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Ottawa, Ontario, July 9, 2018

PRESENT: Mr. Justice Grammond

Docket: T-335-17

BETWEEN:

PETER DOSHI

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

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JUDGMENT AND REASONS

[1] On March 18, 2000, at the age of 15, Vanessa Young died of a heart attack, after taking a prescription drug called Prepulsid. After Vanessa's death, her father, Terence Young, began investigating the practices of the pharmaceutical industry and wrote a book on the topic. He advocated for stronger measures intended to protect the public against the unintended side effects of drugs. He ran for elected office and was a Member of Parliament for Oakville from 2008 to 2015. He played a major role in the debates leading to the adoption of Bill C-17, which amends the *Food and Drugs Act*, RSC 1985, c F-27 [the Act]. Bill C-17 is now known as the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, SC 2014, c 24, and I will refer to it simply as Vanessa's Law. This is the first case in which the courts are called upon to interpret and apply Vanessa's Law.

[2] Vanessa's Law added section 21.1(3) to the Act. That section, which I quote in full below, empowers the Minister of Health [Health Canada] to disclose information concerning drugs to certain persons. Dr. Peter Doshi, who is an Assistant Professor at the University of Maryland, applied to Health Canada to obtain unpublished information, including clinical trial reports, concerning certain drugs. Health Canada replied that it would only accede to that request if Dr. Doshi signed a confidentiality agreement that would prevent him from disseminating or publishing the information to be disclosed. Dr. Doshi refused to sign such an agreement, arguing that Health Canada's request had no basis in law and that signing such an agreement would impede his ability to conduct his research project and to publish its results. Accordingly, Health Canada refused Dr. Doshi's request.

[3] Dr. Doshi now seeks judicial review of this refusal. I am allowing his application, because Health Canada exercised the discretionary power set forth in section 21.1(3) in a manner that contradicts the purpose of Vanessa's Law, which is to improve clinical trial transparency. Health Canada also fettered its discretion by adopting a rigid policy requiring a confidentiality undertaking before disclosing information under section 21.1(3). Lastly, I find that Health Canada failed to assess the effects of its decision on Dr. Doshi's freedom of expression, guaranteed by section 2(b) of the *Canadian Charter of Rights and Freedoms* [Charter].

I. Background

[4] To understand this case properly, it is necessary to provide some detail about the reasons that led to the enactment of Vanessa's Law and the legislative environment within which it finds its place. I will then describe Dr. Doshi's request and its treatment by Health Canada.

A. *Legislative Background*

(1) Legislative Environment

[5] Broadly speaking, legislation concerning drugs pursues two categories of purposes: protecting the health and safety of the public and promoting the economic interests of pharmaceutical companies. These two objectives may be intertwined to a certain extent, as innovation by pharmaceutical companies may result in new drugs being made available, which in turn may result in better health. It remains useful, however, to view these two purposes as being conceptually separate, in particular because they are given effect by two different legislative regimes.

[6] The *Food and Drugs Act* is aimed at protecting the health and safety of the Canadian public through, among other things, a mechanism to ensure that new drugs are safe and effective before they are made available to the public. New drugs must receive a notice of compliance [NOC] from Health Canada, which may be obtained through a new drug submission [NDS]. An NDS may be described as follows:

> A NDS is comprised of various sections, including pre-clinical, clinical, chemistry and manufacturing sections. The pre-clinical portions thereof will consist of all the information pertaining to the experiments that the innovator has conducted in a laboratory so as to test the action and toxicity of the drug. The clinical portions of a NDS provide information with regard to clinical trials with volunteer subjects and/or patients to test the safety and efficacy of the new drug.
>
> (*Apotex Inc. v Canada (Health)*, 2010 FCA 334 at para 12, [2012] 2 FCR 618 [*Apotex 2010*])

[7] The *Patent Act*, RSC 1985, c P-4, provides inventors with a monopoly limited in time over their inventions, provided that they publicly disclose the invention (*Free World Trust v Électro Santé Inc.*, 2000 SCC 66 at para 13, [2000] 2 SCR 1024). By doing so, Parliament seeks to provide an economic incentive for innovation. Pharmaceutical companies frequently obtain patents over new drugs they invent. It is recognized that developing new drugs is a long and costly process and that the monopoly associated with a patent affords pharmaceutical companies an opportunity to recoup their development costs.

[8] Not all pharmaceutical companies, however, engage in the development of new or innovative drugs. So-called “generic” drug makers seek to manufacture drugs that are equivalent to those developed by “research” companies and sell them at a lower cost. It is not necessary, for the purposes of this case, to describe in detail the measures adopted by Parliament to balance the

interests of “research” and “generic” pharmaceutical companies (see, e.g., *Bristol-Myers-Squibb Co. v Canada (Attorney General),* 2005 SCC 26 at paras 6-12, [2005] 1 SCR 533).

[9] One aspect of the regulatory framework that is relevant to this case flows from Canada’s desire to comply with its international obligations. Canada is a party to the *North American Free Trade Agreement* [NAFTA] and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* [TRIPS]. Article 1711 of NAFTA and Article 39 of TRIPS contain provisions for the protection of data generated by innovator pharmaceutical companies. In order to comply with those provisions, Parliament amended the *Food and Drugs Act* to empower the government to make regulations to implement Article 1711 of NAFTA and Article 39 of TRIPS. Those regulations, known as the “Data Protection Regulation”, were enacted in 2006. They provide that a manufacturer cannot seek an NOC by relying on a comparison with an “innovative drug,” before the expiry of a period of six years after the NOC for the innovative drug was granted, and Health Canada cannot grant the NOC before the expiry of a period of eight years. The validity of the Data Protection Regulation was upheld by the Federal Court of Appeal in *Apotex 2010*.

(2) Clinical Trial Transparency

[10] Clinical trials are a crucial component of the new drug development process. Clinical trials, however, have come under closer scrutiny. The materials submitted in support of Dr. Doshi’s application show important concerns with the manner in which clinical trials currently take place. Clinical trials are undertaken by researchers under contract with pharmaceutical companies. Their results are usually kept secret. While those results are provided to regulators

such as Health Canada, pharmaceutical companies have insisted that they constitute confidential business information that regulators should not make public.

[11] Yet, publicly disclosing clinical trial results may be beneficial to public health. There are concerns that the conduct of those tests may be biased, or that pharmaceutical companies selectively publish results that favour their interests. Increased public scrutiny of the work of regulatory agencies, such as Health Canada, may uncover regulatory failures. In this regard, Dr. Doshi states in his affidavit:

> […] analyses of regulatory data, such as clinical study reports, can overturn conclusions previously thought to be reliable, altering the risk-benefit assessment that is central to the authorization and use of medicines.

[12] Dr. Doshi also provides an example where independent researchers were able to question the results of published studies and to shed light on the high risks associated with the use of certain drugs:

> The conclusions of a highly cited journal article reporting the results of a randomized trial of paroxetine in children and adolescents (Study 329) were contradicted by an independent analysis undertaken by researchers who gained access to previously confidential clinical study reports, electronic individual patient data, and completed case report forms. Based on these data, these researchers re-published the study in The BMJ […], correcting the previous misleading publication. This reanalysis found that paroxetine was not clinically or statistically more effective than placebo but carried significant increases in risk of suicidal ideation and behavior.

[13] For these reasons, many people have advocated for greater clinical trial transparency.

[14] One potential avenue to achieve greater transparency is through access to information legislation. Members of the public, including researchers, may request the disclosure of information in the possession of Health Canada, under the *Access to Information Act*, RSC 1985, c A-1. However, where a request pertains to information submitted to a government agency by a third party, notice must be given to that third party, who may then argue that disclosure is prohibited by section 20 of that Act. Section 20 covers trade secrets, confidential scientific or technical information and information the disclosure of which may result in financial loss, competitive disadvantage or interference with contractual negotiations. Litigation concerning those provisions may be costly and time-consuming, as illustrated by *Merck Frosst Canada Ltd. v Canada (Health)*, 2012 SCC 3, [2012] 1 SCR 23. The information submitted in this application does not show that access to information legislation has been successful in ensuring clinical trial transparency.

(3) Relevant Provisions of Vanessa's Law

[15] Bill C-17, which became Vanessa's Law, was introduced in the House of Commons in December 2013. The initial version of the Bill contained provisions empowering the Minister of Health to order the recall or relabelling of therapeutic products (including drugs) and to request information about, and to mandate the assessment of, therapeutic products. It mandated the reporting of serious adverse drug reactions to the Minister. It also empowered the government to make regulations concerning the same subjects. Those provisions are not in issue in this case.

[16] As a result of discussions at second reading and in Committee, which will be reviewed in more detail later in these reasons, the government proposed amendments to the Bill. The provisions that are directly relevant to this case are the following.

[17] First, a definition of "confidential business information" was added:

2 In this Act,	**2** Les définitions qui suivent s'appliquent à la présente loi.
confidential business information, in respect of a person to whose business or affairs the information relates, means — subject to the regulations — business information	***renseignements commerciaux confidentiels*** Sous réserve des règlements, renseignements commerciaux qui se rapportent à l'entreprise d'une personne ou à ses activités et, à la fois :
(a) that is not publicly available,	a) qui ne sont pas accessibles au public;
(b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and	b) à l'égard desquels la personne a pris des mesures raisonnables dans les circonstances pour qu'ils demeurent inaccessibles au public;
(c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors; (*renseignements commerciaux confidentiels*)	c) qui ont une valeur économique réelle ou potentielle pour la personne ou ses concurrents parce qu'ils ne sont pas accessibles au public et que leur divulgation entraînerait une perte financière importante pour elle ou un gain financier important pour ses concurrents. *(confidential business information)*

[18] Second, provisions were added to empower the Minister to disclose confidential business information in certain circumstances:

21.1 […]	**21.1** […]
(2) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the Minister believes that the product may present a serious risk of injury to human health.	**(2)** Le ministre peut communiquer des renseignements commerciaux confidentiels qui se rapportent à l'entreprise d'une personne ou à ses activités sans obtenir son consentement et sans l'aviser si les renseignements concernent un produit thérapeutique qui, de l'avis du ministre, peut présenter un risque grave de préjudice à la santé humaine.
(3) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to	**(3)** Si l'objet de la communication est relatif à la protection ou à la promotion de la santé humaine ou de la sécurité du public, le ministre peut communiquer des renseignements commerciaux confidentiels qui concernent un produit thérapeutique et qui se rapportent à l'entreprise d'une personne ou à ses activités sans obtenir son consentement et sans l'aviser :
(a) a government;	a) à toute administration;
(b) a person from whom the Minister seeks advice; or	b) à toute personne qu'il consulte;
(c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.	c) à toute personne exerçant des fonctions relatives à la protection ou à la promotion de la santé humaine ou de la sécurité du public.

[19] Section 21.1(3) is the provision invoked by Dr. Doshi in this case.

[20] Third, the regulation-making powers of the government were enlarged to encompass the following:

30(1.2) Without limiting the power conferred by any other subsection of this section, the Governor in Council may make regulations […]	**30(1.2)** Sans que soit limité le pouvoir conféré par les autres paragraphes du présent article, le gouverneur en conseil peut prendre des règlements : […]
(c.1) defining *clinical trial* and *investigational test* for the purposes of this Act; […]	c.1) définissant *essai clinique* et *essai expérimental* pour l'application de la présente loi; […]
(d.1) specifying the business information obtained under this Act in relation to an authorization under paragraph (a) that is not confidential business information, or the circumstances in which business information obtained under this Act in relation to such an authorization ceases to be confidential business information;	d.1) précisant les renseignements commerciaux obtenus en vertu de la présente loi relativement à une autorisation visée à l'alinéa a) qui ne sont pas des renseignements commerciaux confidentiels ou précisant les circonstances dans lesquelles des renseignements commerciaux ainsi obtenus relativement à une telle autorisation cessent d'être des renseignements commerciaux confidentiels;
(d.2) authorizing the Minister to disclose, without notifying the person to whose business or affairs the information relates or obtaining their consent, business information that, under regulations made under paragraph (d.1),	d.2) autorisant le ministre à communiquer des renseignements commerciaux qui se rapportent à l'entreprise d'une personne ou à ses activités sans obtenir son consentement et sans l'aviser si, selon le cas :
(i) is not confidential business information, or	(i) un règlement pris en vertu de l'alinéa d.1) précise que ces renseignements ne sont pas des

	renseignements commerciaux confidentiels,
(ii) has ceased to be confidential business information;	(ii) ces renseignements ont cessé d'être des renseignements commerciaux confidentiels en application d'un règlement pris en vertu de cet alinéa;

(4) Proposed Regulations

[21] As of the date of this judgment, the government has not made regulations pursuant to section 30(1.2). On December 9, 2017, however, the proposed *Regulations Amending the Food and Drugs Regulations (Public Release of Clinical Information)* were published in the Canada Gazette. Subject to certain exceptions, information regarding clinical trials would cease to be considered as confidential business information when an NOC is issued or an NDS withdrawn or refused. Health Canada would be empowered to disclose such information publicly. Of interest, the context and justification of this regulatory proposal are described as follows:

> Health Canada typically treats most clinical information provided by manufacturers in drug submissions and medical device applications as confidential business information (CBI). The Department does not have a formal policy or guidance on the identification of CBI in drug submissions and medical device applications. Consequently, the established practice is not to publicly release detailed clinical data in drug submissions and medical device applications, except where the information has entered the public domain or consent has been granted by the sponsor.
>
> Without access to detailed clinical data, health professionals and researchers are unable to perform independent analyses of the evidence underlying published research findings and Health Canada's regulatory reviews. This approach limits transparency and misses opportunities to promote greater confidence in the oversight of drugs and medical devices. It is also out of step with Health Canada's key regulatory partners, including the European

> Medicines Agency (EMA) and the U.S. Food and Drug Administration, which have increased clinical data transparency over the past 10 years.

B. *Dr. Doshi's Application*

[22] Soon after the coming into force of Vanessa's Law, Dr. Doshi communicated with Health Canada to express his interest in obtaining information pursuant to section 21.1(3). After an exchange of correspondence, Dr. Doshi filed two requests with Health Canada on January 16, 2016. The first request pertained to three HPV vaccines, Gardasil, Gardasil 9 and Cervarix. The second request pertained to two neuraminidase inhibitors, Tamiflu and Relenza. In both cases, Dr. Doshi sought "complete copies of all sections of all clinical study reports." He also asked for "all electronic datasets from these same trials, including participant level datasets." Dr. Doshi stated that he would use the data for two distinct projects. First, he would conduct a "systematic review" of regulatory data (also known as a "Cochrane review"), which he describes as a "well-established methodology for exhaustively and critically reviewing all randomized controlled trials and research studies." Second, he proposed to undertake a "methodology project," "focused on improving the methodology of evidence synthesis and appraisal of regulatory documents."

C. *Health Canada's Decision*

[23] Early in the discussion with Dr. Doshi, Health Canada made it clear that it would only disclose the data if Dr. Doshi signed a confidentiality agreement. This, in fact, was consistent with a "Draft Guidance Document" regarding section 21.1(3)(c) prepared by Health Canada on March 10, 2016. Initially, Dr. Doshi indicated that he would consider the terms of a proposed

confidentiality agreement. Subsequently, he revised his position and objected to any form of a confidentiality agreement.

[24] On February 7, 2017, Health Canada issued its decision regarding Dr. Doshi's requests. First, Health Canada accepted that Dr. Doshi, given his credentials and current position, is "a person who carries out functions relating to the protection or promotion of human health or the safety of the public." With respect to the systematic review project, Health Canada also accepted that the proposed disclosure would be "related to the protection or promotion of human health or the safety of the public." With respect to the methodology project, however, Health Canada determined that Dr. Doshi had not provided enough information to allow it to reach a conclusion.

[25] Nevertheless, because Dr. Doshi had refused to sign a confidentiality agreement, Health Canada denied his request. Health Canada also noted that Dr. Doshi had failed to provide a signed declaration of conflict of interest.

D. *Dr. Doshi's Application for Judicial Review*

[26] Dr. Doshi now seeks judicial review of Health Canada's rejection of his requests. Two separate applications for judicial review have been filed. File no. T-335-17 relates to Gardasil, Gardasil 9 and Cervarix. File no. T-336-17 relates to Tamiflu and Relenza. The evidence and the submissions in both files are identical. These reasons apply to both.

[27] For the purposes of these applications, both parties agree that the information sought by Mr. Doshi constitutes confidential business information within the meaning of section 21.1(3)

and I am prepared to accept this. This is without prejudice to Dr. Doshi's more general assertion that clinical trial results should usually not be considered as such. In this connection, I observe that the proposed regulations would provide that clinical trial results cease to be confidential business information when a decision is made on an NDS. They would also authorize Health Canada to disclose such information. However, until such regulations are made, section 21.1(3) applies only to confidential business information. Thus, if Dr. Doshi were to argue that clinical trial results are not confidential, this would undercut his position that this information is covered by section 21.1(3).

[28] Dr. Doshi also agrees that Health Canada rightly requires him to sign a declaration of conflict of interest. As he is prepared to sign such a declaration if the application is allowed, I need not delve further into this issue and I will make my order conditional on Dr. Doshi providing such a declaration to Health Canada.

II. Analysis

[29] As I mentioned above, I find that Health Canada's decision was unreasonable. To explain why, I must first lay out certain principles of administrative law regarding the exercise of discretionary powers. I will then examine the text, structure and history of Vanessa's Law to discern its purpose. I will then be in a position to analyse Health Canada's decision.

A. *Reviewing the Exercise of Discretionary Powers*

[30] Administrative decision-makers who are granted discretionary powers enjoy a considerable margin of appreciation with respect to the manner in which they exercise their powers and the considerations they take into account (*Mount Sinai Hospital Center v Quebec (Minister of Health and Social Services)*, 2001 SCC 41 at para 58, [2001] 2 SCR 281). Nevertheless, since at least *Roncarelli v Duplessis*, [1959] SCR 121 [*Roncarelli*], it is recognized that discretionary powers are never absolute. Administrative law now comprises several principles guiding the exercise of discretionary power. These principles may act independently, but they may also reinforce each other in particular cases. Three such principles are invoked in this case. I will review them briefly before turning to an examination of the purposes of Vanessa's Law and, finally, the analysis of Health Canada's decision in this case.

(1) Compatibility with Statutory Purposes

[31] The first relevant administrative law principle is that a discretionary power must be exercised in a manner compatible with the purposes of the statute that grants the power. It is a matter of fidelity to legislative intent.

[32] This principle was indeed outlined in *Roncarelli*, where Justice Martland said that the power to revoke Mr. Roncarelli's liquor licence could not be exercised "for reasons which are unrelated to the carrying into effect of the intent and purpose of the Act" (at 156). Likewise, in *Shell Canada Products Ltd. v Vancouver (City)*, [1994] 1 SCR 231, the Supreme Court of

Canada stated that a municipality must exercise its powers for "municipal purposes," that is, purposes which are contemplated by the legislation creating the municipality (at 278).

[33] This principle is sometimes expressed using slightly different language or from a slightly different perspective. For example, in *Delta Air Lines Inc. v Lukács*, 2018 SCC 2 at para 20 [*Delta Air Lines*], it was said that a discretionary power must not be exercised in a manner "contrary to the scheme of the Act." In *Montréal (City) v Montreal Port Authority*, 2010 SCC 14 at para 47, [2010] 1 SCR 427, the Supreme Court required administrative decisions to be consistent with the "principles governing the application" of the legislation and with "Parliament's intention."

[34] It is also said that a discretionary power must not be exercised for irrelevant or extraneous considerations: *City of Prince George v Payne*, [1978] 1 SCR 458. Likewise, a decision-maker must not overlook relevant factors: *CUPE v Ontario (Minister of Labour)*, 2003 SCC 29 at paras 172-176, [2003] 1 SCR 539. What is relevant or irrelevant is delineated according to the legislation's purpose.

[35] In *Chamberlain v Surrey School District No. 36*, 2002 SCC 86, [2002] 4 SCR 710, the Supreme Court held that certain statements of principles in British Columbia's school legislation prevented a school board from making decisions based on certain motives. While the majority of the Court did not resort to the concept of statutory purpose, it is clear that it considered that the school board's decision not to approve pedagogical materials that depicted families with same-sex parents was contrary to the legislation's declared purpose of having a "strictly secular"

school system. That decision "was unreasonable in the context of the educational scheme mandated by the legislature" (at para 59). In his concurring opinion, Justice LeBel wrote that the legislation's statements of purposes imposed limits on the discretion of the school board (at paras 207, 215).

[36] This principle of administrative law is aptly summarized by Justice Wilson in *Reference re Bill 30, an Act to Amend the Education Act (Ont.)*, [1987] 1 SCR 1148 at 1191:

> It is, however, well established today that a statutory power to make regulations is not unfettered. It is constrained by the policies and objectives inherent in the enabling statute. […] It cannot be used to frustrate the very legislative scheme under which the power is conferred.

(2) Compatibility with Charter

[37] As the Constitution is the supreme law of the land, discretionary powers must be exercised in a manner compatible with the Constitution, which includes the Charter. In *Doré v Barreau du Québec*, 2012 SCC 12, [2012] 1 SCR 395 [*Doré*], the Supreme Court of Canada established a framework for the review of the exercise of discretionary powers that impinge upon Charter rights or values. This framework was summarized in a later decision, *Loyola High School v Quebec (Attorney General)*, 2015 SCC 12, [2015] 1 SCR 613, at para 4:

> Under *Doré*, where a discretionary administrative decision engages the protections enumerated in the *Charter* — both the *Charter*'s guarantees and the foundational values they reflect — the discretionary decision-maker is required to proportionately balance the *Charter* protections to ensure that they are limited no more than is necessary given the applicable statutory objectives that she or he is obliged to pursue.

(3) No "Fettering" of Discretion

[38] It is generally accepted that decision-makers may issue guidelines indicating the factors they will take into consideration when exercising their discretionary powers. However, those guidelines do not become law themselves. Decision-makers must still examine all relevant factors, whether mentioned in their guidelines or not. If they treat their guidelines as binding, they are "fettering" their discretion and their decisions may become unreasonable (see, for example, *Maple Lodge Farms v Government of Canada*, [1982] 2 SCR 2 at 5-6; *Kanthasamy v Canada (Citizenship and Immigration)*, 2015 SCC 61 at para 32, [2015] 3 SCR 909; *Delta Air Lines* at para 18; *Stemijon Investments Ltd. v Canada (Attorney General)*, 2011 FCA 299).

B. *Purposes of Vanessa's Law*

[39] The first two principles described above require me to ascertain the purpose of Vanessa's Law and, in particular, of section 21.1(3).

[40] In *R v Moriarity*, 2015 SCC 55, [2015] 3 SCR 485, and *R v Safarzadeh-Markhali*, 2016 SCC 14, [2016] 1 SCR 180 [*Safarzadeh-Markhali*], the Supreme Court of Canada outlined a method for determining the purpose of a statute. While that method was developed in the context of a constitutional challenge to the statute in question, it is equally applicable in this case. Purpose must not be confused with the means employed by the statute. It must be articulated at an appropriate degree of generality, which is neither a general social value nor a mere rephrasing of the provision. It must focus on the provision that is at issue. To ascertain statutory purpose, "courts look to (1) statements of purpose in the legislation, if any; (2) the text, context, and

scheme of the legislation; and (3) extrinsic evidence such as legislative history and evolution" (*Safarzadeh-Markhali* at para 31).

[41] The parties have put forward different characterizations of the purpose of Vanessa's Law. Dr. Doshi says that it is to improve transparency. The Attorney General says that Vanessa's Law cannot be considered in isolation from the *Food and Drugs Act* that it amends. She then characterizes the purpose of that Act as the promotion of public health through the reconciliation and balancing of several competing objectives, in particular the need to foster the development of new drugs and the need to ensure greater public scrutiny of the practices of pharmaceutical companies. In my view, both characterizations are unhelpful. Dr. Doshi's characterization is too broad, while the Attorney General's is too vague.

[42] Indeed, as Professor Ruth Sullivan notes, "[t]he legislature never pursues a goal single-mindedly, without qualification, and at all costs" (*Statutory Interpretation*, 3rd ed. (Toronto: Irwin Law, 2016) at 186). Thus, a purpose cannot be entirely divorced from the actual means that are deployed to pursue it. Indeed, the fact that the legislature goes only so far in the pursuit of a purpose is often due to the presence of competing values or needs that must be balanced with the legislation's purpose. But this does not mean that the balancing becomes the purpose itself. Nevertheless, those competing values or needs are helpful in contextualizing the statutory purpose.

[43] With this in mind, I propose to describe the purpose of Vanessa's Law by analyzing the factors identified by the Supreme Court in *Safarzadeh-Markhali*.

(1) Statements of Purpose

[44] The *Food and Drugs Act* does not contain a preamble or a purpose section. Vanessa's Law, in contrast, includes a preamble, which reads as follows:

Whereas the safety of drugs and medical devices is a key concern for Canadians;	Attendu :
And whereas new measures are required to further protect Canadians from the risks related to drugs and medical devices, other than natural health products;	que l'innocuité des drogues et des instruments médicaux est une préoccupation fondamentale des Canadiens;
	que de nouvelles mesures s'imposent pour protéger davantage les Canadiens contre les risques liés aux drogues et aux instruments médicaux, à l'exclusion des produits de santé naturels,

[45] This preamble suggests, with little specificity, that Vanessa's Law is intended to afford greater protection against "risks related to drugs." The implication is that it provides for stricter regulation of the pharmaceutical industry. There is nothing in this preamble that supports the Attorney General's assertion that the purpose of Vanessa's Law can be described as the balancing of competing objectives. Nor can it be said that the measure was adopted with the purpose of fostering the development of new drugs.

[46] This conclusion is reinforced by Vanessa's Law "alternative title," set forth in section 1: the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*. The "mischief" towards which Vanessa's Law is geared is clearly identified – unsafe drugs.

[47] A "summary" is also provided when bills are tabled in Parliament. This summary does not form part of the Act. However, it is akin to marginal notes, which may be given some weight in the interpretive process, according to all the circumstances: Ruth Sullivan, *Sullivan on the Construction of Statutes*, 6th ed. (Toronto: LexisNexis Canada, 2014) at 439-440. It reads as follows:

This enactment amends the *Food and Drugs Act* regarding therapeutic products in order to improve safety by introducing measures to, among other things,	Le texte modifie la *Loi sur les aliments et drogues* relativement aux produits thérapeutiques afin d'améliorer la sécurité en introduisant des mesures pour notamment :
(a) strengthen safety oversight of therapeutic products throughout their life cycle;	*a)* renforcer la surveillance de l'innocuité de tels produits au cours de leur cycle de vie;
(b) improve reporting by certain health care institutions of serious adverse drug reactions and medical device incidents that involve therapeutic products; and	*b)* améliorer la déclaration, par certains établissements de soins de santé, des réactions indésirables graves aux drogues et des incidents liés à des instruments médicaux et mettant en cause de tels produits;
(c) promote greater confidence in the oversight of therapeutic products by increasing transparency.	*c)* favoriser une confiance accrue dans la surveillance des produits thérapeutiques en augmentant la transparence.

[48] It should be noted that the third paragraph was added after the Bill was amended in Committee. It thus reflects the purpose of the amendments made in Committee, in particular sections 21.1(3) and 30(1.2). This summary thus confirms that the general goal of the Bill is to "improve safety." It provides some precision as to the means through which this will be achieved. It confirms that "transparency" was a goal pursued by Parliament. But transparency of what, and to what extent? That remains to be seen.

(2) Text, Context and Scheme of Legislation

[49] There is no doubt that Vanessa's Law is aimed at improving the safety of drugs. It does not do so, however, in an all-encompassing manner, but rather through a set of targeted measures. For example, it empowers Health Canada to recall certain drugs or to mandate further testing of drugs, but it does not deal with the process Health Canada is using when approving new drugs.

[50] Closer attention to the provisions at issue and to their relationship with other components of the normative environment provides some insight as to their purpose.

[51] What is striking about the "transparency amendments" adopted in committee, and that became sections 21.1(3) and 30(1.2), is that they resort to a two-track approach. Section 21.1(3) empowers Health Canada to disclose "confidential business information." On the other hand, section 30(1.2) empowers the government to define what is, what is not and what ceases to be "confidential business information," and to make public what is not or no longer confidential. Thus, the structure of Vanessa's Law suggests that Parliament intended some information to

become public and some other information to remain confidential, and empowered the government to draw the line between the two categories.

[52] This two-track approach to transparency parallels the provisions of Article 1711 of NAFTA and Article 39 of TRIPS, to which I have alluded earlier and which may now be examined more closely. These provisions deal separately with what they call “trade secrets” and what could be called regulatory data. Let me illustrate this with NAFTA first. The first paragraph of Article 1711 is worded as follows:

1. Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:	1. Chacune des Parties assurera à toute personne les moyens juridiques d'empêcher que des secrets commerciaux ne soient divulgués à des tiers, acquis ou utilisés par eux, sans le consentement de la personne licitement en possession de ces renseignements et d'une manière contraire aux pratiques commerciales honnêtes, dans la mesure où :
(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;	a) les renseignements sont secrets, en ce sens que, dans leur globalité ou dans la configuration et l'assemblage exacts de leurs éléments, ils ne sont pas généralement connus de personnes appartenant aux milieux qui s'occupent normalement du genre de renseignements en question ou ne leur sont pas aisément accessibles;
(b) the information has actual or potential commercial value because it is secret; and	b) les renseignements ont une valeur commerciale, réelle ou potentielle, du fait qu'ils sont secrets; et

(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.	c) la personne licitement en possession de ces renseignements a pris des dispositions raisonnables, compte tenu des circonstances, en vue de les garder secrets.

[53] It will be appreciated that the definition of trade secret in NAFTA closely parallels the definition of confidential information in Vanessa's Law.

[54] However, Article 1711 deals separately with regulatory data, which apparently includes clinical trial reports. The fifth and sixth paragraphs of that provision read as follows:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.	5. Lorsqu'une Partie subordonne l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des éléments chimiques nouveaux, à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées nécessaires pour déterminer si l'utilisation de ces produits est sans danger et efficace, cette Partie protégera ces données contre toute divulgation, lorsque l'établissement de ces données demande un effort considérable, sauf si la divulgation est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre toute exploitation déloyale dans le commerce.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.	6. Chacune des Parties prévoira, en ce qui concerne les données visées au paragraphe 5 qui lui sont communiquées après la date d'entrée en vigueur du présent accord, que seule la personne qui les a communiquées peut, sans autorisation de cette dernière à autrui, utiliser ces données à l'appui d'une demande d'approbation de produit au cours d'une période de temps raisonnable suivant la date de leur communication. On entend généralement par période de temps raisonnable, une période d'au moins cinq années à compter de la date à laquelle la Partie en cause a donné son autorisation à la personne ayant produit les données destinées à faire approuver la commercialisation de son produit, compte tenu de la nature des données, ainsi que des efforts et des frais consentis par cette personne pour les produire. Sous réserve de cette disposition, rien n'empêchera une Partie d'adopter à l'égard de ces produits des procédures d'homologation abrégées fondées sur des études de bioéquivalence et de biodisponibilité.

[55] The “data” referred to in those two paragraphs is distinguished from the “trade secrets” that are the subject of paragraphs 1 to 4. The protection afforded to that “data” is much more circumscribed. “Trade secrets” are protected from disclosure. Disclosure of “data” is authorized,

however, either where it is necessary to protect the public or where adequate protection against unfair commercial use has been provided. That protection is described in paragraph 6, in terms of a prohibition from use by a competitor for a limited period of time.

[56] This two-track protection is also the mechanism found in Article 39 of TRIPS, which distinguishes between “undisclosed information” (defined in terms very similar to NAFTA) and “data submitted to governments.” Paragraph 3 of Article 39 sets forth the protection afforded to the latter:

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.	3. Lorsqu'ils subordonnent l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des entités chimiques nouvelles à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées, dont l'établissement demande un effort considérable, les Membres protégeront ces données contre l'exploitation déloyale dans le commerce. En outre, les Membres protégeront ces données contre la divulgation, sauf si cela est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre l'exploitation déloyale dans le commerce.

[57] There is no equivalent to paragraph 6 of Article 1711 of NAFTA. Given the striking similarities between the two provisions, however, one could argue that parties to TRIPS

understood “protection against unfair commercial use” in a manner similar to what is found in NAFTA.

[58] It can be inferred from the comparison between Vanessa’s Law and the provisions setting out Canada’s international obligations that Parliament intended to afford greater protection to what can properly be called “trade secrets” or, to use the language of Vanessa’s Law, “confidential business information,” in contrast to “data submitted to governments,” which would include clinical trial reports.

[59] Indeed, the provisions of Vanessa’s Law appear to be closely tailored to comply with Canada’s obligations under TRIPS and NAFTA and to provide the maximum degree of transparency compatible with those obligations.

[60] To understand how Parliament achieved that objective, it is useful to recall that Health Canada’s traditional position was that all information submitted by pharmaceutical companies, including clinical trial reports, is “confidential business information” that cannot be disclosed. As that stance came under increasing criticism, Parliament decided that a narrower definition of “confidential business information” would be appropriate, provided that it was not narrower than the definitions in NAFTA and TRIPS. Instead of enacting such a definition itself, Parliament delegated this task to the government. Thus, section 30(1.2) of Vanessa’s Law empowers the government to make regulations defining confidential business information. The obvious assumption is that information that is dealt with in paragraphs 5 and 6 of Article 1711 of NAFTA or in paragraph 3 of Article 39 of TRIPS would no longer be considered as such and could be

disclosed to the public. This is so because a prohibition against the use of such information by generic drug makers is already in place – this is the Data Protection Regulation, adopted in 2006, as mentioned above. In contrast, information that comes more directly within the definition of "trade secret" would be subject to a more stringent regime, designed to ensure that it cannot be used by others. This is where section 21.1(3) comes in. It provides for the disclosure of confidential business information to specific categories of persons for specific purposes. Likewise, section 21.1(2) authorizes disclosure "if the Minister believes that the product may present a serious risk of injury to human health." Arguably, the test for disclosure in those two cases ensures compatibility with NAFTA and TRIPS.

(3) Legislative History

[61] The purpose of Vanessa's Law may also be inferred from its legislative history, which includes the debates in Parliament and the sequence in which its various components were proposed. Legislative debates have typically been given limited weight in the interpretation of statutes. Nevertheless, legislative debates may be especially useful to shed light on a statute's purpose, as speeches in Parliament are more likely to describe a bill's broad purposes rather than its precise workings.

[62] Parliamentary debates may also reveal that a statute is the product of a compromise between the positions advocated by various stakeholders. When that is so, the statute should not be interpreted in a way that detracts from the compromise or that deprives a stakeholder group from gains it made during the Parliamentary process. Those stakeholders often appear before

Parliamentary committees. In their speeches, politicians may also describe how a statute was designed to give effect to the demands of certain stakeholders.

[63] When Bill C-17 was introduced in the House of Commons on December 6, 2013, it did not contain provisions concerning clinical trial transparency. Upon second reading of the Bill in the House of Commons, Mr. Young, who delivered the first speech in favour of the Bill, indicated that the government would be open to amendments that would strengthen the protections offered by the Bill. Members from the Opposition parties expressed their general support for the Bill, but mentioned that the lack of any provisions mandating clinical trial transparency was a shortcoming that needed to be addressed.

[64] Bill C-17 was then sent to committee, where clinical trial transparency was a frequent theme. A number of university professors suggested that the Bill be amended to include provisions mandating greater clinical trial transparency. How this was to be accomplished, however, was not clearly set out. For example, on June 10, 2014, Professor Matthew Herder of Dalhousie University suggested that the precise means to achieve transparency should be left to the discretion of government:

> Second, empower the Minister of Health to disclose clinical study reports. Access to clinical study reports and the data they contain can be critical to understanding the quality of the evidence behind a given drug.
>
> […]
>
> The optimal procedures for sharing clinical study reports are the subject of live debate. For that reason, defining the procedures by which clinical study reports should be made available by way of regulations is appropriate. But vesting the minister with the authority to make them available is critical.

[65] He then summarized his recommendations in a way that includes both mandatory and discretionary provisions:

> Second, all clinical trials and other investigational studies involving a therapeutic product shall report the results thereof on a publicly accessible, searchable database within one year of the completion of the trial or study, in accordance with the regulations. […] Third, the minister may publicly disclose clinical study reports in accordance with the regulations.

[66] On his part, Professor Joel Lexchin of York University explained his recommendations as follows:

> First of all, I would say that the clinical study reports would have to be made available. These are comprehensive documents. Sometimes they run into thousands of pages. Not everybody's going to read them, but people who do things like develop guidelines for practitioners, who do systematic reviews, will definitely read these and analyze them.
>
> The other feature we need to make sure comes out, and this is not something that's particularly radical—GlaxoSmithKline has already made a commitment to do this—is that the full reports of all of the trials that have been undertaken will be released to qualified researchers. People will make applications to GlaxoSmithKline. The company is going to set up an independent committee to evaluate those requests to make sure they are legitimate, and if they are legitimate then GlaxoSmithKline will release all of the information. That's the raw data they collected in the conduct of the trials for their drugs.
>
> I think we need two things. One is an unequivocal release of the clinical study reports without any formal requests. Secondly, the companies, on receipt of a valid request from researchers, will release all of the raw data for the clinical trials.

[67] After the hearing of witnesses was concluded, the committee studied a number of amendments to the Bill. The provisions that are now at issue were introduced by Mr. Young on behalf of the government. No detailed explanation of their functioning or intended purpose was

provided. However, a number of amendments introduced by Opposition members that would have mandated in clear terms the publication of clinical trial results were defeated.

[68] The Bill was then adopted in its amended form by the House of Commons and sent to the Senate. Upon second reading in the Senate, Senator Judith Seidman described the amendments as follows:

> These amendments respond directly to feedback from medical and legal experts and greatly improve transparency measures to ensure that Canadian patients, clinicians and researchers, are able to access critical drug-safety information. These amendments require that both positive and negative decisions about drug authorizations be disclosed and explained on a public website; they define the scope of confidential business information, CBI, and allow the Minister of Health to disclose CBI about a product if the minister believes the product may pose a serious risk to Canadians; and they oblige the disclosure of clinical trial information on a public registry.

[69] It should be noted that at the committee hearings in the Senate, a representative of the pharmaceutical industry addressed the issue of confidentiality. On October 1, 2014, Gerry Harrington, Director of Public Affairs of Consumer Health Products Canada, asserted that:

> […] the provisions related to confidential business information raise a number of concerns and seem at odds with worthwhile initiatives on regulatory cooperation with our most important trading partner. Both the lowered threshold for the release of CBI and the lack of provisions holding recipients of CBI to respect that confidentiality are at odds with the practices of our major trading partners.

[70] These excerpts from Parliamentary debates show that Vanessa's Law was amended to respond to criticism that it failed to provide for clinical trial transparency. Hence, one should assume that the purpose of the provisions inserted in the Bill at the committee stage was to

improve clinical trial transparency. Senator Seidman said as much when introducing the Bill in the Senate.

[71] This is somewhat more precise that the characterization put forward by Dr. Doshi. It recognizes that the main focus of the transparency debate related to clinical trial reports and data and that it was understood that this information could no longer be hidden from public view. It also recognizes that Parliament adopted a careful approach to the issue. Parliament expressly refrained from enshrining in the legislation itself a rule mandating clinical trial transparency. Rather, it decided that its purpose would be better achieved by delegating to the government the power to delineate what categories of information would be made public (section 30(1.2)) and by authorizing Health Canada to disclose confidential information in specific circumstances (sections 21.1(2) and (3)). This two-track approach seems to be in line with the suggestions of certain experts who testified in committee.

C. *Analysis of Health Canada's Decision*

[72] This brings me to the crux of the matter. Is Health Canada's decision to deny Dr. Doshi's request reasonable? I find that it is not, but for reasons that are slightly different from those advanced by Dr. Doshi – or, to use the language of the criminal law, for reasons that are "lesser and included."

[73] In his memorandum of argument, Dr. Doshi took the position that under section 21.1(3), Health Canada has simply no power to impose a confidentiality requirement. At the hearing, he argued that Health Canada's decision was based on an irrelevant consideration – Vanessa's Law,

and the Food and Drugs Act in general, are not aimed at protecting the commercial interests of pharmaceutical companies, and Health Canada could not exercise its discretion under section 21.1(3) with that objective in mind.

[74] Either way, the gist of Dr. Doshi's argument is that Health Canada can never impose a confidentiality requirement when disclosing data under section 21.1(3). I disagree. Such a position overlooks the two-track approach espoused by Parliament. The scheme of the legislation is that certain categories of information, defined by the regulations, would be made public, but that other categories would still be described as "confidential business information." The definition of "confidential business information" closely parallels that of "trade secret," which suggests that Parliament considered that there could be a legitimate interest in keeping such information private. In other words, there will be situations where Health Canada may validly impose a confidentiality requirement with respect to specific categories of information, but that decision must be made on a case-by-case basis.

[75] Nevertheless, Health Canada's decision in this case is unreasonable, because it entirely disregards one of the main purposes of Vanessa's Law, namely to improve clinical trial transparency, it amounts to a fettering of discretion and it does not result in a proportionate balance between Dr. Doshi's freedom of expression and Health Canada's purposes.

(1) Purpose of Vanessa's Law

[76] In its letter of February 7, 2017 to Dr. Doshi, Health Canada explained its decision as follows:

> In reaching my decision, I considered the reasons you have presented in support of disclosing information identified in your request without a requirement to maintain confidentiality. You have emphasized the importance of unpublished regulatory data in enabling systematic drug reviews as this information can be more comprehensive than published reports. Health Canada recognizes that regulatory information can make a valuable contribution to systematic drug reviews. The decision to deny your request was made on the basis of current policy and practice which treats unpublished regulatory data as CBI. Health Canada has informed Canadian stakeholders of its intent to review current policy and practice regarding the confidentiality of clinical data, and to engage with all stakeholders, including industry, academic researchers, health professionals and patient groups in a fair and deliberate manner. Any changes to current policy and practice will be based on thorough consideration of all stakeholder views and positions. Until this time, Health Canada will continue to administer the CBI disclosure authority based on current policy and practice.

[77] Thus, Health Canada's decision is not based on a review and balancing of competing factors. It is based on "current policy and practice" to the effect that no information will be disclosed under section 21.1(3) absent a confidentiality undertaking. That policy is not new. It was expressed to Dr. Doshi as early as October 21, 2015. It was a component of Health Canada's draft guidelines regarding section 21.1(3), made public on March 10, 2016. Yet, Health Canada never outlined the substantive justifications of that "current policy and practice." It appears to be a carry-over from the pre-Vanessa's Law period, when Health Canada took the position that all information submitted by pharmaceutical companies was confidential.

[78] The difficulty of this case is that one of the two tracks of the approach adopted by Parliament to ensure greater transparency has not been implemented yet. No regulations have been made under section 30(1.2), although a proposal has been published in the Canada Gazette. Thus, according to the logic of the legislation, the information sought by Dr. Doshi remains

"confidential business information" that may be disclosed under section 21.1(3), because regulations that would take it out of that category are not yet in place.

[79] Thus, Health Canada had to appreciate that, pending the adoption of regulations under section 30(1.2), section 21.1(3) could be used to seek the disclosure of clinical trial reports that Parliament intended to make public, although through a different route. (That would no longer be true once the regulations are in force, because clinical trial reports would no longer be considered "confidential business information," and section 21.1(3) applies only to such information.)

[80] It thus becomes clear that Health Canada's blanket confidentiality policy is unreasonable. It ran against one of the purposes of Vanessa's Law. It had the effect of perpetuating the mischief against which Vanessa's Law was aimed. Quite simply, Health Canada cannot ignore that Parliament intended to make clinical trial data public and adopt a policy that is in direct contradiction with that purpose.

(2) Fettering of Discretion

[81] The policy also resulted in Health Canada fettering its discretion. While I recognize that some information may be disclosed pursuant to section 21.1(3) on the condition that it remain confidential, Health Canada cannot take the position that it will always be so. That would be tantamount to adding words to the legislation. Yet, as we saw above, Parliament was invited to stipulate that information disclosed under section 21.1(3) would remain confidential, but declined to do so. Health Canada's blanket policy thus reverses a choice made by Parliament.

[82] The publication of draft regulations in the Canada Gazette only makes Health Canada's position more untenable. By announcing those regulations, the government is in effect accepting that there is no legitimate interest in keeping the results of clinical trials private. In its accompanying statement, quoted above at paragraph [21], the government recognized the value of clinical trial transparency. It is difficult to understand how Health Canada can disregard such a statement and insist on a confidentiality undertaking as a condition of disclosing clinical trial reports and data to Dr. Doshi, even if the disclosure is pursuant to section 21.1(3) and not pursuant to regulations made under section 30(1.2).

(3) Disproportionate Impact on Freedom of Expression

[83] Moreover, Health Canada's decision appears to ignore Dr. Doshi's freedom of expression guaranteed by section 2(b) of the Charter. In a letter he sent to Health Canada on December 9, 2016, Dr. Doshi insisted that his constitutional rights should be taken into account. Yet, Health Canada's decision is silent on this topic. There is no indication that it undertook the balancing exercise mandated by *Doré*. In any event, I fail to see how Health Canada's decision can be said to achieve a reasonable balance between freedom of expression and any statutory purposes that it was implementing.

[84] I need not insist on the importance of freedom of expression in the academic context. Freedom of expression certainly includes the freedom to disseminate research results, even where those results are controversial or contrary to accepted opinion. Researchers must also be free to choose how they will formulate their results. In this context, the ability to quote sources and supporting material is crucial. Without references to sources, research results may be viewed

as mere opinion. An opinion is only as good as the facts on which it is based. If they are unable to communicate those facts, researchers will be significantly hampered in the dissemination of their results. The possibility of conducting an informed public debate will be eroded.

[85] In this context, Health Canada's confidentiality requirement would prohibit Dr. Doshi from quoting from the clinical trial reports disclosed to him. Thus, if a clinical trial report concludes that a drug is ineffective or has undesirable side effects, Dr. Doshi could not reproduce that conclusion in a paper outlining the results of his research. As drafted, the proposed confidentiality agreement would even prohibit Dr. Doshi from referring to the contents of the documents disclosed to him, for example by summarizing or paraphrasing them. It is difficult to understand how, in practice, Dr. Doshi could meaningfully communicate the results of his research under such constraints.

[86] What, then, could offset this breach of Dr. Doshi's freedom of expression? In its decision, Health Canada does not identify any countervailing considerations. It simply reiterated a policy that pre-dated Vanessa's Law. The objectives of that policy are unstated and unclear. As far as one can understand, they appear to contradict the purposes of Vanessa's Law. The mere fact that the policy is aligned with the preferences of the pharmaceutical industry would be insufficient to justify a restriction on Dr. Doshi's freedom of expression. The policy is overbroad and cannot be a proportional balance between Charter rights and statutory purposes. To achieve such a balance, Health Canada had to consider the effects of granting Dr. Doshi's request, which pertained to clinical trial results, on the pursuit of its statutory mandate. Given Vanessa's Law's purpose of improving clinical trial transparency and the recent regulatory proposal, it is difficult to

understand how the restriction of freedom of speech that results from Health Canada's confidentiality requirement can be justified.

[87] Thus, I conclude that it was unreasonable for Health Canada to impose a confidentiality requirement as a condition for the disclosure of data requested by Dr. Doshi.

[88] I would like to add that nothing in these reasons is intended to detract from the privacy and anonymity of clinical trial participants. University research ethics guidelines guarantee research participant anonymity. Dr. Doshi does not propose to reveal the identity of participants, if such information is included in the documents disclosed to him, and I understand that this is not a contentious issue between the parties.

[89] Given that I have decided the case on the basis of freedom of expression, it is not necessary for me to decide whether section 2(b) of the Charter protects access to information, or whether section 7 of the Charter is engaged.

[90] Nor do I need to decide whether it was reasonable for Health Canada to refuse to disclose documents to Dr. Doshi for the purposes of his "methodology project." As I have decided that Health Canada cannot impose a confidentiality requirement, it follows that Dr. Doshi will be able to use the documents disclosed on the basis of his "systematic review project" for the purposes of his "methodology project."

III. Remedy

[91] Dr. Doshi seeks an order of *mandamus*, effectively forcing Health Canada to disclose the requested information.

[92] *Mandamus* is only available in specific circumstances. Typically, *mandamus* will issue only if the respondent has a non-discretionary duty to act (*Apotex Inc v Canada (Attorney General)*, [1994] 1 FC 742 (CA) at 766-769 [*Apotex*], affirmed [1994] 3 SCR 1100). Where the power involved is discretionary, respect for the autonomy of the executive branch of government normally requires that the reviewing court limit itself to quashing the impugned decision. As Justice Yves de Montigny of the Federal Court of Appeal said in *Canada (Citizenship and Immigration) v Yansané*, 2017 FCA 48 at para 15 [*Yansané*]:

> In general, the role of a superior court in a judicial review of an administrative decision is not to replace the administrative decision-maker's decision with its own decision; rather, its role is limited to verifying the legality and reasonableness of the decision rendered, and to returning the file to the same decision-maker or another decision-maker in the same organization if it finds that an error was made and that the decision was illegal or not within the range of possible, acceptable outcomes in respect of the facts and the law […].

[93] Thus, *mandamus* cannot be used to force the exercise of discretion in a particular way (*Apotex* at 768; *Canada (Health) v The Winning Combination Inc.*, 2017 FCA 101 [*Winning Combination*]). Nevertheless, courts have issued *mandamus* where there is only one reasonable outcome (see, for example, *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at paras 150-151, [2011] 3 SCR 134; see also, *a contrario*, *Winning Combination* at para 75).

[94] At the hearing, I asked counsel for the Attorney General why *mandamus* would not be appropriate in this case. He replied that, had Health Canada known that it could not impose a confidentiality requirement on Dr. Doshi, it could have reached a different conclusion with respect to the other requirements of section 21.1(3), namely, whether Dr. Doshi is "a person who carries out functions relating to the protection or promotion of human health or the safety of the public" and whether his research project is "related to the protection or promotion of human health or the safety of the public." Such a statement is astonishing. It assumes that Health Canada's decision and detailed reasons with respect to those two questions are not the result of careful consideration. At best, it suggests that Health Canada was engaged in a form of results-oriented reasoning whereby the decision not to make clinical trial reports public had to be justified in any conceivable manner. This only reinforces my conclusion that Health Canada fettered its discretion. At worst, it suggests that Health Canada would try to circumvent a decision of this Court in favour of Mr. Doshi by rescinding conclusions favourable to him.

[95] I fail to see how Health Canada could reasonably decide not to disclose the data requested by Dr. Doshi. Counsel's suggestion that Health Canada might take a different view of Dr. Doshi's credentials or the suitability of his research project is entirely devoid of merit. There remains the possibility that Health Canada could exercise its discretion against disclosure for reasons that were not invoked in its February 7, 2017 letter. However, no such reasons were suggested to me. Dr. Doshi seeks clinical trial reports and data. This information will become public when the regulations are adopted. There is no principled basis to keep them private now.

[96] Therefore, I will issue an order of *mandamus* requiring Health Canada to grant Dr. Doshi's request and to communicate the information sought.

[97] Both parties agreed not to seek costs, given the public interest nature of the case. Accordingly, I make no order as to costs.

JUDGMENT in T-335-17 and T-336-17

THIS COURT'S JUDGMENT is that

1. The application for judicial review is allowed;

2. Upon receiving an executed Declaration of Conflict of Interest from the applicant, the Minister of Health is ordered to disclose to the applicant complete copies of all sections of all clinical study reports and all electronic datasets from these same trials, including participant level datasets with respect to Gardasil, Gardasil 9, Cervarix, Tamiflu and Relenza;

3. Each party will pay its own costs.

"Sébastien Grammond"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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