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Re: Draft Guidance – Document: Disclosure of Confidential Business Information Under Paragraph 21.1(3)(c) of the *Food and Drugs Act*"

To whom it may concern:

We, a group of law professors and legal scholars, write to provide our comments with respect to Health Canada's Draft Guidance on the Disclosure of Confidential Business Information.

Section 21.1(3)(c), added to the *Food and Drugs Act*, R.S.C. 1985, c. F-27 [the "*F&D Act*"] as part of other amendments introduced by what is known as "Vanessa's Law", was intended to enhance the regulation of pharmaceutical drugs and thereby protect Canadians from harm. These amendments gave the regulator, Health Canada, new powers to, *inter alia*, recall drugs, require active post-market surveillance, and improve the transparency of information around pharmaceutical drugs.

Section 21.1(3)(c) is one of the transparency-related provisions. It authorizes the Minister of Health to disclose "confidential business information" ["CBI"] provided "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…a person who carries out functions relating to the protection or promotion of human health or the safety of the public." The *F&D Act* does not provide any other conditions for the disclosure, nor does it authorize the Minister to impose other conditions.

However, Health Canada Draft Guidance introduces significant limitations into this provision. In particular, Health Canada's Draft Guidance takes the position that s. 21.1(3)(c) requires those who request information pursuant to this provision to,

i. Demonstrate qualifications as a health professional and research expertise;
ii. Enter into a confidentiality agreement;
iii. Agree not to disclose the information to any third parties; and,

iv. Demonstrate prior efforts to obtain the information from all other possible sources.

We submit that s. 21.1(3)(c) does not provide Health Canada with the power to impose these four limitations on disclosure. The power to impose these limitations is not set out in the statute and the limitations are at odds with the purpose of the amendments and the rest of the statutory scheme. Moreover, two of the proposed limitations purport to impose on otherwise eligible recipients of information new legal duties and liabilities that only Parliament can create or impose, not the Minister of Health. Further, these limitations potentially violate the *Charter of Rights and Freedoms*. We explain each of these points in greater detail below.

First, Parliament chose to extend s. 21.1(3)(c) to persons "who carr[y] out *functions* relating to the protection *or* promotion of human health *or* the safety of the public." (emphasis added) Parliament was encouraged to define, with greater particularity, what types of persons fell into this category during the legislative process. However, Parliament chose not to do so within the four corners of the legislation, suggesting that Parliament did not intend to limit, *ab initio*, the types of persons who are eligible to receive information pursuant to s. 21.1(3)(c). This was wise: many people are involved in the protection or promotion of human health or public safety. For example, practicing physicians' prescribing decisions may be better informed with access to unpublished drug risks.

Second, the idea that those who are eligible to receive information under s. 21.1(3)(c) can only obtain access under strict terms of confidentiality does not follow from the scheme or object of the legislation. Parliament explicitly authorized the Minister to *disclose* the information to qualified persons, and thereby made it lawful for the Minister to disclose the information and for the recipient to receive and use it. Parliament neither imposed any new legal duties on the recipient, nor did it require or authorize the Minister to impose them. In the absence of an explicit statutory mandate, the Minister cannot impose conditions or create new legal obligations upon otherwise eligible recipients of information under s. 21.1(3)(c).

Moreover, the proposed requirement of entering into a confidentiality agreement is not only *ultra vires*, but also frustrates the purpose of Vanessa's Law. Parliament's intention in enacting Vanessa's Law was, in significant part, to break from past practice and to strengthen transparency. This is in line with international commitments and with significant improvements to transparency in other jurisdictions, including Canada's trading partners. In the past, drug related information that was categorized as proprietary under the *Access to Information Act*, R.S.C. 1985, c. A-1, was almost uniformly exempt from disclosure. Recognizing the importance of increased transparency to protecting Canadians from harm, Parliament chose to open up—to eligible persons for eligible purposes—such information when it enacted Vanessa's Law. The Draft Guidance's proposal to require all information sharing under s. 21.1(3)(c) to perpetuate confidentiality is thus inconsistent with the new scheme and object of the *F&D Act* and Parliament's intention. There is, moreover, no obligation under international law to impose confidentiality upon recipients of information. Canada is only obliged to protect data from "unfair commercial use", which it has already done, by granting a limited period of data exclusivity to drug companies (*Food and Drug*

Regulations, C.R.C., c. 870, C.08.004.1), and by limiting disclosure under s. 21.1.(3) to certain non-commercial purposes undertaken by certain qualified persons. To comply with the *F&D Act* and with Canada's international obligations, the Minister needs no more than requiring applicants to warrant that they intend to use the information for the purposes mentioned in s 21.1(3) before the information is disclosed.

Third, while the Draft Guidance allows recipients of information under s. 21.1(3)(c) to disseminate the "results" of their research, it precludes them from reproducing, in whole or part, the underlying information. Again, this obligation is *ultra vires*; the statute provides no authority for the Minister to impose additional obligations upon otherwise eligible recipients of information under s. 21.1(3)(c). Nor can the obligation be implied due its practical necessity under the legislative scheme. On the contrary, precluding recipients from further disclosing information will seriously hamper their ability to disseminate research findings and thereby protect and promote human health because the publication of research in reputable journals is increasingly contingent upon sharing the information underlying those findings. More fundamentally, it is impossible to detect selective reporting and fabrication of results without data openness. For example, a recent re-analysis of the research data used to justify the use of the anti-depressant paroxetine (tradename: Paxil) in adolescents reveals that the drug was neither safe nor effective for that population. (See Noury, Joanna Le et al. "Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence" (2015) 351 BMJ h4320.) The paroxetine case is far from an isolated example in the pharmaceutical context where the financial incentives to skew research findings in favour of a drug are powerful. This and other controversies reveal how the scientific community and other public health oriented professionals are crucial partners in the promotion and protection of the health of Canadians. In order to fulfill this function, they need unfettered access to the data.

Fourth, the Draft Guidance's stipulation that would-be requesters seek information from "all other possible sources", including the originating company, prior to obtaining access through Health Canada, promises to completely frustrate the purpose of s. 21.1(3)(c). Some companies have indeed begun to make some drug information available through their own or third-party data platforms. However, there is no guarantee that any source of information is the same. In some cases, pharmaceutical companies have misled regulators, providing only some of the information pertaining to a given drug. Further, the originators of the of information (i.e. pharmaceutical companies) have an incentive to appear as though they are transparent in the public eye while in practice working to delay and complicate researchers' access to, and analysis of, the information, particularly where the purpose of the research is interrogate past findings that support a drug already on the market. This is precisely what occurred in the paroxetine case. The originator, GlaxoSmithKline, ultimately provided access to the data in question. But they did so slowly and in a manner that was far from conducive to analysis; the researchers involved had to scrutinize thousands of pages of data in 'read only' format on a company computer. (Doshi, P. "Putting GlaxoSmithKline to the test over paroxetine" (2013) 347:nov12 2 BMJ f6754; Noury et al., supra.) The obligation to obtain data from all other possible sources will also delay access to data and create an often insurmountable practical burden for health researchers and others.

Fifth, the Draft Guidance may violate the *Charter of Rights and Freedoms*, in particular the right to freedom of expression enshrined in s. 2(b), and the s.7 right to life, liberty and security of the person.

The right sought to be exercised is grounded in freedom of expression—the right of requesters to express themselves by publishing their research and speaking to patients, colleagues and the media regarding the risks and benefits of drugs, and the right to obtain and use information that may be relevant or even essential to protect and promote one's health. We put forward that individuals may have a right to access information held by governments that is relevant to the protection of their health and physical security, even where that information is obtained via the intermediary of requesters with sufficient expertise to interpret and analyse safety and effectiveness data. We emphasize that we are dealing with information that Parliament explicitly recognized may be important to be disclosed to persons (broadly understood) who carry out functions related to the protection or promotion of human health or public safety.

Eligible persons within the meaning of s. 21.1(3)(c) cannot research without the data and they cannot publish in a number of journals without disclosing the data. Those who need the information to make decisions regarding their physical integrity and general health-related decisions are prevented from doing so and are prevented from receiving the help they require in accessing and understanding relevant health information.

For all of the foregoing reasons, we call upon Health Canada to remove these four limitations from its Draft Guidance.

In closing, we must also stress that we do not accept Health Canada's view that information about a drug's safety or effectiveness falls within the scope of "confidential business information" (CBI). Despite the broadly worded definition of CBI in Vanessa's Law, we submit that any information about a drug's safety or effectiveness should be regarded as *clinical* information—derived from patients in the course of clinical studies or treatment and intended to create knowledge—rather than *business* information. Further, the definition also requires CBI to hold "actual or potential economic value", the disclosure of which "would result in a material financial loss to the person or a material financial gain to its competitors." Allowing greater scrutiny of the unpublished information about a drug could only result in financial loss to the person who submitted it if the data does not actually support the claim that the drug is safe and effective. Clearly, Parliament did not intend to enact a regulatory regime that would allow drug companies to make unsubstantiated claims about safety and efficacy when it passed Vanessa's Law. Thus, drug safety and effectiveness data should also not be regarded as fulfilling the economic value component of the statutory definition of CBI.

We therefore urge Health Canada to immediately exclude drug safety and effectiveness information from the scope of CBI as a matter of practice as well as draft regulations to that same effect in an expedited manner pursuant to s. 30(1.2)(d.1) of the *F&D Act*. The fundamental flaws in Health Canada's Draft Guidance that we outline above are in addition to this problematic approach regarding the scope of CBI.

Respectfully,

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*Added following submission to Health Canada on May 24, 2016.