participating in, and the review of patent applications which disclose information about the pharmaceutical being studied, as discussed above.\textsuperscript{17} While it is undoubtedly less time consuming to procure the strategic information from disclosure by a regulator, it is not impossible for industry members to obtain that information by other means, in particular in light of the resources at the disposal of the pharmaceutical industry.\textsuperscript{18}

In addition, transparency policies are not inherently anti-competitive, given that all drug developers would be equally affected.\textsuperscript{19} The competitive advantage argument can also be used to support some of the more underhanded and problematic industry practices,\textsuperscript{20} which are described further below in Section 2.2.2 of this paper.

Importantly, the concern about the loss of competitive advantage only relates to commercial competitors, meaning it is irrelevant to the issue of disclosing information to independent researchers who may want to use the data for other research, or to conduct a meta-analysis or

\begin{itemize}
  \item \textsuperscript{16} Peter C Gøtzsche, “Why we need easy access to all data from all clinical trials and how to accomplish it” (2011) 12:249 Trials, available online at: <http://www.trialsjournal.com/content/12/1/249> at 7.
  \item \textsuperscript{17} See Lemmens & Bouchard, “Mandatory”, supra note 9 at 42; Ali, supra note 9 at 36-37; and Lemmens & Telfer, supra note 6 at 81.
  \item \textsuperscript{18} Lemmens & Bouchard, “Mandatory”, ibid.
  \item \textsuperscript{19} See Gøtzsche, supra note 16 at 7; and Lemmens & Bouchard, “Mandatory”, ibid.
  \item \textsuperscript{20} Gøtzsche, ibid.
\end{itemize}
systematic review of the data to study the product’s safety and effectiveness. As the concern only relates to competitive concerns, and not research more generally, it is illogical to use a concern in one arena to prevent disclosure for all possible uses of the data. More finely-tuned regulations can help prevent commercial misappropriation of the data, while permitting other uses; it is not an all-or-nothing proposition.

Although disclosure may in some circumstances allow a competitor to obtain regulatory approval in another jurisdiction by relying on that disclosed data, the market distortions and competitive unfairness described above are not inevitable. Regulatory protections could be crafted that would protect data from commercial misappropriation, by prohibiting the data from being used to support an application for marketing authorization, as is done in the European Union; by delaying disclosure until after a specified period of time has passed so that the initial drug developer can comply with regulatory requirements in other jurisdictions; or by limiting the information that is published so that the data can be independently reviewed but cannot be used to obtain marketing approval.

In addition to the regulatory protections that can be enacted, a number of intellectual property protections exist which prevent competitors from bringing their own drugs to the market, such as patent rights protecting the drug itself, data exclusivity with respect to the trial data, and market exclusivity for orphan drugs. The period during which a drug developer enjoys patent protection is designed to provide some compensation for the costs of bringing the drug to market, rewarding investment in innovation; intellectual property protections thus permit pharmaceutical companies to recoup their research and development costs. In fact, disclosure serves to fulfill the underlying bargain of those intellectual property protections, in particular the patent law protection. The Supreme Court of Canada described patent protection as follows:

21 Andanda, supra note 7 at 158.
22 See Section 4 below.
23 Ali, supra note 9 at 38-39.
25 Lemmens & Telfer, supra note 6 at 81.
“[p]atent protection rests on the concept of a bargain between the inventor and the public. In return for disclosure of the invention to the public, the inventor acquires for a limited time the exclusive right to exploit it.”

The trade-off between disclosure and protection permits the sharing of ideas, and the advancement of innovation; it allows others to work with the information while protecting the commercial interests of the inventor for a limited period of time. The same is true for clinical trial information. While it has been argued that data exclusivity is a sui generis form of intellectual property, that does not mean that data exclusivity should escape from a fundamental feature of the intellectual property regime, specifically that the monopolized information must be fully disclosed.

As with any intellectual property, protection of data is not an inherent right, but instead is a monopoly granted as a reward for innovative endeavours, and the cost for that monopoly is the public dissemination of the information.

Underlying the competitive advantage argument is the assumption that competition drives innovation in medical treatments, which is problematic in two significant ways. First of all, it ignores the fact that many major medical science breakthroughs have been the result of publicly-sponsored research. Secondly, it protects commercial interests as the overriding interest in clinical trial information, placing it above the public interest, which will be discussed below in Section 2.2.

The context within which clinical trial information is initially communicated to Health Canada also does not promote its being treated as confidential. The purpose of communicating clinical trial information to Health Canada is to provide scientific evidence that the drug for which regulatory approval is being sought is safe and effective. In order for the claims of safety and


27 Ali, supra note 9 at 46.

28 Ibid. In the international sphere, there is an additional issue of how the disclosure of clinical trial information might be supported by, or contrary to, international treaties such the North America Free Trade Agreement and the Trade-Related Aspects of Intellectual Property Rights Agreement. For a thorough discussion of the issues at stake, see Ali, supra note 9; Andanda, supra note 7; and Jerome H Reichman, “Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach” (2009) 13 Marquette Intellectual Property L Rev 1, available online at: <http://ssrn.com/abstract=1433392>.

29 Gøtzsche, supra note 16 at 7.
efficacy to be assessed scientifically, the methods and results of those trials must be reviewed, understood and re-tested. Only then can the results of the trial be truly understood and flaws or mistakes be exposed. The importance of disclosure for the scientific method will be discussed in greater detail in Section 2.2 below.

None of this is to argue that the sponsoring pharmaceutical company does not have an interest in the data: their contribution in developing the drug and running the trial in question should not be ignored. The fact that this contribution is already recognized and rewarded through intellectual property law is also significant, however. A regime that does not disclose clinical trial information on the basis that it is confidential business information does not recognize the public interest in that information. By only recognizing the commercial interest, without any concessions to the public interest, and without taking into account the protections that already exist for the commercial interest, the current regime makes no attempt to strike a balance between those interests. Pharmaceutical companies treat data sharing as an all-or-nothing proposition: either the information is released for all purposes or it is kept completely confidential. In reality, however, data sharing can be more nuanced through appropriate regulation, by prohibiting commercial uses, for example, or controlling when the data becomes public.

The commercial interest cannot be considered in a vacuum – the risk that a drug developer will lose a competitive advantage, as well as the speculative impact on innovative drug development, must both be weighed against the importance of ensuring that the public has access to clinical trial data. The issue is particularly fraught with respect to pharmaceuticals, given that the protection of commercial interests must be balanced against the promotion and protection of public health by ensuring the provision of safe and effective pharmaceutical products. There is no doubt that developing new drug therapies is valuable and desirable; nevertheless, it is difficult to argue that it is more important than promoting transparency and sharing important

30 Lemmens & Bouchard, “Mandatory”, supra note 9 at 42.
31 Andanda, supra note 7 at 163.
information, given that the risks are undefined and seemingly limited. The public health dimension will be explored further below in the next section.

2.2 The Public Interest in Clinical Trial Information

As was mentioned in the introduction, a public interest in clinical trial information has started to be recognized more recently. This public interest derives from the fact that clinical trial information can be viewed as a public good, based on the public’s investment in the clinical trial, both directly and indirectly, and because of the impact disclosure or non-disclosure can have on public health. As a result of these public health effects, human rights considerations are also implicated.

2.2.1 Clinical Trial Information is a Public Good

The public interest in clinical trial information is grounded in the fact that clinical trial information can be viewed as a public good, given that a number of individuals and entities other than the sponsoring pharmaceutical company contributed to the applicable clinical trial, and thus to the information that trial produced.

One way the public has invested in a clinical trial, whether that clinical trial is industry-sponsored or publicly-funded, is through the provision of trial participants. Individual trial participants undertake personal risk when participating in a clinical trial, the treatment being tested may not be fully understood, for example, or the participant may be selected into the control group of a placebo-controlled study. The trial sponsors may not fully understand or appreciate all risks at the outset of a trial. For many trial participants the risks are worth it, because even if the individual does not receive the treatment being studied, he or she

32 Lemmens & Bouchard, “Mandatory”, supra note 9 at 42.

33 See Andanda, supra note 7 at 159; and Gøtzsche, supra note 16 at 7.
nevertheless contributes to scientific knowledge more generally.\textsuperscript{34} It is only when a trial’s methods and findings are made broadly available, however, that the trial in question truly adds to scientific knowledge.\textsuperscript{35} When the methods and findings of a clinical trial are made public, information is available to other researchers for further study, making the most out of the contributions of the participants in the initial trial. All research that involves human subjects relies on those subjects’ altruism in recruiting participants;\textsuperscript{36} given the importance of disclosure for expanding scientific medical knowledge, that altruism is best rewarded when the results of the trial are disclosed.\textsuperscript{37} By not disclosing less-favourable results and adverse events, on the other hand, pharmaceutical sponsors could be seen as exploiting participants for commercial or career gains.\textsuperscript{38}

It is particularly important that clinical trial information gathered for a trial that was discontinued for any reason be disclosed, because it is unlikely that a discontinued trial will be published in a peer-reviewed journal, making it even more difficult for other researchers to avoid making the same mistakes and exposing new trial participants to known harms. It is easier to protect not only patients receiving the treatment as part of their care but also participants of future clinical trials when the clinical trial information is made available to the public; non-disclosure of clinical trial information, on the other hand, can expose patients to ineffective treatments and trial participants to unnecessary risks.\textsuperscript{39}

In light of the expectation by trial participants that they are contributing to medical knowledge more generally, it is unethical not to release particulars of clinical trials, as the covenants

\begin{enumerate}
\item See Nav Persaud & Peter Doshi, “North American regulatory agencies can and should make clinical trial data publicly available” (2016) 188:2 Can Medical Assoc J 96 at 96; and Kay Dickersin & Drummond Rennie, “Registering Clinical Trials” (2003) 290:4 J American Medical Assoc 516 at 517.
\item Persaud & Doshi, ibid.
\item Lemmens & Bouchard, “Mandatory”, supra note 9 at 40.
\item Ali, supra note 9 at 30.
\item Andanda, supra note 7 at 161.
\item Persaud & Doshi, supra note 34 at 96.
\end{enumerate}
between the researcher and the trial participant, and between the ethical review board that
approved the trial and the trial participant, are broken when the trial data is not disclosed
publicly.\footnote{Dickersin & Rennie, supra note 34 at 517.} The most recent Declaration of Helsinki imposes an obligation to release clinical trial
information on researchers, stating in s. 36 that “[r]esearchers have a duty to make publicly
available the results of their research on human subjects [...] Negative and inconclusive as well
as positive results must be published or otherwise made publicly available.”\footnote{“Declaration of Helsinki: Ethical principles for medical research involving human subjects”, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, most recently amended by the 64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013, online: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.} By not doing so, the researchers are failing to fulfil their ethical duties.

In addition to the contributions of trial participants, the public interest in clinical trial information
also stems from the public investment in research, both directly and indirectly.\footnote{See Trudo Lemmens, “Pharmaceutical Knowledge Governance: A Human Rights Perspective” (2013) 31:1 JL Med & Ethics 163 at 170; and Andanda, supra note 7 at 159.} Public funds have been used to directly invest in research through organizations such as the Canadian Institutes of Health Research. The public has also indirectly invested in research by providing necessary infrastructure for trials, whether those trials are publicly-funded or industry-sponsored.\footnote{See Andanda, supra note 7 at 159; and Gøtzsche, supra note 16 at 7.} Some of that infrastructure takes the form of biobanks, which often rely on governmental investment for their development and which are used by both academic and commercial researchers.\footnote{Lemmens, “Knowledge”, ibid at 170.} Governments also invest in research by providing tax breaks and training programs for researchers, and by providing science education more broadly.\footnote{Ibid.} Taxpayers not only contribute to research through their taxes, but also by purchasing pharmaceuticals. Publicly-funded or publicly-subsidized healthcare systems are among the largest purchasers of pharmaceutical products, and thus provide a steady stream of income to the

\begin{footnotesize}
\begin{enumerate}
\item \footnote{Dickersin & Rennie, supra note 34 at 517.}
\item \footnote{“Declaration of Helsinki: Ethical principles for medical research involving human subjects”, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, most recently amended by the 64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013, online: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.}
\item \footnote{See Trudo Lemmens, “Pharmaceutical Knowledge Governance: A Human Rights Perspective” (2013) 31:1 JL Med & Ethics 163 at 170; and Andanda, supra note 7 at 159.}
\item \footnote{See Andanda, supra note 7 at 159; and Gøtzsche, supra note 16 at 7.}
\item \footnote{Lemmens, “Knowledge”, ibid at 170.}
\item \footnote{Ibid.}
\end{enumerate}
\end{footnotesize}
pharmaceutical industry. The public healthcare system also helps protect the pharmaceutical industry from some of the costs of undertaking clinical trials by looking after the health of trial participants, including those harmed in the course of the trial.

An important feature of public goods is the fact that the value of the good is not reduced because someone benefits from it; this feature is true of clinical trial information, as recognizing the public interest does not have a detrimental impact on other interests in that information, including the interests of those who hold the underlying intellectual property rights for either the products themselves or the processes used to create those products. Given the public’s contributions to, and investment in, the development of pharmaceuticals, an expectation that there would be a degree of reciprocity and benefit sharing by the pharmaceutical industry is not unreasonable, at the very least by sharing knowledge and providing access to the information held by industry. Section 2.2.2 below will further examine how disclosure permits a better understanding of the safety and effectiveness of medical interventions, thus providing a societal benefit.

2.2.2 Transparency in the Interest of Public Health

The argument that there is a public interest in clinical trial information is bolstered by the fact that public health harms are more likely to result when clinical trial information is not disclosed. Public disclosure of clinical trial information can be used to hold pharmaceutical companies to account for the claims they make with respect to particular pharmaceuticals, and the regulators to account for drugs they have approved; it allows independent researchers to review the information, including as part of a meta-analysis which looks at the results of a number of

46 Ibid. See also Gøtzsche, supra note 16 at 7.
47 Gøtzsche, ibid.
48 Reichman, supra note 28 at 51.
49 Ibid at 51-52.
50 Lemmens, “Knowledge”, supra note 42 at 170.
different studies to look for patterns across all studies, including patterns that may be too subtle to be revealed in any single study.

The requirement that pharmaceutical company sponsors provide regulators with evidence that a product is safe and effective created a clinical trial industry. While those regulatory requirements did remove many flawed products from the market, they also concentrated knowledge production in pharmaceutical companies that not only have a financial interest in the knowledge produced but who also became almost exclusive producers of that knowledge, giving them control over clinical trial data and the opportunity to develop sophisticated ways of misrepresenting that data. Industry was thus left free to market their products as though the fact that they have not released any data showing evidence of harm from the use of a product is the same as there being evidence that there is no harm in using a product. Not only does the pharmaceutical industry have a monopoly over the production of clinical trial information, but it also has a vested interest in ensuring that the drugs it produces are shown to be safe and effective; it is only by demonstrating that a product is safe and effective that it can receive marketing approval by regulators such as Health Canada, and that the product can be sold in the jurisdiction in question.

Pharmaceutical companies thus have a vested financial interest in the outcome of clinical trials which often results in deficiencies in the data produced by industry-run or industry-sponsored trials. Studies have repeatedly shown manipulation, misrepresentation and misleading use of clinical trial data by the pharmaceutical industry. Research that is sponsored by the pharmaceutical industry is more likely to be biased and yield positive results, that is, to support the preferred outcome of the sponsor, than independent research. The results of a clinical trial

---

51 Ibid at 173.
52 Ibid at 174.
54 Lemmens, “Knowledge”, supra note 42 at 174.
55 See Lemmens & Gibson, supra note 53 at 956; and Lemmens & Telfer, supra note 6 at 92.
can be biased in a number of ways, including through the design of the trial, the recruitment of participants, the statistical analyses used, the exclusion of negative findings or over-inclusion of positive findings, changing the timing of the study, removing individuals from the experimental group, or being biased in interpreting the results. While there may be a number of factors which explain why these biases exist, the financial interests associated with selling pharmaceuticals is clearly part of the explanation.

Industry also takes advantage of a number of manipulative publication practices which distort the medical literature, such as underreporting negative data; spinning data by presenting neutral or negative studies as positive studies; repetitively publishing single studies to boost the perception that a drug is safe and effective; over-emphasizing smaller but positive studies while ignoring evidence that runs contrary to the desired outcome; and using established academics to ghost-write publications, and thus increase the credibility and appearance of independence of a study. Academics face a number of incentives to take part in practices such as ghost-writing articles, including receiving payments from industry for agreeing to be identified as an author and being able to add a peer-reviewed publication to their CV, which is increasingly important in the publish-or-perish culture of academia. For their part, peer-reviewed journals control which studies are accepted for publication and which are not, and so can also incentivize some underhanded practices. As more interesting results are generally seen as more publishable, it is


57 Lemmens & Telfer, *ibid* at 92-93.

58 Separate from the issue of manipulative publication practices is the issue that not all studies are published. The selective publication of trials is known as “publication bias”, and its effects can be lessened by mandating that all clinical trials must be registered. A full discussion of the importance of trial registration in the interests of transparency, and how it can counteract publication bias is beyond the scope of this paper. See Dickersin & Rennie, *supra* note 34; So, Joly & Knoppers, *supra* note 6; and Herder, “Jurisprudence”, *supra* note 4.

59 See Lemmens & Telfer, *supra* note 6 at 93; and Ross, Gross & Krumholz, *supra* note 56.

60 Lemmens, “Knowledge”, *supra* note 42 at 175.
not surprising that some researchers may misrepresent or manipulate the protocol or results of a study in order to arrive at a more interesting, and consequently more publishable, result.\textsuperscript{61}

Manipulation or misrepresentation of data by the pharmaceutical industry can produce bad information which, together with their aggressive marketing practices, has led to a range of health risks.\textsuperscript{62} Almost all major pharmaceutical companies have been associated with the problematic promotion of drugs that have caused significant injuries and even death.\textsuperscript{63}

Disclosure of clinical trial information that was used by regulators to determine whether a pharmaceutical product is sufficiently safe and effective for sale also holds the regulators accountable for their regulatory decisions. Independent researchers are equipped to discover errors in a regulator’s assessment of a particular pharmaceutical.\textsuperscript{64} Regulatory agencies are under political pressure to make their licensing decisions quickly, increasing the risk that the quality of their review of the evidence provided, and thus patient safety, will suffer in the interest of speed; Peter Gøtzsche, for example, notes that 5.3\% of the drugs approved between 1997 and 2000 were later withdrawn from the market due to the risk of serious harm, up from 1.6\% of the drugs approved between 1993 and 1996.\textsuperscript{65} Not only might a regulator’s ability to make a good decision be affected by pressure to make that decision quickly, their decision-making might also be affected by lobbying by the pharmaceutical industry.\textsuperscript{66}

There are a number of benefits associated with disclosure of clinical trial information. For one thing, it would mean that there were fewer incentives to cheat by misrepresenting or manipulating data because others can check trial methods and conclusions against the raw trial

\textsuperscript{61} \textit{Ibid.}

\textsuperscript{62} Lemmens & Gibson, \textit{supra} note 53 at 946.

\textsuperscript{63} Lemmens, “Knowledge”, \textit{supra} note 42 at 165.

\textsuperscript{64} Ali, \textit{supra} note 9 at 28.

\textsuperscript{65} Gøtzsche, \textit{supra} note 16 at 5.

\textsuperscript{66} Ali, \textit{supra} note 9 at 29.
data and protocol.\textsuperscript{67} As is noted by Nav Persaud and Peter Doshi, “[f]ailing to disclose clinical trial data publicly supports unethical research conduct”.\textsuperscript{68} Transparency can therefore help redress some of the issues described above that result from the pharmaceutical industry having control over clinical trials and the resulting data. It can be used to hold the pharmaceutical industry accountable for the claims they make with respect to the safety and efficacy of their products by permitting the verification of results, thereby preventing marketing from having a disproportionate effect on clinical practices.\textsuperscript{69} Transparency also prevents pharmaceutical companies from designing, conducting and reporting clinical trials so that they can be used as a marketing tool, rather than as a source of information on safety and effectiveness.\textsuperscript{70} In evaluating developer’s claims, independent researchers can use the raw data to perform a meta-analysis, which is a more reliable method of evaluating treatments than when a meta-analysis relies on data summaries.\textsuperscript{71}

Essentially, clinical trial transparency permits the scientific method to operate as intended, with subsequent researchers reviewing, questioning, re-analyzing and re-testing the results of the initial trial. It allows more information to become available about the true benefits and potential harms of pharmaceutical treatments, which promotes better decision-making about healthcare.\textsuperscript{72} By permitting the verification of results, and disincentivizing unethical behaviour, both physicians and patients are able to make informed and evidence-based medical decisions.\textsuperscript{73} Peer review and independent scrutiny are the foundation of the scientific method. The commitment to

\textsuperscript{67} Lemmens & Gibson, supra note 53 at 975. See also Andanda, supra note 7 at 171.

\textsuperscript{68} Persaud & Doshi, supra note 34 at 97.

\textsuperscript{69} So, Joly & Knoppers, supra note 6 at 323.

\textsuperscript{70} Lemmens & Telfer, supra note 6 at 93.

\textsuperscript{71} Andanda, supra note 7 at 171. See also Gøtzsche, supra note 16 at 5.

\textsuperscript{72} See Andanda, ibid; and Lemmens & Gibson, supra note 53 at 975.

\textsuperscript{73} So, Joly & Knoppers, supra note 6 at 323.
open and disinterested skeptical inquiry are what legitimates scientific knowledge and thus leads to scientific progress.  

Transparency would also permit the use of existing data to answer new research questions, and to stimulate follow-on research and innovation. Data sharing can reveal new trends, and enable further research; pre-existing data is often extremely useful in developing drugs for rare diseases, for example, partly because there are a limited number of patients who suffer from the disease and those patients may have a shorter lifespan. Independent review of clinical trial information might reveal new information about the drug’s characteristics, highlighting risks that were not evident before, and potentially causing the dosage or label to be changed or the drug to be removed from the market altogether. Healthcare research would also become more efficient, because a number of questions can be answered using the same, existing data, meaning that researchers would not have to spend the time and money to collect new data. Currently, there is an artificial scarcity of clinical trial information, which not only hampers public health efforts, but also the industry’s ability to develop drugs efficiently. At its most basic, science is the accumulation of information, and clinical trial information transparency would add to that cumulative knowledge, permitting follow-on innovation, providing the opportunity to find secondary medical uses, and providing valuable information for understanding how the human body works and how drugs are absorbed.

74 Herder, “Jurisprudence”, supra note 4 at 249-250.
75 Andanda, supra note 7 at 171.
76 Reichman, supra note 28 at 52.
77 So, Joly & Knoppers, supra note 6 at 323.
78 Ali, supra note 9 at 28.
79 Lemmens & Gibson, supra note 53 at 975.
80 Lemmens & Telfer, supra note 6 at 90. The lack of information on failed trials also contributes to this artificial scarcity of clinical trial information. Although the disclosure of failed trials can be increased by requiring registration of all trials prior to their commencement, a full discussion of trial registration as a transparency measure is beyond the scope of this paper. See Gøtzsche, supra note 16.
81 Ali, supra note 9 at 29.
Decision-making can also be improved in a variety of ways through clinical trial transparency. It can improve regulatory decision-making by opening up the reasoning behind the decision to independent scrutiny from disinterested third parties, rather than the reasons only being available to those who have a direct stake in the decision. Transparency can assist drug regulators to better fulfill their role as guardians of the public’s health by increasing the number of people who can review clinical trial data, which permits a more thorough review than the regulators would be able to undertake on their own.

Transparency also improves healthcare decision-making. The best decisions are made when the best evidence is available, and independent review ensures that the evidence is rigorously tested and claims are confirmed. Ensuring the availability of information about the safety and efficacy of pharmaceuticals is essential to making sure that the prescription and consumption of pharmaceuticals is appropriate, and drug prescriptions are more accurate when physicians have a better understanding of how a drug functions. The transparency of clinical trial information can therefore not only promote certainty that a product is safe and has therapeutic value, it can also provide better guidance for clinical practices. This permits limited healthcare resources to be allocated in a rational way, as decisions can be made using evidence that has been tested and confirmed, and researchers are not required to duplicate trials unnecessarily, which costs both time and money.

Following the H1N1 flu outbreak, for example, Tamiflu was promoted as reducing influenza-related complications. Billions of dollars were spent stockpiling Tamiflu around the world, including over $1 billion in the United States, notwithstanding the fact that the US Food and Drug Administration challenged the manufacturer’s claims that Tamiflu reduced complications. The Food and Drug Administration’s assessment is now supported by other analyses, which raise doubts about the reliability of the manufacturer’s synthesis of the data, which formed the basis of the decision by a number of public health agencies to stockpile the

---

82 Lemmens & Telfer, supra note 6 at 95.
83 Ali, supra note 9 at 30.
84 Reichman, supra note 28 at 52.
85 Gøtzsche, supra note 16 at 5.
drug. Partly as a result of the new evidence which suggests Tamiflu may not be as effective as previously thought, the World Health Organization downgraded Tamiflu from a core drug to a complementary drug, a category used for less cost effective drugs.

When clinical trial information is not disclosed, a significant amount of information is wasted because it is inaccessible, and trials can be unnecessarily duplicated. As approximately 95% of all drugs that enter clinical trials fail to reach the market; the knowledge collected in connection with those drugs is lost, even if that knowledge involves years of research and hundreds or thousands of research participants. If the drug in question has been submitted to a regulator, that regulator will have access to a trove of information which can be useful, even if the drug never received marketing authorization. When there is a lack of transparency, not all information will be publicly known, even if that information is held by a government regulator. The knowledge base is therefore incomplete, potentially resulting in redundant research, which is not only wasteful and unnecessary but also exposes trial participants to potential harm. Given the risks that participants are exposed to, it is unethical to run new trials which simply duplicate existing trials for which the data has not been disclosed.

The arguments set out above with respect to how a lack of transparency of clinical trial information can contribute to public health harms within society add an additional dimension to the public goods nature of clinical trial information, and the public interest in that information.

86 Lemmens, “Knowledge”, supra note 42 at 165.
88 Dickersin & Rennie, supra note 34 at 520.
89 Herder, “Jurisprudence”, supra note 4 at 248.
90 Gøtzsche, supra note 16 at 5.
91 Dickersin & Rennie, supra note 34 at 518. See also Herder, “Jurisprudence”, supra note 4 at 248.
92 See Andanda, supra note 7 at 143; and Ali, supra note 9 at 30.
Given the potential consequence of non-disclosure, there is also an argument that human rights considerations support government regulators making clinical trial information publicly available. I will now turn to consider potential human rights claims.

2.2.3 Transparency to Fulfill Human Rights

Many have argued that access to clinical trial information is necessary for the fulfillment of “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” guaranteed by article 12.1 of the *International Covenant on Economic, Social and Cultural Rights*. Although Canada ratified the ICESCR, Chief Justice McLachlin and Justice Major in the Supreme Court of Canada decision *Chaoulli v. Quebec (Attorney General)* note that “[t]he Charter does not confer a freestanding constitutional right to health care”. Although there is no right to health, other rights guaranteed by the Charter support the disclosure of clinical trial information held by Health Canada. Before considering how the Charter might require the disclosure of clinical trial information, it must first be determined whether or not the Charter applies to the information.

Pursuant to s. 32(1) of the Charter, the Charter applies to the Parliament and the government of Canada, and the legislature and government of each province. The Charter therefore clearly applies to government, but clinical trial information was not developed by a government actor; it was developed by an independent third party. Nevertheless, it could be argued that the Charter should apply to the information because a government actor, Health Canada, relied on that information when granting or withholding regulatory approval for a pharmaceutical product. Because the information was central to the government’s decision in performing a regulatory function, the Charter should apply to ensure that the government action was consistent with the rights guaranteed by the Charter.

Notwithstanding the fact that there is no freestanding right to health protected by the Charter, two other Charter rights are implicated by the failure to disclose clinical trial information: the

---


right to freedom of expression and the rights to life, liberty and security of the person. The right to freedom of expression is protected by s. 2(b) of the Charter, and is implicated because the reporting of clinical trial results can be an expressive activity. The rights to life, liberty and security of the person are protected by s. 7 of the Charter, and are implicated because the information that is being withheld relates to the safety and efficacy of medical interventions, and therefore may affect not only the health of patients, but also the patient’s personal autonomy and ability to provide informed consent to the treatment. While the implication of each of these rights will be considered in turn, a full analysis of whether any infringement could be justified pursuant to s. 1 of the Charter\textsuperscript{95} is beyond the scope of this paper because it is impossible to undertake that analysis in the abstract.

\subsection*{2.2.3.1 Freedom of Expression}

Pursuant to s. 2(b) of the Charter, freedom of expression is a fundamental freedom which is held by everyone. The Supreme Court of Canada considered the relationship between freedom of expression and the right of access to information in its 2010 decision \textit{Ontario (Public Safety and Security) v. Criminal Lawyers’ Association}.\textsuperscript{96} In a unanimous decision, the Supreme Court concluded that, while s. 2(b) guarantees freedom of expression, it does not guarantee access to information, so there is no guarantee of access to all documents held by the government.\textsuperscript{97} Nevertheless, the Court recognized that access to information is a derivative right of freedom of expression, and that s. 2(b) does include a right to access documents when that access is “necessary to permit meaningful discussion on a matter of public importance, subject to privileges and functional constraints.”\textsuperscript{98} Freedom of expression therefore guarantees the right to access information held by the government where: (1) the matter the documents relate to is of

\begin{footnotes}
\item[95] Section 1 of the Charter provides that the rights guaranteed by the Charter are “subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society”. Section 1 is therefore a limiting provision, pursuant to which the government can demonstrate that an infringement of a Charter right is justifiable.
\item[96] 2010 SCC 23, [2010] 1 SCR 815 [CLA].
\item[97] \textit{Ibid} at para 30.
\item[98] \textit{Ibid} at paras 30-31.
\end{footnotes}
public importance; and (2) a meaningful discussion of the matter is only possible by having access to the documents. The Supreme Court of Canada provided clarity about derivative rights in *Ontario (Attorney General) v. Fraser*\(^9\) in the context of collective bargaining and the s. 2(d) right to freedom of association. In *Fraser*, the Court held that the exercise of the right itself is impaired by denying the derivative right, because that denial renders the original right itself effectively useless.\(^10\) The derivative right must be a necessary precondition for the exercise of the fundamental freedom.\(^11\) The connection between access to information and freedom of expression has also been explicitly recognized in international law,\(^12\) supporting the conclusion of the Supreme Court of Canada in *CLA*. Nevertheless, the derivative right of access is not unlimited: it can be limited when other interests outweigh the interest in releasing the information, such as when the information is subject to solicitor-client or other privileges.

Citing previous Supreme Court decisions, the Supreme Court in *CLA* set out the test for determining whether freedom of expression had been infringed. Under the test, the following must be determined: “(1) Does the activity in question have expressive content, thereby bringing it within the reach of s. 2(b)? (2) Is there something in the method or location of that expression that would remove that protection? (3) If the activity is protected, does the state action infringe that protection, either in purpose or effect?”\(^13\) When determining that the activity has expressive content in the context of obtaining access to government-held documents, and therefore that it falls within the scope of s. 2(b) pursuant to the first branch of the test set out above, the Supreme Court confirmed that, if the claimant establishes “that the denial of access effectively precludes meaningful commentary”, the claimant will have established a *prima facie*

\(^9\) 2011 SCC 20, [2011] 2 SCR 3 [*Fraser*].
\(^10\) *Ibid* at para 54.
\(^11\) *CLA*, *supra* note 96 at para 30.
\(^12\) Lemmens & Telfer, *supra* note 6 at 102. See article 19(2) of the *International Covenant on Civil and Political Rights* (G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, 999, U.N. Doc. A/6316, at 52 (Dec. 16, 1966)) which states that “[e]veryone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and all kinds of ideas […]”
\(^13\) *CLA*, *supra* note 96 at para 32.
Essentially, the claimant will have established a rebuttable presumption that the documents should be released, which can be rebutted if the second branch of the s. 2(b) test applies, that is, if there are factors in the case that remove the protection of s. 2(b), such as the documents being protected by privilege or if releasing the documents interferes with the ability of the government institution in question to properly function. If the claimant establishes the *prima facie* case, and there are no reasons that the s. 2(b) protection should be removed, the final question is whether the government action infringes s. 2(b) protection, as set out in the third branch of the s. 2(b) test.

According to the Supreme Court, when a demand is made for access to a government document, in order for s. 2(b) to be implicated, the purpose of access must be to further a discussion on a matter of public importance. Because not every demand for government information fulfills that purpose, that there is no general constitutional right of access to information. Access to the applicable information must be “necessary for the meaningful exercise of free expression on matters of public or political interest”. As set out above in Section 2.2.2, it is only through disclosure of clinical trial information that the conclusions and analysis of a trial can be independently confirmed. There are public health implications to being able to verify the claims made by pharmaceutical companies considering the tendency of pharmaceutical companies to manipulate or mispresent the results of clinical trials in order to ensure that drugs receive regulatory approval quickly. The potential deficiencies in the data produced by industry-run or industry-sponsored trials, coupled with the pressures on regulators like Health Canada to quickly approve drugs, can mean that drugs which have not been thoroughly reviewed and which are potentially harmful may nevertheless receive regulatory approval; a thorough analysis of the safety and efficacy of a pharmaceutical is only possible when all information on a product is

---

104 *Ibid* at para 33.
available and analysed, preferable with raw data. As a result, denying disclosure would impair the ability of independent researchers to exercise their freedom of expression with respect to drugs that receive or are denied marketing authorization by Health Canada to such a degree that the freedom of expression would be rendered effectively useless. The public has an interest in knowing that the drugs they are using and purchasing through the health care system are safe, effective and preferable to any cheaper alternatives that are already available. A *prima facie* case would therefore be established that the clinical trial information should be produced in order to further meaningful discussion on a matter of public importance, thus meeting the requirements of the first branch of the s. 2(b) test.

After that *prima facie* case is made out, the claimant must show that the protection afforded by freedom of expression should not be removed due to countervailing considerations that are inconsistent with the release of the requested information.\(^{109}\) The Supreme Court in *CLA* identified two categories of documents which would not enjoy the protection of s. 2(b), and so could be withheld from disclosure without implicating the freedom of expression. Firstly, documents that are privileged are recognized as not enjoying the protection of s. 2(b), whether the privilege in question is recognized at common law, such as solicitor-client privilege, or in statute, such as s. 39 of the *Canada Evidence Act*\(^ {110}\) which protects confidences of the federal Cabinet.\(^ {111}\) The second category of documents which may lose constitutional protection for their disclosure covers documents whose disclosure is incompatible with a government function. When the proper functioning of the affected institution may be impacted, certain types of documents can be exempted from disclosure, notwithstanding that there is an expressive interest.\(^ {112}\)

While it is unlikely that privilege would be found with respect to clinical trial information, Health Canada could argue that the clinical trial information was provided to it by a third party

\(^{109}\) *Ibid* at para 38.

\(^{110}\) *RSC 1985, c C-5*.

\(^{111}\) *CLA, supra* note 96 at para 39.

\(^{112}\) *Ibid* at para 40.
on the understanding that it would be treated as confidential business information, whose disclosure may affect the commercial interests of the pharmaceutical company seeking marketing authorization. Because the information was provided on the assumption it would be kept confidential, Health Canada’s relationship with the pharmaceutical companies may be harmed if the information were subsequently made public, which could theoretically affect Health Canada’s ability to obtain the cooperation of pharmaceutical companies. This is a weak argument, however, given that Health Canada nevertheless retains the power to grant regulatory approval for pharmaceuticals, which is necessary for any pharmaceutical company to sell their pharmaceutical products in Canada, and therefore to profit from them.

Arguably, disclosure would also better permit regulators to fulfill their function, because it may lead to an increase in confidence in the regulatory decisions made by the agency. Access to information can be “critical in promoting and ensuring public accountability” of regulatory bodies, as it can promote public debate and allows the public to oversee the actions of regulators. Additionally, a policy of transparency will eventually result in all industries being on the same footing, because all clinical trial information would be disclosed publicly, and the basic assumptions will shift in light of the new status quo. Finally, as mentioned above in Section 2.1, intellectual property rights which are held by the pharmaceutical company, and which are granted on the understanding that the company will share certain information, continue to operate and ensure that only the pharmaceutical company holding the patent can profit from it. Assuring access to good quality drugs is necessary for health, and that assurance requires not only monitoring by government regulators, but also a system of scientific debate and scrutiny; given that human rights obligations are imposed on governments and not private institutions, governments have a duty to promote and protect that scientific debate.

An argument could therefore be made that access to information held by Health Canada with respect to marketing authorizations is a derivative right that is essential for the full enjoyment of

113 Lemmens & Telfer, supra note 6 at 106.
114 Ibid at 105.
115 Ibid.
the freedom of expression. This argument is further supported by other freedom of expression jurisprudence, where the Supreme Court of Canada has recognized that “[u]nderlying freedom of expression are the core values of (1) seeking the truth and the common good; (2) promoting self-fulfilment of individuals by allowing them to develop thoughts and ideas as they see fit; and (3) ensuring that participation in the political process is open to all persons.”

When considering an infringement of the s. 2(b) right to free expression, the closer the speech being considered lies to the core values, the more difficult it will be to justify the infringement on the freedom of expression under the Charter. The disclosure of clinical trial information directly fulfills one of those core values, specifically “seeking the truth and the common good”. As is further elaborated in Section 2.2.2 above, the disclosure of clinical trial information is directly related to the proper operation of the scientific method, which is necessary to truly understand the harms and benefits of a pharmaceutical treatment. Transparency is therefore not only absolutely necessary for the truth to be found, it is also in the interest of the common good of Canadians, as it protects public health.

As the above demonstrates, there is a strong human rights argument in favour of disclosure under s. 2(b) of the Charter. I will now turn to consider the possible claim under s. 7.

2.2.3.2 Rights to Life, Liberty and Security of the Person

It could also be argued that Canadians’ rights to life, liberty and security of the person, which are guaranteed by s. 7 of the Charter, are implicated by the non-disclosure of clinical trial information. While there is no right to health in Canada, the rights to life, liberty and security of the person can easily be understood as health-related rights. As with the right to health as guaranteed internationally by the ICESCR, there is a connection between these health-related rights and the importance of ensuring that our medical knowledge systems are appropriate and accurate.

117 Ibid.
118 Lemmens & Telfer, supra note 6 at 100.
Internationally, according to Trudo Lemmens, there are “some interesting precedents linking the right to life with access to crucial safety information to enable the protection of people’s physical integrity.”\(^{119}\) Although the risk to life is often more remote in the context of pharmaceuticals, given that data sets must be linked, adverse events must be carefully observed, and statistical data which suggests that while some people may be harmed, others may benefit, must be interpreted in order for the risk to be assessed.\(^{120}\) Although the links of non-disclosure of clinical trial information to the right to life may be remote, there is a much closer tie of non-disclosure to personal choices and personal autonomy, and therefore to liberty and security of the person.

As the recent Supreme Court of Canada decision in *Carter v. Canada (Attorney General)*\(^ {121}\) demonstrated, decisions related to health care are intimately tied up with the rights guaranteed by s. 7 of the *Charter*. *Carter* involved a challenge to criminal prohibitions against assisted suicide, with the Supreme Court of Canada concluding that the prohibitions violated the s. 7 rights of Canadians. In determining that the provisions were unconstitutional, the Court found that both the right to liberty and the right to security of the person are underlined by “a concern for the protection of individual autonomy and dignity”: while the right to liberty protects an individual’s right to make “fundamental personal choices free from state interference”, the right to security of the person “encompasses a notion of personal autonomy involving control over one’s bodily integrity”.\(^ {122}\) Access to reliable information about pharmaceuticals plays a significant role in an individual’s self-determination and empowerment with respect to their physical integrity and healthcare,\(^ {123}\) vital aspects of the right to security of the person. The ICESCR right to health includes a right to participate in one’s own health and healthcare choices, and access to

---

\(^{119}\) Lemmens, “Knowledge”, *supra* note 42 at 167.

\(^{120}\) *Ibid.*

\(^{121}\) 2015 SCC 5, [2015] 1 SCR 331 [*Carter*].

\(^{122}\) *Ibid* at para 64.

\(^{123}\) Lemmens & Telfer, *supra* note 6 at 105.
information is necessary for participation to be meaningful;\textsuperscript{124} likewise, participation in choices that have a direct impact on one’s personal integrity are vital components of the rights to liberty and security of the person, given how closely those rights are tied to the concept of informed consent.

The importance of medical decision making and informed consent was also highlighted by the Supreme Court of Canada in its earlier decision \textit{AC v. Manitoba (Director of Child and Family Services)}.\textsuperscript{125} In \textit{AC}, the Supreme Court recognized the right of a minor to refuse medical treatment, noting that individuals “must give their ‘informed consent’ before treatment occurs”.\textsuperscript{126} The Court in \textit{AC} cited two Ontario Court of Appeal decisions with respect to informed consent. The Court first adopted the statement from \textit{Malette v. Shulman} that the “doctrine of informed consent is plainly intended to ensure the freedom of individuals to make choices concerning their medical care.”\textsuperscript{127} It then went further in adopting the statement from \textit{Fleming v. Reid} that:

\begin{quote}
[t]he right to determine what shall, or shall not, be done with one’s own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law. […] [T]he common law right to determine what shall be done with one’s own body and the constitutional right to security of the person, both of which are founded on the belief in the dignity and autonomy of each individual, can be treated as co-extensive.\textsuperscript{128}
\end{quote}

The ability to consent to treatment is deeply ingrained in Canadian health law jurisprudence, and these principles have in turn been incorporated into Canadian constitutional law jurisprudence.

\textsuperscript{124} \textit{Ibid.}

\textsuperscript{125} 2009 SCC 30, [2009] 2 SCR 181 [\textit{AC}].

\textsuperscript{126} \textit{Ibid} at para 40.

\textsuperscript{127} \textit{Ibid} at para 41.

\textsuperscript{128} \textit{Ibid} at para 44.
The Supreme Court of Canada set out what is required when obtaining the consent of a patient to a medical procedure in *Hopp v. Lepp*, where it found that, in addition to answering any specific questions posed by the patient as to the risks of the procedure, a surgeon should “disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation.”

Arguably, it is impossible for an individual to give his or her informed consent to a medical treatment, as required by *Hopp v. Lepp*, if he or she does not have all known information with respect to the potential risks and claimed efficacy of that treatment. Because the pharmaceutical companies have a monopoly over trials and the results of those trials, it can be difficult to get a clear and complete picture of the safety and efficacy of a pharmaceutical. Health Canada has the ability to clarify the picture somewhat, because it holds much of the information necessary for independent researchers to make their own assessments, including information on the methods and results of those trials.

Other *Charter* decisions have further recognized the importance of health and its relation to the human rights of Canadians. *Chaoulli* is a complicated decision that dealt with a patient’s ability to obtain private health services and avoid long wait times in the public health system. Justice Deschamps found that the prohibition from accessing private health care services violated the rights to life and to personal inviolability, which are protected by s. 1 of the *Quebec Charter of Human Rights and Freedoms*. Deschamps, J. found that the right to life was infringed because wait times increased the risk of mortality, and that the delays caused an additional risk to a person’s health and was state-imposed suffering. She concluded that the increased risks and suffering would be a violation of security of the person under the *Charter*, and was therefore a violation of the inviolability of the person under the *Quebec Charter*, because the scope of the right to personal inviolability is broader than the right to security of the person.

Chief Justice McLachlin, Justice Major and Justice Bastarache concurred with Deschamps, J.’s conclusion that the *Quebec Charter* was violated to form the majority on the seven-justice panel,

---


130 *Chaoulli*, *supra* note 94 at para 38-43.
but then went further and found that the prohibition also violated the rights to life, liberty and security of the person protected by s. 7 of the Charter.\textsuperscript{131} McLachlin, C.J. and Major, J. concluded that Supreme Court of Canada jurisprudence “holds that delays in obtaining medical treatment which affects patients physically and psychologically trigger the protection of s. 7 of the Charter”.\textsuperscript{132} In the specific case, prohibiting private health insurance, which would permit Canadians to access health care when the government is failing to deliver the health care in question in a reasonable manner, increases the risk of complications and death, and thus interferes with life and security of the person.\textsuperscript{133}

An argument could be made that, similar to delays in medical care caused by wait times, the government’s refusal to disclose clinical trial information increases the risks of death or harm to Canadians who use pharmaceuticals or participate in clinical trials. As discussed above in Section 2.2.2, the failure to disclose clinical trial information permits many unethical practices to continue by preventing conclusions from being reviewed and re-tested, and preventing researchers from developing a full understanding of the pharmaceutical products in question.

Above in Section 2, I reviewed the private and commercial interest in clinical trial information, and why the public interest should also be recognized, given that clinical trial information is a public good which can cause public health harms when it is kept confidential, and that those public health harms in turn support arguments that non-disclosure of clinical trial information violates the rights of freedom of expression and life, liberty and security of the person, both of which are protected by the Charter. I will now further elaborate on Health Canada’s role in the regulation of pharmaceuticals in Canada, and the regimes and mechanisms that are available to obtain clinical trial information from Health Canada.

\textsuperscript{131} Deschamps, J did not consider this issue, having found the violation under the Quebec Charter of Human Rights and Freedoms (Chaoulli, ibid at para 102).

\textsuperscript{132} Ibid at para 118.

\textsuperscript{133} Ibid at para 124.
3 Health Canada and Trial Data

3.1 Health Canada’s Role

The FDA, along with the Food and Drug Regulations\textsuperscript{134}, govern the regulatory approval of pharmaceuticals in Canada. Health Canada administers the FDA and the FDR through the Therapeutic Products Directorate of the Health Products and Food Branch. The Therapeutic Products Directorate verifies that the regulatory requirements for the safety, efficacy and quality of pharmaceuticals and other therapeutic products are satisfied by reviewing scientific assessments, including product and establishment licensing, surveillance and monitoring, and compliance and enforcement activities.\textsuperscript{135}

Before a new drug may be sold or advertised in Canada, the drug’s manufacturer must file a new drug submission with Health Canada, and Health Canada must issue a notice of compliance.\textsuperscript{136} A new drug submission must contain sufficient information and material to allow Health Canada to assess the safety and effectiveness of that drug, including substantial evidence of the clinical effectiveness of the drug.\textsuperscript{137} Health Canada also has the power to request any additional information or material it may require respecting the safety and effectiveness of the new drug.\textsuperscript{138} Each new drug submission must include a summary of the methods used in the clinical trials, the results of those trials and the conclusions arrived at based on those results, and the manufacturer must provide the raw data within 30 days of a request by Health Canada.\textsuperscript{139} After reviewing the evidence provided in the new drug submission, if Health Canada determines that the benefits of a

\begin{itemize}
\item \textsuperscript{134} CRC, c 870 [FDR].
\item \textsuperscript{136} FDR, supra note 134, s. C.08.002(1).
\item \textsuperscript{137} Ibid, s. C.08.002(2).
\item \textsuperscript{138} Ibid, s. C.08.002(3)(d).
\item \textsuperscript{139} Ibid, s. C.08.005.1.
\end{itemize}
drug outweigh the risks, and identified risks can be managed, it will issue a notice of compliance pursuant to s. C.08.004(1)(a) of the FDR, which confirms that the submission complies with the FDR. Once a drug is sold in Canada, the manufacturer is responsible for reporting serious adverse reactions, and providing annual summary and case reports pursuant to s. C.01.017 and s. C.01.018 of the FDR.

The regulations are clearly intended to ensure that drugs marketed in Canada are safe, effective, and of high quality; nevertheless, there are limits to how much those conclusions can be relied upon. Although the drug manufacturer is required to provide trials showing that the drug is relatively effective, the pharmaceutical product can receive regulatory approval even if there are many more trials that do not demonstrate efficacy, simply because those trials were not provided to the regulator for review. Additionally, positive trials may be limited to a small population, so they may fail to provide sufficient information as to who may be harmed by the pharmaceutical product. Further, the clinical trials provided typically fail to evaluate whether the drug is more effective than existing treatments, meaning that the new drug may be inferior to existing treatments. The new drug will inevitably be the focus of marketing strategies by the pharmaceutical company, given that it can be sold at a higher price and without competition from generics, increasing the likelihood that patients and physicians will switch to the new treatment, even though that new treatment may not be an improvement on existing treatments. Drug manufacturers not only control the clinical trials, which are the process by which the required scientific evidence is generated, but also prepare publications and then integrate those publications into their marketing strategies. The fact that the pharmaceutical industry retains the power to manipulate and control research with respect to their products is problematic, given

141 Ibid at 338.
142 Ibid.
143 Ibid.
144 Ibid.
that the system relies on self-reporting by that same industry, who has a significant financial interest in the outcome of the research being undertaken.\(^{145}\)

As is discussed above in Section 2.2.2, many of these problems can be nullified through data transparency. Disclosure of clinical trial information permits the protocol of the trial to be reviewed and incorporated into meta-analysis and systematic reviews, which may nullify problems with the trial protocol such as the size and features of the population being studied. Independent review further provides the opportunity to compare new treatments with existing treatments. Finally, disclosure allows researchers to independently review and evaluate marketing claims by the drug’s manufacturer, to a degree protecting the public from the influence of pharmaceutical companies’ self-interest.

Although Health Canada has access to the raw clinical trial information, they have long treated that information as confidential, preventing independent researchers and physicians from studying the data. Once a drug has been approved by Health Canada, for example, they make a “summary basis of decision” publicly available, which sets out the scientific and benefit-risk information that was considered when the approval was granted. Given the limited information included in the summary basis of decision, however, it is difficult for any independent assessment of the safety and efficacy of the new drug to be completed.\(^{146}\)

If an individual wants to obtain any meaningful information about a drug submitted to Health Canada for marketing approval, he or she will have to turn to a source other than the summary basis of decision for the information. One route for obtaining such information is the federal access to information regime, which allows Canadian citizens and permanent residents to obtain documents from government institutions. Alternatively, the individual can look to Vanessa’s Law, which amended the FDA with the intention of increasing transparency. Pursuant to Vanessa’s Law, s. 21.1 of the FDA was enacted which authorizes disclosure of clinical trial information if that disclosure is in the public interest. Further, Health Canada recently proposed a new regulatory regime pursuant to the regulation-making power enacted by Vanessa’s Law.

\(^{145}\) Ibid at 339.

\(^{146}\) Lemmens & Gibson, supra note 53 at 974.
The new regime would reclassify clinical trial data, moving it out of the category of confidential business information and thereby making it subject to release. Each of these routes for obtaining information from Health Canada will be considered in turn.

3.2 The Access to Information Regime

One path pursuant to which Canadian citizens and permanent residents can access information held by government agencies and institutions is through the access to information regime, which is governed federally by the Access to Information Act.\(^{147}\) The purpose of the Access to Information Act is to provide a right of access to records that are under the control of a government institution, highlighting the principle that government information should be publicly available, and that any exceptions to that right of access must be necessary, limited and specific.\(^{148}\) In s. 4(1) of the Access to Information Act, every Canadian citizen or permanent resident has a right to access any record under the control of a government institution. As a federal government department, Health Canada is a “government institution” and thus is subject to the Access to Information Act. As is discussed above in Section 2.2.3.1, access to information has been found to be a derivative right to the freedom of expression by the Supreme Court of Canada.

Unless the record is exempted from disclosure by another provision of the Access to Information Act, information held by Health Canada must be disclosed in connection with an access to information request, including clinical trial information submitted in connection with a new drug submission. Section 20(1) of the Access to Information Act sets out the exceptions that apply when a government institution holds third party information. Pursuant to s. 20(1)(b), the government institution will refuse to disclose a requested record that contains “financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the

\(^{147}\) RSC 1985, c A-1.

\(^{148}\) Ibid, s 2(1).
third party”. Section 20(1)(c) provides an additional exception, stating that the government institution will not disclose any record that contains information that, if disclosed, “could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party”.

Typically, when requests are made for the clinical trial information held by Health Canada, that request is refused on the basis that the information is exempted from disclosure because it is the confidential business information of a third party, meaning that the information is protected pursuant to s. 20(1)(b) of the Access to Information Act. This position prevents independent researchers and physicians from studying the data that was supplied to Health Canada in connection with a new drug submission, and which formed the basis for Health Canada’s decision to grant regulatory approval. As is discussed above in Section 2.2.2, this lack of independent review can lead to public health harms, as underhanded practices of the pharmaceutical industry may continue unchecked, and the conclusions of Health Canada and the claims of pharmaceutical companies cannot be verified independently.

The Access to Information Act does include a provision which attempts to balance any public interest in the records that are exempted from disclosure. Notwithstanding the exceptions to disclosure of third party records, the government institution may disclose a record requested under the Access to Information Act that contains information protected under s. 20(1)(b) and (c) if:

(a) the disclosure would be in the public interest as it relates to public health, public safety or protection of the environment; and
(b) the public interest in disclosure clearly outweighs in importance any financial loss or gain to a third party, any prejudice to the security of its structures, networks or systems, any prejudice

149  Ibid.
150  Ibid.
151  Persaud & Doshi, supra note 34 at 96.
to its competitive position or any interference with its contractual
or other negotiations.\textsuperscript{152}

The provision therefore explicitly requires that the competing interests for and against disclosure
be assessed against each other, requiring that the potential financial loss or harm to the
competitive position of a third party be outweighed by the public interest in disclosure.

Notwithstanding the public health harms in non-disclosure set out above, Health Canada and
Canadian courts have consistently held that the potential financial loss or harm to competitive
position that may be caused by the release of clinical trial information outweighs the public
interest in disclosure. In \textit{Rubin v. Canada (Minister of Health)}\textsuperscript{153}, for example, Mr. Rubin was
seeking a report which contained information with respect to the safety of calcium channel
blockers for non-commercial purposes. After contacting the third parties that would be affected
by the release of the information, and receiving representations against release, Health Canada
released an edited version of the requested report to Mr. Rubin, stating that some of the
information had been withheld because it fell within the exceptions set out in s. 20(1)(b) and
s. 20(1)(c) of the \textit{Access to Information Act}.\textsuperscript{154} Justice Nadon of the Federal Court of Canada
concluded that Health Canada was correct in refusing to disclose the information in question,
which included information on clinical trials, unpublished scientific reports, unpublished raw
data, independent reviews by foreign agencies, and market analyses and practices, because the
information was correctly classified as falling within s. 20(1)(b).\textsuperscript{155} Nadon, J. concluded that the
information was of a financial, commercial, technical or scientific nature, that it was supplied to
a government institution by a third party, and that it had been consistently treated as confidential
by the third party that provided it to Health Canada.\textsuperscript{156}

\begin{footnotes}
\item[152] \textit{Access to Information Act, supra} note 147, s 20(6).
\item[153] 2001 FCT 929, [2001] FCJ No 1298, 14 CPR (4th) 1 [\textit{Rubin}].
\item[154] \textit{Ibid} at paras 5-6.
\item[155] \textit{Ibid} at para 45-46.
\item[156] \textit{Ibid} at paras 46-48.
\end{footnotes}
Mr. Rubin argued that, even if the information was protected by s. 20(1)(b), it should nevertheless be released pursuant to s. 20(6) because there was a public interest in its disclosure. Nadon, J. concluded that although Health Canada has a discretion to disclose information that is in the public interest pursuant to s. 20(6), it is under no obligation or duty to do so. As long s. 20(6) was considered, and there is no evidence of bad faith on the part of the regulator, it is a proper exercise of the discretion granted under s. 20(6) of the Access to Information Act.\textsuperscript{157} Nadon, J.’s decision was affirmed by the Federal Court of Appeal.\textsuperscript{158}

Interestingly, those attempting to secure clinical trial information from Health Canada have not made the argument that the failure to disclose is an infringement of the freedom of expression protected by s. 2(b) of the Charter, as is argued in Section 2.2.3.1 above. The finding that access to information is necessary for the full enjoyment of the freedom of expression with respect to clinical trial information and pharmaceuticals may change the interpretation of s. 20(b) of the Access to Information Act: the public interest coupled with Charter protection may impose a duty to disclose on Health Canada.

Even if Health Canada can be convinced that clinical trial information is properly the subject of disclosure under the Access to Information Act, that is no guarantee that the information will be released. In some circumstances, Health Canada has attempted to disclose clinical trial information over the objection of the third party that provided that information, only for the courts to side with the third party. In the 2016 Federal Court of Canada decision Martin v. Canada (Minister of Health)\textsuperscript{159}, for example, Dr. Martin was appealing Health Canada’s decision to disclose certain documents related to clinical trials undertaken by Dr. Martin. Justice G. L. McVeigh concluded that the information contained in the documents was protected from disclosure pursuant to s. 20(1)(b) of the Access to Information Act because it related to technical details, requirements and processes of the clinical treatment, and was confidential and

\begin{flushleft}
\textsuperscript{157} Ibid at para 54.
\textsuperscript{158} Rubin v. Canada (Minister of Health), 2003 FCA 37.
\textsuperscript{159} 2016 FC 796, [2016] FCJ No 863 [Martin].
\end{flushleft}
consistently treated confidentially by Dr. Martin.\textsuperscript{160} \emph{Martin} demonstrated that, even when Health Canada concludes that the information can be disclosed, the specific language of the s. 20(1)(b) exception in the \textit{Access to Information Act} and the jurisprudence interpreting that provision can prevent it from doing so. Interestingly, Health Canada does not seem to have exercised its discretion under s. 20(6) in \emph{Martin}; we can only speculate as to the reasons why.

The provisions of the \textit{Access to Information Act} exempting confidential scientific and technical information from disclosure, along with the unwillingness of either the regulator or the courts to recognize an overriding public interest in clinical trial information, means that it is extremely difficult for the \textit{Access to Information Act} to be used to obtain clinical trial information from Health Canada, even when there is little reason to believe that disclosure would result in financial harm to, or prejudice to the commercial interests of, the sponsoring pharmaceutical company. Although the clinical trial information would be subject to disclosure if it were not scientific or technical in nature, it would be difficult to make that argument, given that it is the result of scientific studies and its scientific nature is the very reason that independent researchers want access to it.

An additional requirement is that the information must be confidential and treated confidentially by the third party, but both Health Canada and the courts seem willing to simply assume that such information is confidential. In \emph{Rubin}, for example, Nadon, J. relies on the introduction of the report in question, which stated that “most of the information gathered comes from the \[calcium channel blockers\] manufacturers” to conclude that the information is, objectively, confidential.\textsuperscript{161} There is no real assessment of whether the information should in fact be treated as confidential; the source of the information is enough to assume confidentiality.

Finally, the courts have found that s. 20(6) does not impose an obligation on Health Canada to release information that is in the public interest, it simply provides them with the discretion to do

\textsuperscript{160} \textit{Ibid} at paras 88 and 102-103.

\textsuperscript{161} \textit{Rubin}, supra note 153 at para 48.
so which must be exercised in good faith. If the individual seeking the information cannot demonstrate bad faith, or that the public interest was not considered by Health Canada, there is no effective judicial review of the decision not to release the information under s. 20(6); the court will simply defer to the conclusions of the regulator without determining whether there is any evidence of the third party’s claim of financial or competitive harm, meaning there is no assessment to determine whether the fear of harm is real or imaginary.

As the above demonstrates, there are limitations to using the access to information regime to obtain clinical trial information from Health Canada. The broad language of the exceptions, along with reluctance to find that the public interest in disclosure outweighs the commercial interests of the pharmaceutical company have operated against transparency. By incorporating the Charter arguments, detailed above in Section 2.2.3, those attempting to secure clinical trial information may have greater success, as it may lend weight to the public interest side of the scale.

Given its limitations, exacerbated by judicial interpretation of the relevant provisions, it is fortunate that the access to information regime is not the only means of gaining access to clinical trial information held by Health Canada. Researchers can also turn to Vanessa’s Law.

3.3 Vanessa’s Law

In 2014, the federal government endorsed greater transparency when it enacted Vanessa’s Law. Vanessa’s Law amended the FDA to increase transparency and improve safety, and as a result promote greater confidence in the federal government’s oversight of pharmaceutical and other therapeutic products. In interpreting Vanessa’s Law, Health Canada has acknowledged that the publicly available information is insufficient to properly evaluate drugs sold in Canada, so

\textit{Ibid} at para 54.

Health Canada, “Amendments to the Food and Drugs Act: Guide to New Authorities (power to require and disclose information, power to order a label change and power to order a recall)”, available online at: <http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php> [Amendments to the FDA].
access to documents provided to Health Canada in the course of obtaining a marketing authorization which also contain confidential business information can help researchers and practitioners improve patient safety and contribute to better health outcomes for Canadians.  

Vanessa’s Law enacted a number of amendments which were intended to authorize the release of information held by Health Canada, even if that information would typically be categorized as confidential business information pursuant to the access to information regime. One such amendment was s. 21.1 of the FDA; the other was a new regulation-making power. Each will be considered in turn.

### 3.3.1 Disclosure pursuant to Section 21.1 of the FDA

Pursuant to s. 21.1(2) of the FDA, Health Canada is authorized to disclose confidential business information about a therapeutic product if it believes that the product may present a serious risk of injury to human health; the provision does not require Health Canada to notify or obtain the consent of the person whose business the information relates to. Health Canada must have reasonable grounds, in the form of documented evidence, to believe that the product poses a serious risk to human health, and the confidential business information that is disclosed must be limited to that which is necessary to mitigate the risk.

Section 21.1(3) of the FDA provides Health Canada with a broader disclosure power, authorizing the disclosure of confidential business information if the purpose of that disclosure is related to the protection or promotion of human health or public safety, and the disclosure is to (a) a government; (b) a person from whom the Minister is seeking advice; or (c) a person who carries out functions relating to the protection or promotion of human health or public safety.  

\[\]

---


165 FDA, supra note 2.

166 Amendments to the FDA, supra note 163.

167 FDA, supra note 2.
Health Canada is not required to notify or obtain the consent of the person whose business the information relates to.\footnote{Ibid, s. 21.1(3).} The guidance documents prepared by Health Canada interpret the requirement that the disclosure be for the “protection or promotion of human health” as permitting Health Canada to disclose confidential business information to either protect patients from safety risks or to promote the safe use of a therapeutic product, including for the purpose of determining the appropriate prescription practices to optimize the use of a therapeutic product.\footnote{Amendments to the FDA, supra note 163.}

Before Health Canada will release any information under s. 21.1(3), it will assess the qualifications of the requestor to confirm that it is an individual or organization “who carries out functions relating to the protection or promotion of human health or the safety of the public”,\footnote{Disclosure of CBI, supra note 164 at para 3.2.} as is required by (c) above. In completing this assessment, Health Canada will consider the relevance of the requestor’s qualifications for the proposed purpose of the disclosure, his or her record of contributions to the health and safety of Canadians, and his or her record of disseminating information to advance scientific knowledge for non-commercial purposes.\footnote{Ibid.}

Health Canada will also confirm that “the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public”.\footnote{Ibid at para 3.3.} The confidential business information should relate to a therapeutic product that is publicly available,\footnote{Ibid note 164 at para 3.2.} meaning that the provision cannot be used to obtain information on a therapeutic product for which Health Canada refused to issue a notice of compliance. In determining that the proposed purpose is appropriate, Health Canada may consider the following: (i) the relevance of the proposed project to the protection or promotion of health and safety; (ii) the severity of the health or safety issue, or the vulnerability or size of the affected population; (iii) whether the proposed use of the confidential business

\footnotesize

\footnote{Ibid, s. 21.1(3).}
\footnote{Amendments to the FDA, supra note 163.}
\footnote{Disclosure of CBI, supra note 164 at para 3.2.}
\footnote{Ibid.}
\footnote{Ibid at para 3.3.}
\footnote{Ibid.}
information is feasible; and (iv) the anticipated impact of the proposed use of the confidential business information on the health and safety of Canadians.\footnote{Ibid.}

Health Canada has said that it will be judicious in exercising its authority to disclose confidential business information to eligible persons for the purpose of protection or promoting human health or public safety pursuant to s. 21.1(3)(c) of the FDA.\footnote{Ibid at para 3.1(i).} The information disclosed should contribute to improving Canadians’ health, access to the information must be necessary to achieve the stated purpose, there must be no other avenues for the information to be obtained, and the information cannot be used for commercial purposes.\footnote{Ibid at paras 3.1(ii), (iii) and (iv).} Health Canada defines a “commercial purpose” as using the information “to support a marketing authorization anywhere in the world or selling or trading the data to another person” but excludes research into the comparative effectiveness of products.\footnote{Ibid at para 5.}

On its face, this disclosure regime supports the public interest in clinical trial data described above in Section 2.2 by recognizing the public health harms that can arise when clinical trial information is kept confidential. It also recognizes how disclosure can lead to better regulatory decision-making. What the regime does not do, however, is consider clinical trial information as a public good, as its sole focus on the commercial interest and the public health harms leaves no room for a broader conception of the nature of the information itself. The lack of explicit recognition of the public interest leaves the regime open to a number of interpretations by Health Canada, which in turn leads to the largest flaw in how Vanessa’s Law has been implemented: the continued requirement for confidentiality.

While Vanessa’s Law does include discretionary powers to share data, as set out above, the law itself did not include any provisions setting out the terms pursuant to which the information can be shared; given the lack of guidance, Health Canada made the policy decision to require a
confidentiality agreement from those who receive the information.\(^{178}\) In its guidance document, Health Canada stated that the information disclosed pursuant to s. 21.1(3)(c) of the FDA must be kept confidential. As a result, Health Canada requires potential recipients of confidential business information to sign a legally-binding confidentiality agreement.\(^{179}\) The guidance document does explicitly provide that the confidentiality agreement will not prevent the requestor from publishing the results of their analysis of the disclosed information;\(^{180}\) practically, however, publication may be difficult without the ability to make the raw clinical data available, given the recent push of journals, including the British Medical Journal which requires that data be made available upon reasonable request before publishing a clinical trial\(^{181}\) and PLOS which provides that, with rare exceptions, all authors must make the data underlying their articles fully available.\(^{182}\) Even without a publication having an explicit policy, best practice when publishing a clinical study is to make the underlying clinical data publicly available. To do so when the information is obtained pursuant to s. 21.1 of the FDA would violate Health Canada’s confidentiality agreement,\(^{183}\) meaning that the researchers could be held liable.

The experience of Dr. Nav Persaud provides a useful example. Dr. Persaud was an early researcher to take advantage of the new disclosure provisions of Vanessa’s Law. Through the regime, he gained access to the data on the morning sickness medication diclectin. Dr. Persaud was required to execute a confidentiality agreement, pursuant to which he agreed not to share the data with anyone, even a colleague such as a statistician who might be able to assist in interpreting or analysing the data, not to reproduce the data in any document that he intends to

---


\(^{179}\) Disclosure of CBI, supra note 164 at para 3.1(iv).

\(^{180}\) Ibid.

\(^{181}\) Fiona Godlee, “Clinical trial data for all drugs in current use” (2012) 345 British Medical J e7304, DOI: 10.1136/bmj.e7304.


\(^{183}\) Herder & Lemmens, supra note 178.
make public, and to destroy the data once he completes his project.\textsuperscript{184} Given the terms of the confidentiality agreement, it is difficult for there to be any kind of constructive debate about the interpretation of the data,\textsuperscript{185} because not everyone has access to the data to inform that debate.

Rather than relying on onerous confidentiality agreements, Health Canada could have looked to the terms of use which are required in connection with the EMA’s policy on clinical trial data. The terms of use do not impose any obligation of confidentiality, and leave researchers relatively free to use the data how they wish, subject to their agreement not to use the data for commercial purposes or to re-identify the participants of the clinical trial in question.\textsuperscript{186} Health Canada’s interpretation of Vanessa’s Law thus fails to meet the goals of encouraging independent scrutiny of a drug’s safety and efficacy, and better protecting the public.\textsuperscript{187}

Additionally, while the disclosure provisions of Vanessa’s Law do create new transparency powers, they also legitimate Health Canada’s practice of treating drug safety and efficacy information as proprietary.\textsuperscript{188} While the regime has provided Health Canada with the authority to release confidential business information, Health Canada arguably already enjoyed that authority under s. 20(6) of the \textit{Access to Information Act}. Health Canada’s interpretation of its “new” powers suggest that transparency will continue to be an issue, in particular given its requirement that the information continue to be treated as confidential.

Both the FDA s. 21.1 regime and the regime under s. 20(6) of the \textit{Access to Information Act} have their advantages and their disadvantages. One advantage of the s. 21.1 regime is that the public interest does not need to be weighed against the private, commercial interest; the only consideration is the promotion and protection of public health. When information is released

\begin{itemize}
  \item \textsuperscript{184} Ibid.
  \item \textsuperscript{185} Ibid.
  \item \textsuperscript{186} Ibid.
  \item \textsuperscript{187} Ibid.
  \item \textsuperscript{188} Matthew Herder, “Reinstitutionalizing Transparency at Health Canada” (2016) 188:3 Can Medical Assoc J 218, DOI: 10.1503/cmaj.150765 at 218.
\end{itemize}
under the access to information regime, however, it is not subject to the restrictions of a confidentiality agreement, as it would be under the s. 21.1 regime. Further, s. 21.1 has been interpreted by Health Canada to only apply to information related to products that are publicly available, which means that the regime cannot be used to obtain information with respect to pharmaceuticals that were refused a notice of compliance. This limits the amount of data that would be available, eliminating a source of data that could be used to better understand how drugs are absorbed by the body or the study of similar drugs. There continues to be a risk that studies will be unnecessarily duplicated because of this failure, not only increasing costs but also unethically exposing trial participants to harm. This limitation does not exist under the access-to-information regime.

Based on Health Canada’s requirements in interpreting s. 21.1 of the FDA, it is clear that disclosure will only occur when there is a known potential issue with an existing pharmaceutical product. The confidential business information will only be available if the requestor can articulate a potential problem with a product that is publicly available, and will not be available for more general public health reasons, such as confirming the efficacy of the product, or assessing whether it is a more effective product than existing, cheaper treatments. As is discussed above, it is only by meta-analysis using raw clinical data, systematic review and other independent reviews of clinical trial information that many issues will become known. Because it does not permit a full and frank discussion of the issues, only being available when issues are already known to the public, it does not fulfil the freedom of expression and does not protect personal integrity, as safeguarded by the rights to liberty and security of the person. Although s. 21.1 does not consider the commercial interest in the information, it also does not recognize the information as a public good, does not alleviate many of the public health harms described above, and does not promote human rights. These limitations, taken together with the requirements for confidentiality, mean that the s. 21.1 regime is extremely limited in its ability to make clinical trial information available for more general public health reasons, as set out above. Fortunately, s. 21.1 of the FDA is not the only amendment introduced by Vanessa’s Law that was designed to increase transparency. I will turn now to discussing the White Paper recently released by Health Canada.
3.3.2 Disclosure of Confidential Business Information

Two additional provisions of the FDA both enacted pursuant to Vanessa’s Law grant the Governor-in-Council certain powers with respect to confidential business information. In s. 30(1.2)(d.1), the FDA grants the Governor-in-Council the power to make regulations which specify that certain information collected under the FDA in connection with the authorization of a drug or other therapeutic product either is not confidential business information or will cease to be confidential business information under certain conditions.\(^{189}\) Section 30(1.2)(d.2) of the FDA then grants the Governor-in-Council the authority to disclose that information.\(^{190}\)

Health Canada recently released the White Paper, pursuant to which it proposes to use this regulation-making power to make clinical information collected as part of a drug submission publicly available for non-commercial purposes after Health Canada completes its regulatory review process of the drug submission.\(^{191}\) The information that will no longer be considered confidential business information, and so will be available for disclosure, includes the clinical summaries, reports and supporting data of completed clinical trials which were submitted to Health Canada in support of a drug submission and are not part of an ongoing clinical development program; basically all information used to assess the safety and efficacy of a drug in humans, including methodological details, specifications and validation of information.\(^{192}\) Portions of methodological details that are not commonly used by industry, such as in-house modifications or procedures with respect to analytical, bioassay, immunogenicity or sample size calculation methods, that is, clinical data that provides insight into a drug’s stereochemistry which is not already known and is necessary for ongoing clinical development will continue to be treated as confidential.\(^{193}\) In excluding information that is part of an ongoing clinical

\(^{189}\) FDA, *supra* note 2.

\(^{190}\) *Ibid.*

\(^{191}\) White Paper, *supra* note 3, at para 1. For clarity, the information will be released both if the drug in question receives regulatory approval and if it does not.

\(^{192}\) *Ibid* at para 5.

\(^{193}\) *Ibid.*
development program, the intention is to exclude interim clinical study results, as the disclosure of results prior to completion of the study may jeopardize that study’s completion, effectively un-blinding a blinded study.\textsuperscript{194} The delay also provides pharmaceutical companies with the time to put all intellectual property in place prior to disclosure, so that their ability to obtain a patent, for example, is not jeopardized.

In the White Paper, Health Canada acknowledges that permitting public access to clinical trial information with respect to the safety and efficacy of drugs approved for sale in Canada supports the federal government’s commitment to open government, will increase public confidence in Health Canada’s regulatory decision-making process, and permits the clinical data to be analyzed independently, leading to a more complete understanding of the drug in question.\textsuperscript{195} Disclosure is in the public’s interest, as it benefits patients and healthcare providers by permitting them to make better informed health decisions and ensure that drugs are used appropriately; it benefits clinical trial participants because it avoids duplication of research that exposes participants to harm unnecessarily and advances the altruistic motivations of participants who participate in clinical trials by furthering medical science; and it benefits medical research by preventing the inefficient use of health resources by avoiding the unnecessary duplication of studies and enabling secondary analysis of the clinical information for purposes that are different from the original study.\textsuperscript{196} The White Paper therefore explicitly acknowledges not only many of the public health arguments in favour of disclosure, but also some of the arguments that clinical trial information is a public good, privileging the public interest over the private interest.

In recognition of the private interest, the information disclosed can only be used for non-commercial purposes, so it cannot be used to support a market authorization application anywhere in the world, and cannot be sold or traded to another person.\textsuperscript{197} It is also clear that Health Canada will continue to treat all clinical information provided as part of a drug

\footnotesize{\begin{itemize}
\item\textsuperscript{194} Ibid.
\item\textsuperscript{195} Ibid at para 2.
\item\textsuperscript{196} Ibid.
\item\textsuperscript{197} Ibid at para 1.
\end{itemize}}
submission as confidential during the regulatory review process: only once a final decision has been made will the clinical trial information cease to be confidential, whether or not the drug ultimately receives regulatory approval.\textsuperscript{198} The drug’s manufacturer will also have the opportunity to argue that certain information included in the drug submission should be exempted from public disclosure.\textsuperscript{199} The manufacturer will be expected to provide specific justifications for each proposed redaction, however.\textsuperscript{200} Based on the foregoing, clinical trial information will by default be disclosed and any redactions will have to be justified, rather than the presumption being that the information is confidential, with the requestor having to justify each disclosure as being in the public interest, as is required under s. 20(6) of the \textit{Access to Information Act} and s. 21.1 of the FDA.

The proposed regulations will apply both to information included in past submissions and in submissions filed after the regulations come into force.\textsuperscript{201} They are intended to provide a new path for public access to clinical information contained in drug submissions to Health Canada, so it will operate concurrently with the access to information regime and disclosure of information pursuant to s. 21.1(3)(c) of the FDA.\textsuperscript{202}

While these proposed regulations are an improvement on the current system, which continues to promote confidentiality and business interests over transparency and the public interest, there is nonetheless room for improvement. Although the classification of the information as confidential business information will automatically cease once a final regulatory decision has been made by Health Canada, there is no indication in the White Paper that any information will be proactively released. Although the presumption will be in favour of disclosure, individuals will still be required to apply to Health Canada to obtain the information. A proactive disclosure system like the one in the European Union, which will be discussed in greater detail below in

\textsuperscript{198} \textit{Ibid}.
\textsuperscript{199} \textit{Ibid}.
\textsuperscript{200} \textit{Ibid} at para 5.
\textsuperscript{201} \textit{Ibid}.
\textsuperscript{202} \textit{Ibid} at para 6.
Section 4, would prevent this additional hurdle by making the information publicly available immediately. Although users under the EMA system still have to identify themselves if they want to download, save or print the information, no identification is required for users who only wish to review the information on a screen; the presumption is thus that the information should be available for anyone who wants to review it. Proactive disclosure is also more efficient, as researchers do not have to wait for the regulator to assess the request for information, approve the request, consult with the pharmaceutical sponsor, and redact any information, if appropriate, as is necessary under a policy of reactive disclosure, meaning that additional studies such as systematic reviews and meta-analyses can be undertaken more quickly following approval of the drug in question.

As discussed above, the access to information regime and the s. 21.1 regime continue to suffer from some severe limitations. The White Paper represents an important step forward, even without proactive disclosure. It favours the public interest in clinical trial information, recognizing the public goods nature of the information and the public health concerns supporting disclosure, both of which promote the freedom of expression and the rights to life, liberty and security of the person. At the same time, the White Paper does not completely discount the commercial interest, incorporating many safeguards to ensure that transparency does not cause market distortions or a loss of competitive advantage. It must be remembered that the White Paper is only a proposal made available for public comment: it may not ever be enacted, or may be extensively amended prior to enactment. Only the intention and purpose of the regulations have been provided, the actual wording of those regulations is still unknown. The White Paper also has some limitations in the context of supporting transparency, as it continues to rely solely on reactive disclosure rather than proactive disclosure. Given its longer tradition of transparency, and its move toward proactive disclosure, the European Union’s experience can be illustrative. I will turn there next.

4 The European Medicines Agency as a Model

While Health Canada has hesitantly taken steps towards transparency, the EMA has more confidently started implementing a regime promoting transparency, including proactive disclosure. In the European Union, the EMA fulfills a similar role as Health Canada, overseeing
the scientific evaluation and safety monitoring of pharmaceuticals that are used in the European Union.\textsuperscript{203} The disclosure of information provided to the EMA in connection with that scientific evaluation is governed by regulations of the European Union and policies of the EMA.

One of the applicable regulations is \textit{Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents}\textsuperscript{204}, which is the regulation of the European Parliament that governs access to government documents, similar to the \textit{Access to Information Act} in Canada. Like the Canadian regime, the \textit{EU Access Regulation} provides that citizens of the European Union or people residing in a member state have a right of access to the documents of the institutions of the European Union.\textsuperscript{205} Despite the general right of access, access will be refused when disclosure of a document would undermine a person’s commercial interests, including their intellectual property, “unless there is an overriding public interest in disclosure”;\textsuperscript{206} as a result, the exception to disclosure in the European Union is narrower than the Canadian exception discussed in Section 3.2 above: in Canada, a record only needs to contain confidential scientific or technical information to fall within the exception, without any consideration of whether a commercial interest will be affected. Although the public interest is taken into account in s. 20(6), the use of s. 20(6) is purely discretionary, as is discussed above. In the European Union, on the other hand, a person must have a commercial interest in the document, and that commercial interest must be undermined by the document’s disclosure for the document to be exempted from disclosure. Like in Canada, the European Union permits disclosure when there is an overriding public interest, permitting a balancing of the affected commercial and public interests. If the document in question is from a third party, the EU institution will consult with

\begin{footnotesize}

\textsuperscript{204} [2001] OJ, L145/43 \textit{EU Access Regulation}.

\textsuperscript{205} \textit{Ibid}, s 2.1.

\textsuperscript{206} \textit{Ibid}, s 4.2.
\end{footnotesize}
the third party to determine whether one of the exceptions applies, unless it is clear that the
document can be disclosed.\textsuperscript{207}

In 2010, the “European Medicines Agency policy on access to documents (related to medicinal
products for human and veterinary use)”\textsuperscript{208} was adopted as a result of the recommendations of
the European Ombudsman, who strongly advocated for widespread access to clinical trial
data.\textsuperscript{209} When the decision to release a document held by the EMA depends on a balancing of
public and private interests, the EMA Access Policy provides that the commercial interest will be
protected by not disclosing “commercially confidential information”, which is defined as any
information that is not publicly available and which may undermine the owner’s economic
interest or competitive position.\textsuperscript{210} Third-party documents are classified as confidential by
default, although access to those documents is ultimately determined in accordance with the
EMA Access Policy.\textsuperscript{211} Nevertheless, the EMA Access Policy includes a general principle that
the EMA “will ensure the widest possible access to EMA documents concerning any matter
related to the policies, activities and decisions falling within the Agency’s remit and
responsibilities”; although the EMA will protect personal data and commercially confidential
information, access will only be denied if the information falls within an exception listed in art. 4
of the \textit{EU Access Regulation}.\textsuperscript{212} One type of document held by the EMA is clinical study
reports, which are comprehensive documents submitted to regulatory authorities that contain

\begin{itemize}
\item \textsuperscript{207} \textit{Ibid}, s 4.4.
Policy].
\item \textsuperscript{210} EMA Access Policy, \textit{supra} note 208, para 4.1.
\item \textsuperscript{211} \textit{Ibid}, para 4.3.
\item \textsuperscript{212} \textit{Ibid}, para 4.1.
\end{itemize}
detailed information on the design and results of a clinical trial. While these documents have traditionally been treated as confidential by regulatory agencies, the EMA Access Policy would provide for their disclosure upon request, unless the pharmaceutical company could argue that the particular clinical study report contains commercially confidential information.

In both the EU Access Regulation and the EMA Access Policy, commercial interests are of prime importance when determining whether or not a document should be released. Much like the access to information regime in Canada, the EU Access Regulation and the EMA Access Policy are forms of reactive disclosure, requiring an individual to request a document’s disclosure. The European Union’s access to information regime does contain narrower exceptions to the presumption of disclosure than the Canadian regime, while also making the competing interests more explicit, permitting a framer discussion of the pros and cons of disclosure. The EMA Access Policy does explicitly move the EMA toward greater transparency, clarifying that only documents that fall within the exceptions to disclosure set out in the EU Access Regulation will be exempted, putting the pharmaceutical industry on notice that more documents will be released unless they can demonstrate harm to their commercial interest. It explicitly provides that the greatest possible access will be provided, greatly increasing access to important documents like clinical study reports.

More recently, the EMA has moved even closer to full transparency by adopting the “European Medicines Agency policy on publication of clinical data for medicinal products for human use” in 2014. Under the EMA Data Policy, “clinical data”, which includes clinical overviews, clinical study reports and the individual data separately recorded for each participant in a clinical study, will be made available proactively. Proactive data release means that data will be made made

---

214 Ibid.
216 Ibid at paras 3 and 4.1.
publicly available on a website without an explicit request for the information. The clinical reports will include anonymized individual patient-level data. The EMA explicitly recognizes that access to clinical data benefits public health by allowing third parties to verify the original analysis of the data and the conclusions drawn from it, to conduct further analyses, and to examine, and if appropriate challenge, the EMA’s regulatory positions, the objective of proactive disclosure is to support public health.

The EMA Data Policy permits publication of data from clinical trials which are submitted as part of an application for a marketing authorization, whether or not that authorization is ultimately granted, as is proposed by the White Paper in Canada. The EMA Data Policy does provide that the EMA will not divulge commercially confidential information, but specifically states that, in general, “clinical data cannot be considered [commercially confidential information].” Although any user will be able to access clinical reports on-screen, identified users will also be able to download, save and print clinical reports once they have confirmed their identity to the EMA and confirmed that the intended use of the data is non-commercial. Users must identify themselves to prevent unfair use of the data, and to permit intervention if it is discovered that the information is being put to a commercial use. The EMA Data Policy is being implemented in stages, with individual patient data to be made available in the second phase in compliance with privacy and data protection laws. The EMA Data Policy provides that clinical data is not considered confidential, so information in clinical reports will only be redacted when the sponsor

---

217 Lemmens & Gibson, supra note 53 at 980.
218 Kim, supra note 209 at 4.
219 EMA Data Policy, supra note 215 at para 4.1.
221 EMA Data Policy, supra note 215 at para 4.1.
222 Ibid at para 4.2.1.
223 Bonini et al, supra note 220 at 2454.
224 EMA Data Policy, supra note 215 at para 4.2.4.
can justify the need for redaction and the EMA agrees to the proposed redaction, because it contains original laboratory methods that are used for development of the drug, for example, or to protect exploratory endpoints or biomarkers that will be used for future drug development. One flaw in the EMA Data Policy is that it does not apply to information collected prior to its effective date, which was January 1, 2015. Nevertheless, the first two clinical study reports, without individual patient data, were published by the EMA under the EMA Data Policy in October 2016, and they contained over 100 clinical reports comprised of approximately 260,000 pages of information. The release of information by the EMA, both under the EMA Data Policy and the EU access to information regime comprised of the EU Access Regulation and the EMA Access Policy, demonstrated many of the benefits of data transparency. Beate Wieseler and Natalie McGauran looked at one study which analyzed the benefits and harms of duloxetine in treating stress urinary incontinence by reviewing the clinical study reports and individual patient data for four clinical trials which were obtained from the EMA. While looking at the drug’s benefits and harms generally, the authors of the study also looked at the rare psychiatric adverse events that arose during the trial and concluded that the harms of duloxetine outweighed its benefits. This conclusion was in contrast to journal publications and registry reports of the trials, neither of which provided specific information about psychiatric adverse events. It also contrasted with the conclusions of the EMA which determined that there was a positive benefit-risk ratio for duloxetine and approved the drug in Europe in 2004 on the basis of the same data. Wieseler and McGauran note that this study highlights the potential value of the data that is held by regulatory agencies, noting that “clinical study reports contain an

225 *Ibid* at para 4.2.2. See also Bonini *et al*, *supra* note 220 at 2454.

226 Bonini *et al*, *ibid* at 2453.

227 *Kim*, *supra* note 209 at 2.


230 *Ibid*. 
abundance of information, including substantially more information relevant for trial evaluation than is available in journal publications and registry reports.” Even if the drug remains on the market, this study does highlight some potentially harmful side effects that clinicians and patients should be aware of when prescribing and taking the medication in question.

In another recent move towards transparency, in 2014 the European Union enacted Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC pursuant to which the European Union not only harmonised the rules that govern the conduct of clinical trials in the European Union but also established a database to ensure that clinical trials are transparent by making sure that all relevant information with respect to clinical trials are publicly accessible. In addition to ensuring the highest standards for the safety of trial participants, a goal of the EU Trial Regulation is to provide for increased transparency of clinical trial information; not only does transparency increase the efficiency of clinical trials in Europe, it also fosters innovation and research, and avoids the unnecessary duplication or repetition of clinical trials.

The EU Trial Regulation provides that all information stored on the database will be made publicly available unless the information is exempted from disclosure to protect, amongst other things, personal or commercially confidential information; the exemption will not apply, however, if there is an overriding public interest in disclosure. The information stored on the database includes marketing authorization application dossiers but those dossiers will not be

231 Ibid.
232 [2014] OJ, L158/1 [EU Trial Regulation].
233 Kim, supra note 209 at 3.
235 EU Trial Regulation, supra note 232, s 81(4).
made public until a marketing authorization decision has been made. Whether or not the outcome of the trial is positive, negative or neutral, the sponsors will submit a summary of the trial results to the database within one year of completion, and will submit a full clinical trial report within 30 days of receiving marketing authorization. In its recitals, the EU Trial Regulation confirms that “in general the data included in a clinical study report should not be considered commercially confidential once a marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, [or] the application for marketing authorisation has been withdrawn”, additionally, the characteristics of the trial, the decision on the authorisation of the trial, any substantial modifications, and the results of the trial, including, if applicable, the reasons it was temporarily halted or terminated early, should not generally be considered confidential. By providing that clinical study reports should generally not be considered commercially confidential information, the European Union strengthened the legal basis for transparency.

Although the EU Trial Regulation was adopted and entered into force in 2014, the timing of its application depends on an independent audit confirming that the portal and database are functional; currently, the European Union expects that the EU Trial Regulation will come into application in 2019.

While similar, the EU Trial Regulation and the EMA Data Policy are two separate initiatives: the EMA Data Policy relates to the publication of data submitted to the EMA in connection with a marketing authorization after January 1, 2015; the EU Trial Regulation, on the other hand, applies to data that is generated in a clinical trial that is approved under the EU Trial

236 Ibid, ss 5(1) and 81(5).
237 Ibid, s 37(4). See also Ali, supra note 9 at 41.
238 EU Trial Regulation, ibid, rec 68.
239 Ibid.
240 Wieseler & McGauran, supra note 213 at e186.
241 European Medicines Agency (website), supra note 234.
Together, however, the *EU Trial Regulation* and the EMA Data Policy represent a remarkable attempt by the European Union and the EMA to break away from the presumption that clinical trial data should be treated as confidential. The *EU Trial Regulation* also does not mandate that individual patient-level data be made available, as is envisaged by the EMA Data Policy. Although neither are fully implemented, the EMA Data Policy and the *EU Trial Regulation* are both remarkable for their commitments to proactive disclosure, reversing the presumption that confidential trial information is proprietary and must be kept confidential to protect the commercial interest of pharmaceutical companies. The EMA Data Policy is particularly noteworthy for committing to the release of individual patient data, which is extremely useful for subsequent analysis of the results, demonstrating a commitment to the public interest grounded in public health concerns.

The EMA’s move towards transparency has not been without controversy, however, as the pharmaceutical industry has pushed back. During the consultation phase of the EMA Data Policy, members of the pharmaceutical industry opposed the policy, arguing amongst other things that disclosing clinical trial data, even if that disclosure is for non-commercial research purposes, would impede innovations by hindering commercial incentives. A number of pharmaceutical companies have also brought cases objecting to the disclosure of clinical reports since the adoption of the EMA Data Policy. Although no cases have yet been decided on their merits, the companies have sought an interim suspension of the EMA’s decision to disclose clinical trial data while the merits are being determined. In a number of cases, the President of the General Court of the European Union has ordered the suspension of an EMA decision to disclose clinical trial data while the merits are being considered by the European courts, in order to prevent serious and irreparable harm to the pharmaceutical company’s interests.

---

242 Kim, *supra* note 209 at 3.
244 *Ibid* at 10-11.
246 *Ibid* at 5. The decisions referred to are *Pari Pharma GmbH v European Medicines Agency*, T-235/15R, Order of 1 September 2015, ECLI:EU:T:2015:587 (this order was subsequently cancelled by order of the Vice-President of
those decisions were subsequently appealed to the Vice-President of the European Court of Justice, who found that it is not enough for the pharmaceutical companies to argue that they had a fundamental privacy right over clinical trial information; they would have to demonstrate that it would be impossible to calculate the financial harm they would suffer if the clinical trial information were disclosed.\footnote{247}\

As was mentioned above, there have been no decisions by European courts on the merits in any of the cases where pharmaceutical companies have opposed the EMA’s transparency policies, meaning that the test for when clinical reports can be disclosed by a regulatory authority under the law of the European Union is unclear.\footnote{248} The legal basis for disclosing clinical trial information is therefore rather weak: although an EMA policy\footnote{249} and a recital to a European Union regulation\footnote{250} both state that clinical data is not commercially confidential information, no provision of a European Union regulation does so.\footnote{251} The situation is made worse by two things. First, art. 81(4)(b) of the \textit{EU Trial Regulation} states that data held in the database will be publicly accessible unless it can be shown that it should be kept confidential because it is

\footnotesize{\textsuperscript{247} Lemmens & Gibson, \textit{supra} note 53 at 983. The decisions referred to are: \textit{European Medicines Agency v AbbVie Inc and AbbVie Ltd}, C-389/13 P(R), Order of 28 November 2013, ECLI:EU:C:2013:794; and \textit{InterMune UK Ltd, InterMune, Inc and InterMune International AG v European Medicines Agency}, C-390/13 P(R), Order of 28 November 2013, ECLI:EU:C:2013:795.}

\footnotesize{\textsuperscript{248} Kim, \textit{supra} note 209 at 17.}

\footnotesize{\textsuperscript{249} EMA Data Policy, \textit{supra} note 215 at para 4.1.}

\footnotesize{\textsuperscript{250} \textit{EU Trial Regulation}, \textit{supra} note 232, rec 68.}

\footnotesize{\textsuperscript{251} Kim, \textit{supra} note 209 at 19-20.}
commercially confidential information.\textsuperscript{252} Secondly, in the two cases mentioned above\textsuperscript{253} where the European Court of Justice concluded that the financial harm the pharmaceutical companies claimed they would suffer must be impossible to calculate, the European Court of Justice also sent the cases back for the General Court to determine whether it would be possible to authorize partial access to clinical reports, given the proposals by the respective pharmaceutical companies that the clinical reports could be released if partially redacted, suggesting that the EMA must assess requests by the pharmaceutical industry to redact commercially confidential information on a case-by-case basis, taking into account both the commercial interests and the public interests at stake.\textsuperscript{254} Although access to clinical trial data in the European Union has tilted towards transparency, the scope of data that can be lawfully released remains unclear, and still largely depends on the meaning of commercially confidential information.\textsuperscript{255}

Although the EMA provides an example of how proactive disclosure can be implemented, it is still dealing with resistance from the pharmaceutical industry, and a lack of clear legal foundation authorizing the disclosure of clinical trial information. The European Union thus provides a useful example for how Canada should implement its own transparency policies, not only the need to shift from reactive to proactive disclosure, but also with the need to enact clear legislative provisions that exempt clinical trial information from the category of confidential business information.

5 Conclusion

The overriding interest in clinical trial information is not necessarily the commercial interest of the pharmaceutical industry; transparency recognizes the public interest in clinical trial

\begin{itemize}
\item[\textsuperscript{252}] Ibid.
\item[\textsuperscript{253}] See European Medicines Agency v AbbVie Inc and AbbVie Ltd and InterMune UK Ltd, InterMune, Inc and InterMune International AG v European Medicines Agency, supra note 247.
\item[\textsuperscript{254}] Kim, supra note 209 at 20.
\item[\textsuperscript{255}] Ibid at 28.
\end{itemize}
information, allowing it to be given its appropriate weight. Transparency can be achieved through nuanced regulations that protect technical manufacturing information as confidential, for example, but disclose clinical study reports, study protocols, manuals of procedure, case report forms, electronic data related to individual patients, statistical analysis plans, and investigators’ brochures and correspondence. Disclosure not only ensures better public health outcomes, but it also best protects the human rights of Canadians, both with respect to freedom of expression, by ensuring that a meaningful discussion on a matter of public importance can be furthered, but also the rights to life, liberty and security of the person, by ensuring that patients are able to provide meaningful informed consent to medical procedures through a full understanding of the potential risks and supposed benefits of a medical treatment, thus protecting the patient’s well-being and personal autonomy in medical decision-making.

Although authorizing pharmaceutical regulators to release clinical trial information, including methodology and results, is an important step in ensuring transparency with respect to clinical trials, it does not redress all of the problems associated with the pharmaceutical industry’s dominance in undertaking clinical trials, and pharmaceutical companies’ vested financial interest in the results. It will still be possible, for example, for a pharmaceutical company to not publicly disclose any unfavourable clinical trial results, whether because the trial disclosed safety issues or did not demonstrate that the treatment being tested was effective. Further, because the regulations discussed above only apply to trials that have been submitted to regulators in connection with a drug submission, publication bias remains an issue. Without legal obligations to disclose all trials, the pharmaceutical industry will not be held accountable for all trials it undertakes, regardless of the outcome.

Some creativity is necessary to help resolve these problems, whether through tightening the regulation of clinical trials in Canada, or by de-linking the pharmaceutical company that develops a treatment from the clinical trials undertaken to test the safety and efficacy of that treatment. As the importance of transparency becomes more apparent, it will be interesting to see what solutions are proposed and ultimately adopted by regulators such as Health Canada.

---

256 Persaud & Doshi, supra note 34 at 96.