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• INTERNET PHARMACIES: CANADA'S TRANSNATIONAL ORGANIZED CRIME •

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Introduction

Advertising or selling foreign-sourced medicines that are not approved by Health Canada is a criminal act in Canada. Yet, in the last decade, unscrupulous "Internet pharmacies"—some of which are just call centers and not truly pharmacies at all—located on Canadian soil have built a wildly successful industry on that criminal transaction, pitching unapproved medicines from developing countries such as India to patients and doctors in the United States.[1] While the United States has, at times, prosecuted the Canadians responsible for this criminal cross-border trade—dealing in unapproved medicines violates American law too—no one has been prosecuted in Canada.

Canada's federal government knows only too well that this crime goes on. After some Canadian Internet pharmacies advertised or sold falsified or counterfeit medicines, including a fake cancer treatment made of cleaning solvents, the authors of this article even wrote to Stephen Harper, prime minister of Canada, about it and received a polite, if rather empty, letter back. The Royal Canadian Mounted Police are often asked by foreign law enforcers to investigate this country's Internet pharmacies, and the RCMP has obliged dozens of times. But for all the RCMP's hard work, nobody has ever been prosecuted.

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We argue in this article that Canada's *laissez-faire* attitude towards illegal Internet pharmacies calls into question this country's commitment to the rule of law. Internet pharmacies are organized transnational businesses, and so the decision of the federal government not to prosecute them for flagrantly illegal conduct is, hyperbole aside, a decision to make Canada a haven for transnational organized crime. If Canada wishes to regain the moral high ground, and not to be classed or sanctioned as that kind of criminal haven, then the government has no option but to enforce the laws when persons on Canadian soil operate Internet pharmacies unlawfully.

History of Canadian Online Pharmacies

Canadian Internet pharmacy has been a lucrative business, bringing in over $400 million annually.[2] The industry began around the year 2000, founded on the simple economic idea of arbitrage, or what is sometimes called "parallel trade" in the medical literature.[3] The core business model called for selling real Canadian medicines to American customers at a discount to real American medicines, made possible by a relatively weaker Canadian dollar and legislated price controls on patented medicines in Canada.[4] Buying a familiar medicine, but at a lower price, appealed especially to American seniors, the uninsured or underinsured, or HIV/AIDS patients.[5]

Many credit a young Manitoban pharmacist, Andrew Strempler, for pioneering the industry. Strempler realized the potential of arbitraging Canadian drugs to the U.S. after he sold a box of Nicorette gum on eBay for $20, which would have normally cost Americans $55. Such transactions were of dubious legality, but Strempler soon hoovered up Costco's stock of Nicorette gum, founded the MediPlan

Pharmacy, and began doing business online as RxNorth.com.[6] MediPlan soon expanded its offerings to other medicines and brought in around $80 million a year.[7] A gold-rush mentality took hold, and others entered the business. As one contemporary recounts, it "was like a fire hose spraying money across the Manitoba landscape".[8]

None of this went unnoticed by the American government and the major pharmaceutical companies, both of whom stood to lose money to the arbitrageurs. As early as 2001, America's Food and Drug Administration (FDA) warned Strempler that exporting medicines not approved by the FDA to the United States was illegal, but he carried on anyway.[9] Merck, Pfizer, GlaxoSmithKline, Eli Lilly, AstraZeneca, while lobbying to shut down the Internet pharmacies, took matters into their own hands and suspended deliveries of some medicines at the wholesale level.[10] This partially starved the arbitrageurs of genuine Canadian medicines to sell. Together with a stronger Canadian dollar and the passage of a new drug benefit for American Medicare patients, business for Canadian Internet pharmacies became harder. The gold rush was over.[11]

But a business founded on evading the law is likely, when cornered, to find new ways of doing so—which is exactly what happened. Canada's Internet pharmacies began offering medicines from suppliers or middlemen of uncertain provenance, apparently including Australia, Austria, Chile, China, Cyprus, Germany, India, Israel, New Zealand, Switzerland, the United Kingdom, and Vanuatu.[12] These medicines were trans-shipped to American customers, without crossing Canadian soil. Such foreign-sourced medicines could be cheaper than true Canadian medicines, but with the risk that because Health Canada does not regulate the source countries, there is absolutely no basis to assume that they are equivalent to Canadian medicines in safety and efficacy. This hazard is especially present for India, where drug regulation is notoriously weak.[13]

Strempler flaunted his lifestyle of sports cars, private jets, XO cognac, and posh cigars to any reporter who would listen.[14] Greed got hold of him, and his crimes became audacious. According to a U.S. Justice Department indictment, Strempler controlled an offshore Internet pharmacy, Personal Touch, in the Bahamas that laundered various foreign-sourced medicines to American customers under fraudulent pretenses.[15] False labels were attached to the medicines to make it appear they had come from RxNorth.com in Canada, when that was not true. Not being well regulated, some of the medicines that Strempler portrayed as authentic were actually counterfeit.[16] A laboratory that Strempler claimed was testing the medicines was ill equipped to do any such thing.

But despite the searing detail of the American indictment, Canada's federal government did nothing. It never prosecuted or extradited Strempler. Instead, Strempler was allowed to sell his business, resign his Manitoba pharmacy licence, pay a few thousand dollars, and emigrate with his family and wealth to the Caribbean, where he set up another dubious pharmacy business.

Justice caught up with Strempler thanks to Panama's, not Canada's, government, which extradited him. Strempler is now a convicted criminal in an American prison, having pleaded guilty to conspiracy to commit mail fraud.[17] Nearly a decade after the American indictment, Canada still has not announced any indictment for the offences that Strempler committed here. Nor has Canada done much about the Manitoba

Internet pharmacy that bought Strempler's operations and is now under a cloud for being at the center of a global network that trafficked, advertised, and sold fake cancer medicine to American clinics—a medicine that reportedly contained cleaning solvents rather than any real cancer treatment.[18] In the United States, several persons involved in that scandal have already been indicted, convicted, and imprisoned. However, in Canada, years have passed, and the authorities have not even announced an investigation.

But despite scandals such as fake cancer medicine, some commentators, such as Gabriel Levitt, maintain that Canadian Internet pharmacies are good for public health. Levitt argues that they fill a vital role in supplying Americans with cheaper medicines and that shuttering them would be unethical.[19] Levitt admits that his argument is self-interested—he works for a firm that promotes Canadian Internet pharmacies—but it is obsolete and mistaken anyway.

Levitt's public health argument was tenable a decade ago, when Canadian Internet pharmacies sold Americans genuine Canadian medicines of known quality. But maintaining this argument, now that Canadian Internet pharmacies are criminally offering foreign-sourced medicines that are neither approved nor tested by Health Canada, is preposterous. While we agree that too many Americans lack affordable access to medicines, this does not logically lead to the conclusion that they are well served by taking a chance on cheaper, but riskier, medicines from (say) India or Turkey, offered illegally by Canadian Internet pharmacies. Further, if American patients wanted those Indian or Turkish medicines for whatever reason, presumably, they could buy them more cheaply from an Internet pharmacist in Mumbai or Istanbul, thus cutting out the profit-seeking Canadian middleman—and others like Mr. Levitt—altogether.[20]

A more accurate conclusion is that the Canadian Internet pharmacies serve no useful function but to add a veneer or "gloss" of Canadian respectability, which with no doubt fools some patients into believing that the foreign-sourced medicines being criminally offered are approved in Canada, when actually they are not. Canadian Internet pharmacies of that kind are not testing foreign-sourced medicines for quality, are not giving patients personalized health care advice, as community pharmacies do, and are not offering patients a better price than the price that competing Internet pharmacies in the source countries could offer—so where is the supposed public health benefit? One supposes that Strempler's Lamborghini was not a prize that he won by being a swell guy for public health; rather, he earned it by taking a middleman's profit margin out of patients' pockets, using criminal means.

Simply put, profit drives Canadian Internet pharmacies. And profit is no reason for Canada's government to tolerate the desuetude of the laws and to avoid prosecuting Internet pharmacists who are in violation. We discuss, in more detail below, some specifics of Canada's laws that are being violated.

Legal Status of Unapproved Foreign Medicines Sales

Canada's government has long known that Internet pharmacies operating on Canadian soil and dealing in unapproved foreign medicines are illegal. This is absolutely not controversial. Health Canada wrote to the provincial pharmacy regulators in 2006:

> It is a violation of the [federal] *Food and Drugs Act* and *Food and Drug Regulations* to advertise or sell, at retail or via the Internet, drugs that are not approved for sale in Canada. This applies to all Canadian pharmacies selling over the Internet, even in cases where the unapproved

> drugs do not enter Canada but are dispensed by foreign pharmacies and delivered to patients outside of Canada. Pharmacies licensed in Canada that engage in such activity are considered to be advertising and selling unapproved drugs in Canada.[21]

Health Canada's summary of the laws is both pithy and perfectly correct, although the laws themselves are rather more difficult to follow. Misunderstanding about those laws has enabled Health Canada and the provincial regulators to make excuses or pass the buck when called on to do something about Canada's Internet pharmacies. Since, constitutionally, federal law is paramount to provincial law and is not extinguished by it, we aim in this section to explain the applicable federal law succinctly.

Section C.01.041(1)(a) of the *Food and Drug Regulations* ("Regulations") reads in part:

> No person shall sell a prescription drug unless […] they are entitled under the laws of a province to dispense a prescription drug and they sell it in that province under a verbal or written prescription that they received.[22]

This section should not be misunderstood to mean that a pharmacist can dispense medicines to a buyer only in the pharmacist's home province: the Regulations do not require the buyer be located in the same province as the contractual *situs* of the sale. Instead, this section means that extraterritorial Internet pharmacy is *prima facie* legal in Canada, subject to any other limits of federal or provincial law. However, as will be explained, those other limits forbid it for all foreign-sourced medicines.

Section 9(1) of the *Food and Drugs Act* stipulates *inter alia* that "no person shall […] sell or advertise any drug in a manner that is false, misleading or deceptive". What is "false, misleading or deceptive" is elaborated in subs. (2):

> (2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).[23]

Read together, ss. 9(1) and 9(2) prohibit in Canadian jurisdiction the advertising or sale of medicines that are labeled or packaged contrary to Canada's regulations, *even if the Internet pharmacist never brings the medicines themselves into Canadian territory*. Foreign-sourced medicines that are not approved by Health Canada violate this prohibition in several ways: they would not bear the mandatory Canadian Drug Identification Number (DIN) or the correct package text in both official languages or various other textual requirements that depend on the medicine.[24] It would be wrong to think of these labeling and packaging violations as unimportant technicalities, for they affect the medicine's safe use—a medicine's label or package normally includes dosage instructions, drug interaction alerts, adverse reaction warnings, and other information that if inaccurate or misunderstood by a patient or care giver can cause harm or death.

Thus, for reasons having to do with the package or label, it is illegal for anyone in Canada to advertise or to sell a foreign-sourced medicine that is not approved by Health Canada, leaving totally aside whether the medicine is chemically real or fake. This prohibition applies even if the foreign-sourced medicine never enters Canadian territory, for it is the advertising or selling by a person in Canadian jurisdiction that is the offence.

This conclusion is amplified by ss. C.08.001(a) and C.08.002(1)(a) of the Regulations.[25] The former defines drugs that have not previously been sold in Canada as "new drugs", and the latter contains this prohibition: "no person shall sell or advertise a new drug unless […] the manufacturer of the new drug has filed with the Minister a new drug submission". Canadian Internet pharmacies, obviously, are not manufacturers capable of complying with the requirement of filing a new drug

submission—but they sell and advertise foreign-sourced medicines anyway.

In sum, persons in Canada who advertise or sell unapproved foreign-sourced medicine flagrantly violate federal law. This is not just our conclusion, but that of Canada's government, reflected in the legal opinion that Health Canada sent provincial pharmacy regulators in 2006. It makes no difference whether a Canadian Internet pharmacy engaging in prohibited acts (such as selling unapproved medicines or selling prescription medicines without a prescription) is a registered pharmacy or some unregistered operation like a call centre, and, for that reason, the federal prohibitions are more encompassing than the prohibitions (which also exist) in the various provincial laws governing pharmacies. Violating the federal prohibitions can lead to criminal offences and penalties under the *Food and Drugs Act*,[26] albeit woefully lenient penalties: imprisonment of three years and a fine of $5,000 at most. That seems rather gentle punishment for the disturbing crime of (say) selling someone fake cancer medicine—not that Canada has ever bothered to prosecute any Internet pharmacy.

Systemic Federal and Provincial Non-enforcement

It is hard to reconcile Health Canada's legal opinion of 2006 declaring certain Internet pharmacy practices illegal, with its turning of a blind eye and refusing to enforce the law. This tension leads to dishonesty. For example, a current Health Canada guidance document boasts: "If a product defined as a drug under the *Food and Drugs Act* is sold without a DIN, it is not in compliance with Canadian law and regulatory action will be taken [emphasis added]".[27] Yet, to the best of our knowledge, there has never been a single instance of Health Canada taking coercive regulatory action against those Canadian Internet pharmacies that violate the DIN requirement on a daily basis.

Hoping to resolve such contradictions, we wrote to Prime Minister Harper in March 2013, complaining that the federal government never enforces the laws against illegal Internet pharmacies. In our letter, we quoted Health Canada's 2006 legal opinion that appears at the start of the previous section[28] and cited the aforementioned example of the Manitoba Internet pharmacy and the fake cancer medicine. We emphasized that continued non-enforcement could lead to patients being harmed or killed.

The prime minister's office politely noted our concerns and forwarded the letter to Leona Aglukkaq, the then–Minister of Health. She failed to reply for several months, so we sent a reminder. Almost seven months later, Robin Chiponski, Health Canada's Director General, answered us. While she did not dispute that the agency never enforced the law against illegal Internet pharmacies, she had this to say:

> Health Canada is aware of the health and safety risks posed by the sale and advertisement of unapproved drugs, over the internet or otherwise.... The multi-jurisdictional nature of internet pharmacy poses enforcement challenges to all affected regulators.... Some of Health Canada's authorities are quite clear; some outstanding questions remain. Rest assured that we continue to focus where authorities are unclear and we continue to work regularly with partners.

Health Canada's bizarre response makes the Canadian government's non-enforcement of the law more puzzling. Why would any regulator that is "aware of the health and safety risks" and has certain "quite clear" law enforcement authorities choose instead "to focus where authorities are unclear", while leaving its clear powers unexercised? That is backwards of what a competent regulator would do.

Further, to deflect responsibility for its own non-enforcement, Health Canada points its

finger at the provinces, stating that it is their responsibility to regulate pharmacies.[29] This is true, but irrelevant. Under Canada's constitution, and specifically the paramountcy doctrine, where there is concurrent federal and provincial jurisdiction over a single matter, the laws of both levels of government are valid, except where federal law trumps provincial law because of a conflict.[30] Therefore, if an Internet pharmacy violates a federal statute, the federal regulator has jurisdiction to enforce it, irrespective of what the provincial regulator and provincial law say on the matter.

That said, some provinces also fail to enforce their law. Take Manitoba, the birthplace of Canadian Internet pharmacy, where s. 80(a) of the *Pharmaceutical Regulation* reads:

> A member [pharmacist] must not sell, dispense or use in a compounded preparation […] any drug that is not authorized for sale by Health Canada.[31]

For selling unauthorized medicines in breach of Manitoba's *Pharmaceutical Regulation*, a person convicted of a first offence is subject to a fine of just $10,000—a pittance, with no possibility of imprisonment even for repeat offences.[32] But Manitoba is similarly bad as the federal government in refusing prosecution, and its College of Pharmacists is supine. In Strempler's case, the College struck a deal to stay his case: Strempler would resign his pharmacy licence, and the College would accept his voluntary "contribution to its costs" of $7500 and make no finding of guilt.[33] Lucky is the criminal whose plea bargain allows him to emerge not guilty and with his reputation intact if he pays the authorities a little money! Not only did this arrangement make it appear that Manitoba's College accepted money tantamount to a bribe, but in exiling Strempler with a clean record, the College paved the way for Strempler to start his next pharmacy venture in the Caribbean and utterly failed in its duty to protect the public. Were it not for the American and Panamanian authorities who stopped him, Strempler would probably still be in the medicine business today.

Not all provincial pharmacy regulators are so incompetent. Ontario and Quebec have taken legal action against illegal Internet pharmacies, although only Ontario has done so recently.[34] In the *Global Pharmacy Canada* case, Ontario's College of Pharmacists sought an injunction against several persons and corporations for operating an illegal "pharmacy" without accreditation and contrary to Ontario's regulations. This injunction was granted at trial level and upheld by the Ontario Court of Appeal, which wrote:

> Global Pharmacy Canada is the trade name of a business that uses the internet to market the retail sale of generic prescription drugs to Americans. Although the seller of the drugs is now a Belize company, on its website, the seller refers to itself as Global Pharmacy Canada and directs customers to contact its "dedicated staff of friendly customer service agents located in Toronto, Canada". The "dedicated staff" is actually located in a call centre in Mississauga, Ontario. They take the customer orders and process payments for the drugs. They also ensure that the orders are filled in India and shipped directly to the customers. […] The drugs are sourced in India and never enter Canada. The corporations and individuals involved in operating Global Pharmacy Canada are scattered among Belize, the United States, and Ontario.[35]

With its business spread out over at least four countries, Global Pharmacy Canada was not a real, licensed pharmacy, but a typical Internet pharmacy network of the globalized age. Global Pharmacy Canada argued that because it was a transnational operation, and because its website was designed to turn away business from persons in Canada, it was not within the jurisdiction of Ontario's College.[36] The Court of Appeal rejected both arguments. It interpreted Ontario's pharmacy laws purposively as being to serve and protect the public, including even the American public. As the Court of Appeal wrote:

> In the circumstances of this case, the territorial limits on the scope of the provincial legislative authority relate to the ***conduct*** that the College can regulate. The College's reach is not defined as, or limited to, the Ontario public. […] The principle that regulators may act to protect persons who are located outside the regulator's territorial jurisdiction, when the conduct targeted by the regulator occurs within the jurisdiction, has been repeatedly affirmed. […] In the domain of pharmaceutical drugs, reputation is based on regulation. If a company trades on Ontario's reputation for quality and strong regulatory standards, and sites a critical part of the sales process in Ontario, it will be subject to Ontario's regulation.[37]

Presumably, much the same purposive reasoning would hold true for Health Canada's regulations too, except for the fact that Health Canada, unlike Ontario's College, has never taken a case to court to find out. The court's record shows that Health Canada "expressed concerns" in writing to Global Pharmacy Canada in 2010, but subsequently took no enforcement action.[38]

It is worth pausing briefly to consider what Health Canada's refusal to enforce the law means. When people from several countries intentionally come together in a shared plan to advertise or sell unapproved medicine, which is a crime under the *Food and Drugs Act*, that amounts to transnational organized criminal conspiracy, in the literal meaning of those words. Faced with such a conspiracy, Health Canada chose in the *Global Pharmacy Canada* case not to prosecute the offenders, even after the Ontario Court of Appeal offered up a wealth of prosecution-worthy evidence. There is, therefore, no hyperbole in the statement that Health Canada tolerates transnational organized crime and that on the federal government's watch, Canada is an attractive haven for transnational organized criminals. Is this what Canadians want?

Health Canada cannot plead ignorance. In March 2014, Canada's Senate held hearings on medicine safety, at which the Royal Canadian Mounted Police gave evidence.[39] The Senators posed several questions about illegal Internet pharmacy, which Mike Cabana, RCMP Deputy Commissioner, forthrightly and helpfully answered:

> **Mr. Cabana**: Actually, in 2010, to try to understand the prevalence of the problem and how widespread it was, we initiated a pilot project, Project Centurion. It specifically looked at the sale of medication, without terming it "counterfeit medication", over the Internet. From April 2010 to April 2012, we received 49 referrals from partner law enforcement agencies. We examined 70 Canadian pharmacy websites. Those were determined to have an associated address or server located in Canada. We examined 400 international pharmacy websites and 600 classified ads that were appearing in Canada. This resulted in the initiation of 27 investigations plus 9 major projects.
>
> **Senator Eggleton**: How many successful prosecutions?
>
> **Mr. Cabana:** To my knowledge to this date, none.

To be clear, it is not the RCMP's fault that out of dozens of referrals from partner law enforcement agencies, there have been zero prosecutions. The RCMP, appropriately, did dozens of investigations—but it cannot prosecute. In Canada's justice system, the decision to prosecute under the *Food and Drugs Act* is made by the Public Prosecution Service of Canada (PPSC) in consultation with the line department—in this case, Health Canada. The PPSC's prosecution guidelines are a public document but contain nothing that leads us to believe that they would reject prosecutions unreasonably. More likely, Health Canada is refusing, although its reasons are impossible to know because, unlike the PPSC,[40] Health Canada's prosecution guidelines are secret.

Fortunately, just weeks after the RCMP Deputy Commissioner's Senate testimony, the Senators invited Robin Chiponski for questions. While she might have used the opportunity of Parliamentary oversight to apologize for Health Canada's record of zero prosecutions and explain how it would do better, she did neither:

> **Ms. Chiponski (Director General):** There was the specific question about why we do not prosecute. Because some of these organizations are intentionally operating out of the normal supply chain, the normal measures are not necessarily effective.[41]

This passage once again shows Health Canada contorting itself to avoid the law. Health Canada's answer to why it does not prosecute is that the normal measures are not effective when criminals operate outside the normal supply chain. But if they operated inside the normal supply chain, they would not be criminals!

These facts lead to certain unpleasant but unavoidable conclusions. First, some Internet pharmacies, such as Global Pharmacy Canada, are in fact globalized networks of persons in an organized scheme to intentionally violate Canadian criminal law, and this could be prosecuted as transnational organized crime. Second, Health Canada has deliberately refused to enforce Parliament's laws in this domain, which is not only an affront to the rule of law but vitiates any possible belief that Health Canada is a competent regulator. Third, Canada's non-enforcement of its laws is recognized and tolerated at the highest political levels, because we notified the prime minister in writing about the problems, and nothing has changed further to the reply from his office or further to the Senate's oversight. We canvass some current instances of apparent crimes going unenforced in the next section.

Current Evidence of Illegal Sales by Canadian Online Pharmacies

In order to test whether there were, as of May 2014, Canadian Internet pharmacies that appeared to break the law similarly to Global Pharmacy Canada, we shopped online for a small convenience sample of drugs that actual patients might need to cure or prevent disease (excluding nonessential "lifestyle" drugs like Viagra). To filter out "Canadian" pharmacies that are not actually based in Canada, we restricted ourselves to the Canadian Internet pharmacies accredited by PharmacyChecker.com[42] or the Canadian International Pharmacy Association[43] under a verified Canadian address. According to the economics literature, Internet pharmacies accredited by third parties like these are less likely to sell substandard or falsified medicines.[44]

However, even in this upper tier of Canadian Internet pharmacies, many advertise unapproved, foreign-sourced medicines. To see these websites as an American doctor or patient might, first we had to get rid of our Canadian Internet protocol (IP) address. Many Internet pharmacies block or filter their website content when visited from a Canadian IP address. We, therefore, used a virtual private network (Hotspot Shield) to obtain an American IP address.

Switching from a Canadian to an American IP address often opened different offerings on the web pages (see Appendix A).[45] We found several Internet pharmacies advertising important foreign-sourced medicines. For example, DoctorSolve.com offers generic fluticasone/salmeterol, an asthma drug, from Cipla Limited in India. CanadianPharmacyKing.com offers generic and branded olmesartan, a hypertension drug, from various sources in India and Turkey. PrescriptionPoint.com offers generic galantamine, an Alzheimer's disease drug, from Sun Pharma in India. None of these medicines are registered with Health Canada, and as already explained, it is illegal for persons in Canadian jurisdiction to advertise or sell them.

We also found Canadian Internet pharmacies advertising medicines that do not even exist in Canada, in any form. A good example is Vytorin, which is a cardiovascular drug sold by

Merck, Sharp & Dohme in many countries, but that has never been approved by Health Canada.[46] PolarMeds.com is a licensed Manitoba pharmacy, and yet it advertises Vytorin from New Zealand and generics from India as being among its best sellers. Other licensed Manitoba Internet pharmacies advertise Vytorin too, such as Canada Drugs.com that sources it from Barbados and the United Kingdom. These licensed pharmacies are engaging in a deliberate end run around the fact that Health Canada never even evaluated Vytorin, much less approved it.

The fact that these Internet pharmacies use IP filtering to offer their American, but not their Canadian, customers these products is helpful evidence for prosecutors for two reasons. First, it demonstrates that the directing minds of the enterprise took deliberate steps both to advertise unapproved medicines and to conceal that illegal action from law enforcers in Canada. Actively hiding one's crime is not exculpatory, but rather suggests that *mens rea* exists—much like hiding stolen goods reflects a certain criminal intent and does not excuse the offence. Second, it is settled law that IP filtering does not exclude an Internet pharmacy from Canadian jurisdiction. In the *Global Pharmacy Canada* case, the Ontario Court of Appeal found that an Internet pharmacy was within Ontario's jurisdiction despite using IP filtering.[47]

The ease with which we uncovered Internet pharmacies engaged in illegal activity, mostly in British Columbia and Manitoba, pointedly illustrates that this industry does not much fear law enforcement. Unfortunately, they are right to be sanguine, as we discuss in the next section.

The Political Reasons Why Canada Does Not Enforce the Law

We are not optimistic that Canada's federal government will soon enforce the law. If it had been so inclined, then Health Canada would have acted on its clear pronouncement of the industry's illegality in 2006. It has not because of a general sense that the Internet pharmacies bring jobs to Canada and because of an especially deplorable policy of non-enforcement articulated by the Conservative Party of Canada.

In February 2005, Canada's government was led by the Liberal Party, and Ujjal Dosanjh, the then–federal Minister of Health, was poised to ban Internet pharmacies. That irked the Conservative Party, who left it to Stephen Fletcher, their health critic (or shadow minister) from Manitoba, to decry the Liberals' plan as "very disturbing" and to bring the following motion in Parliament:

> that the Standing Committee on Health request that the Minister of Health refrain from any action pertaining to the Internet pharmacy industry until the committee has fully studied the issue and has submitted its recommendations to the House.[48]

Mr. Fletcher's motion demanding to "refrain from any action" was coolly received by some in Parliament: the Bloc Québécois member of the Standing Committee bluntly said that, "First, we must understand that this is an illegal industry".[49] Nonetheless, Mr. Fletcher's motion passed. Thus, the Standing Committee created the strange, undemocratic situation where it decided against enforcing a law passed by the whole of Parliament.

Nonetheless, when the Conservative government of Prime Minister Harper ejected the Liberals and came to power in 2006, it was in a position to make that undemocratic policy stick. Defending the industry was probably a sop to the Manitobans in the Conservative caucus—those like Fletcher—for electorally, Manitoba is a Conservative Party stronghold and must be cultivated. Since the industry's founding in Manitoba, it has had a sort of sacrosanct status. MaryAnn Mihychuk,

Manitoba's former Industry Minister, often praised the industry and Strempler for their contributions to the economy.[50] When the Manitoba Pharmaceutical Association (the forerunner to the College) was poised to shut down the industry, Gary Doer, the then–Premier of Manitoba, forced the two sides into mediation and kept the industry alive.[51]

Everywhere in the world, organized crime thrives when criminals and politicians make common cause. Canada is no exception, and there is an unseemly "Manitoba mafia" of criminals who enjoy political favour. Recall that Canada's government never arrested, indicted, or extradited Strempler; it shirked those responsibilities onto the United States and Panama. Nor did Canada's government arrest, indict, or extradite Nathan Jacobson, another Manitoban who conspired to launder money for an Israeli Internet pharmacy.[52] Jacobson endeared himself by donating the maximum year upon year to the federal Conservative Party and by lending (or possibly giving—accounts differ) a mysterious $265,000 to a Conservative member of Parliament. Perhaps in exchange, he enjoyed the social company of several cabinet ministers and the prime minister, even after pleading guilty to that serious crime in the United States and jumping bail. Although a fugitive and the subject of a worldwide Interpol "Red Notice" for his arrest, he returned to Canada, where he repeatedly and suspiciously slipped through the fingers of the RCMP—including at a fortress-like political gala where he posed for a photograph between Canada's and Israel's prime ministers.[53] Thus it fell to the Toronto Police Fugitive Squad to arrest Jacobson after one of their easier manhunts: he was apprehended at home in downtown Toronto.[54] One wonders what was going through Gary Doer's mind—now Ambassador Doer, Canada's top official in Washington—as frustrated American officials hammered on diplomatic channels to bring these celebrated men to justice.

It is difficult to look at these facts without thinking that Canadian medicine criminals—transnational organized criminals—have very high-level political protection. How else to explain the way Jacobson managed to get past a tight RCMP security detail, while being a globally wanted fugitive, to snap a photo with the prime minister? It shames the country.

What Should Happen Next?

The available evidence is that Health Canada is either too dysfunctional or too politically hamstrung to enforce Parliament's laws against illegal Internet pharmacies. Parliamentary oversight has now run its course in the Senate, so the time has come for a more probing look at Health Canada's non-enforcement and its causes—most likely by the Auditor General or the Parliamentary Budget Officer. A probing inquiry would raise the political cost of the government protecting medicine criminals and would unsettle the Health Canada officials who have been making excuses, perhaps to the breaking point.

In the meantime, Parliament can lay a better legislative foundation for Health Canada's return to relevance. At a minimum, this means toughening the punishments in s. 31 of the *Food and Drugs Act*.[55] It is striking that the Harper government, which is generally eager about increasing criminal penalties across the board, is actually edging in the other direction when it comes to this crime. At this writing, Bill C-17 is on its second reading in the House of Commons and would *reduce* the maximum imprisonment to two years, although it would raise the fine substantially.[56]

Parliament also should draft new laws specifically governing Internet pharmacy—an activity that did not exist the last time the laws

were amended. Federal constitutional authority to do so certainly exists: both medicines and telecommunications are federal jurisdictions under s. 91 of the *Constitution Act 1867*. While this article has focused on the pharmacy side rather than the Internet side, we emphasize that regulation of the Internet's commercial uses is a deserving and lengthy subject in its own right. Briefly, the main problem on the Internet side is that two Canadian companies, Tucows.com and Rebel.com, whose business is to register website names (or "domain names") have made their services liberally available to Internet pharmacies and are among the world's worst domain name registrars when it comes to not suspending and not locking the websites of Internet pharmacies that are shown to be acting illegally. Most other domain name registrars do this willingly, but Tucows.com and Rebel.com are extraordinarily recalcitrant.[57] There may come a point at which such conduct is rightly prosecuted as an offence of aiding, abetting, or conspiring in Internet pharmacy crimes. Canada's government must define that point, and act on it.

These actions are imperative to save Canada's good name. It is striking that Panama—a country often scorned as a haven for financial crimes like tax evasion or money laundering—actually did more than Canada in Strempler's case to draw a line at truly dangerous conduct like medicine counterfeiting. One can now reasonably ask: which country really deserves the reputation of being a global crime hub and a threat to public safety?

We, therefore, encourage foreign police and prosecutors to renew their cooperation demands to Canada's government. If those demands bear fruit, then dangerous crimes will have been stopped in a spirit of cooperation. But if those demands are deflected, as apparently happened in Strempler's and Jacobson's cases, then we encourage foreign police and prosecutors to adopt a much more aggressive stance and to treat Canada as it would any other haven of transnational organized crime.

Foreign countries are within their rights to apply their criminal laws extraterritorially when their citizens are harmed. This long-arm jurisdiction is known in international law as the *passive personality principle*, and gains support both from jurisprudence, many extradition treaties, and, most recently, the *UN Convention on Transnational Organized Crime*.[58] Canada could be pressured through extraterritorial law enforcement, or through political forums, such as UN's Committee on Crime Prevention and Criminal Justice, where Canada probably would react with great alarm to being named as a haven country of transnational organized crime.

The United States, in particular, can and should apply this kind of international pressure. America has engaged in extraterritorial law enforcement and does so with steep penalties and aggressive prosecutors. Their most ambitious medicine crime cases have resulted in half-billion dollar settlements against fraudulent Indian drug makers (Ranbaxy)[59] and companies that assisted the advertising of illegal Internet pharmacies (Google).[60] Were the U.S. Department of Justice to indict not just Canadian persons but also Canadian corporate targets (*i.e.*, not just rogues like Strempler or Jacobson but also the corporations behind Internet pharmacies such as CanadaDrugs.com, which reportedly advertised unapproved medicines to Americans,[61] or domain name registrars such as Tucows.com and Rebel.com, who are knowingly indiligent about suspending the website addresses of illegal Internet pharmacies[62]), Canada's government might reach the conclusion that it is better to enforce its law than leave industries and jobs vulnerable to foreign justice.

Finally, foreign countries could target Canada with trade sanctions. There is no right in international law to endanger the public health of foreign persons; on the other hand, there is a right in Article XX of the *General Agreement on Tariffs and Trade* (GATT) and in other trade agreements to protect human and animal health. Accordingly, we believe that foreign countries could enact measures to increase the tariff rate on Canadian goods (and not just pharmaceutical goods) by an amount that offsets exactly their additional expenditures on customs inspections and policing to interdict medicines that Canadian Internet pharmacies illegally traffic into their territory. A well-measured offset of this kind is arguably GATT compliant, provided that Canada has been notified and failed to stanch the illegal flow. There is a rule of customary international law in the *Trail Smelter* case that countries are strictly liable for nuisances emanating from their territory, and that doctrine might apply to unregulated and, therefore, presumably dangerous medicines. Any foreign government that would make use of such tariff measures could target its sanctions on prominent industries in Manitoba in recognition of the pivotal role that province has played in thwarting Canadian law enforcement in this area.[63]

Conclusion

The federal government of Canada faces a choice: It can prosecute the organized criminals within Canadian jurisdiction who are responsible for illegal Internet pharmacies, as respect for the rule of law and public health require, or it can not prosecute them and be responsible for making Canada a haven for transnational organized crime and a danger to public health. Our purpose in writing this article is to force that choice and to expose federal Canada's unseemly policy of inaction. The same can be said, to a lesser extent, of Canada's provincial governments, although not all of them are problematic.

Canada will make this choice while foreign governments are watching. There is a social contract among western democracies not to inflict harm on one another's citizens whether by crime or by disease. Canada's illegal Internet pharmacies do both. The way Canada's federal government comports itself going forward places this country either inside or outside the fold. If placed outside, Canadians should expect this country's relations with other western democracies to suffer and those democracies to retaliate against Canada and to coerce proper behaviour.

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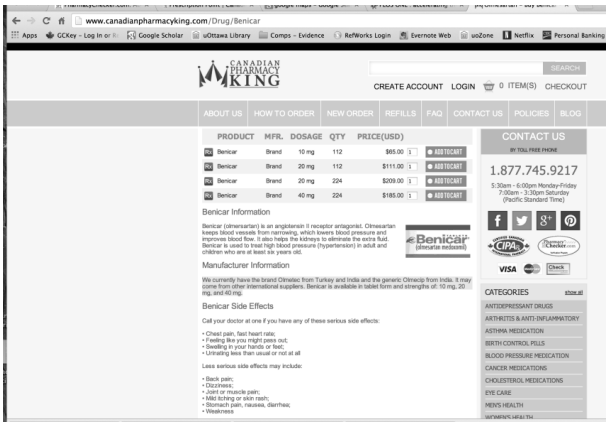
Both are at the University of Ottawa.]

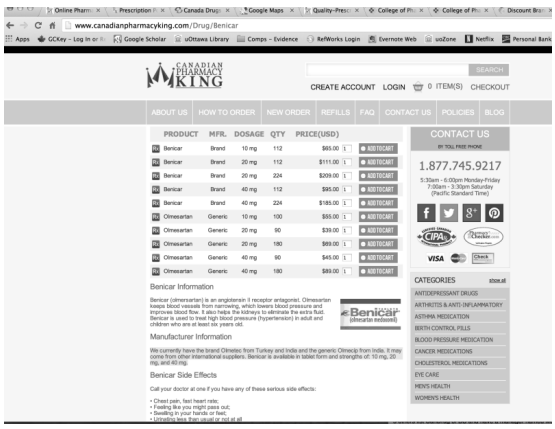
Appendix

Canadian Pharmacy King's website for purchasing Benicar/Olmesartan in Canada versus the U.S.

Canadian IP address

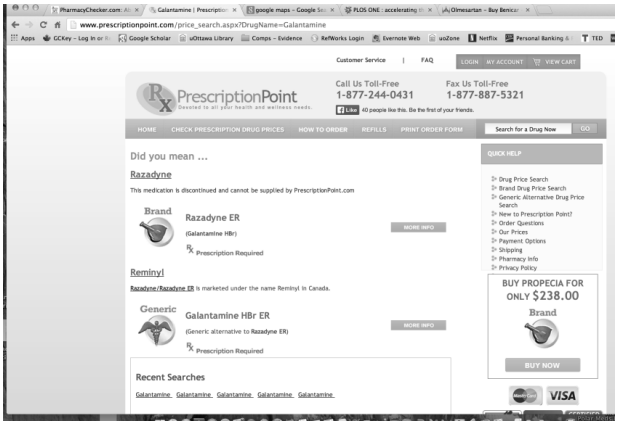


U.S. IP address

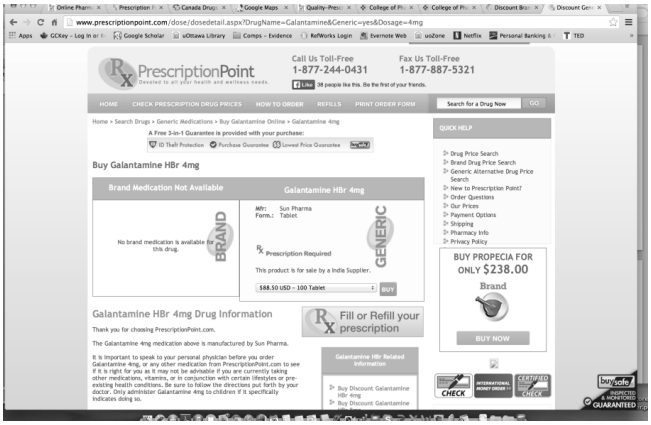


Prescription Point's website for purchasing Galantamine in Canada versus the U.S.

Canadian IP address

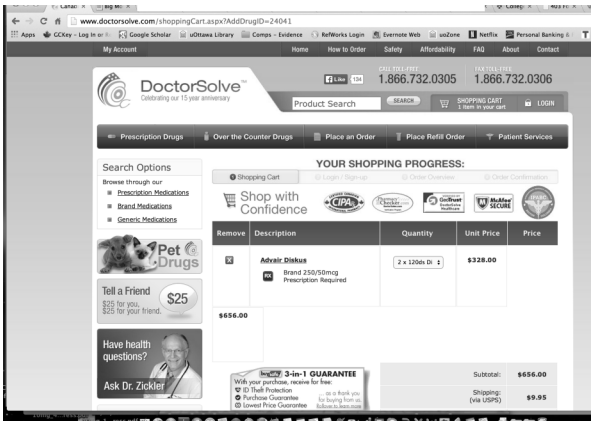


U.S. IP address

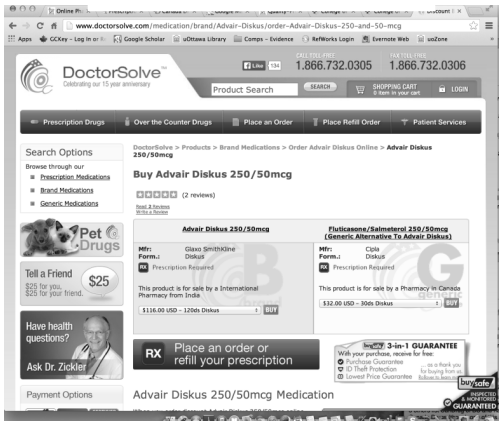


Doctor Solve's website for purchasing Advair Diskus in Canada versus the U.S.

Canadian IP address



U.S. IP address



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1 In this article, we use the term *Internet pharmacy* to denote a business that sells medicines online. Some of those businesses are actually licensed pharmacies, while others are unlicensed brokers that contract with licensed pharmacies. From the consumer's perspective, both offer to sell prescription medicines, and take payment to do so. While some describe the pharmacies that trade in unapproved medicines as "rogues", that is a euphemism, and in proper legal language, their actions are "criminal". In *R. v. Wetmore*, [1983] S.C.J. No. 74, [1983] 2 S.C.R. 284, which concerned the prosecution of a pharmacy, the Supreme Court of Canada held that the penal prohibitions of Canada's *Food and Drugs Act*, R.S.C. 1985, c. F-27, are crimes, just as are the offences in the *Criminal Code*, R.S.C., 1985, c. C-46 (per Laskin C.J.). We, therefore, in most instances prefer the adjective "criminal" to "rogue", for this reflects the jurisprudential position accurately.

2 Brian Whitwham, "Are Online Pharmacies Affecting Drug Supply?", CMAJ 169, no. 4 (August 19, 2003): 328, <http://www.cmaj.ca/content/169/4/328.2.full>. In this article, we do not deal with the situation of Internet pharmacies that claim to be from Canada, but which actually are not. Suffice it to say that Canada has a reputation for Internet pharmacies and honesty, so organized criminals from elsewhere are happy to appropriate Canada's name, a maple leaf, a polar bear, or some such kitsch to adorn their Internet pharmacy websites. Our argument is strictly about Internet pharmacies with a true Canadian nexus.

3 Roger Bate, Ginger Zhe Jin, and Aparna Mathur, "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets", *National Bureau of Economic Research*, Working Paper No. 17955 (March 2012). doi: 10.3386/w17955; Safemedicines.org, "Importing Danger: The Global Threat of Parallel Importation" (2011), <http://www.safemedicines.org/importdanger.html>.

4 Ontario College of Pharmacists, "Internet Pharmacies" (May 11, 2012), <http://www.ocpinfo.com/practice-education/practice-tools/fact-sheets/internet-pharmacies/>.

5 Bill Redekop, "Bitter Pill: The Rise and Fall of Manitoba's Internet Pharmacy Pioneers", *Winnipeg Free Press* (March 30, 2013), <http://www.winnipegfreepress.com/opinion/fyi/generation-rx-200693481.html>; Bill Redekop, "Generation Rx: Waking the Giants", *Winnipeg Free Press* (April 6, 2013), <http://www.winnipegfreepress.com/opinion/fyi/waking-the-giants-201736111.html>.

6 *Ibid*., Redekop (March 30, 2013).

7 *Winnipeg Free Press*, "E-druggist Defies Giant: Manitoba Net Pharmacy Set to Expand, Create up to 300 Jobs" (January 31, 2003), <http://www.winnipegfreepress.com/historic/33173159.html>.

8 Redekop (March 30, 2013), *supra* note 5.

9 *See* David J. Horowitz's letter to Andrew Strempler, Ref. No. 01-HFD-310I-131 (October 31, 2001), <http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM136369.pdf>.

10 *CBSNEWS*, "Seniors Group Sues Drug Makers" (May 20, 2004), <http://www.cbsnews.com/news/seniors-group-sues-drug-makers/>.

11 Redekop (March 30, 2013; April 6, 2013), *supra* note 5.

12 *PharmacyChecker.com*, "Four Canadian Pharmacies Sourcing Drugs from Outside Canada" (July 21, 2004), <http://www.pharmacychecker.com/news/news_072104.asp>; Roger Bate and Kimberly Hess, "Assessing Website Pharmacy Drug Quality: Safer than You Think?", PLOS ONE (August 13, 2010). doi: 10.1371/journal.pone.0012199.

13 Peter Roderick *et al.*, "India Should Introduce a New Drugs Act", 383 *Lancet* 9913 (January 18, 2014): 203. doi:10.1016/S0140-6736(14)60059-3; Amir Attaran *et al*., "How to Achieve International Action on Falsified and Substandard Medicines", *British Medical Journal* 2012 ; 345. doi: http://dx.doi.org/10.1136/bmj.e7381.

14 Redekop (March 30, 2013), *supra* note 5; Clifford Kraus, "Going Global at a Small-Town Canadian Drugstore", *New York Times*, March 5, 2005, <http://www.nytimes.com/2005/03/05/international/americas/05strempler.html?_r=0>.

15 United States District Court, Southern District of Florida, "Indictment: United States of America, Plaintiff v. Andrew J. Strempler, Defendant" (2011), the website of the *United States Department of Justice*, <http://www.justice.gov/usao/fls/PressReleases/Attachments/120614-01.Indictment.pdf>.

16 United States Department of Justice, Office of Public Affairs, "Canadian Citizen Sentenced in Scheme to Defraud Consumers Purchasing Pharmaceuticals Online", *Justice News* (January 9, 2013), <http://www.justice.gov/opa/pr/2013/January/13-civ-035.html>.

17 *Ibid*.

18 Christopher Weaver, Jeanne Whalen, and Benoît Faucon, "Drug Distributor Is Tied to Imports of Fake Avastin", *Wall Street Journal*, March 7, 2012), <http://online.wsj.com/news/articles/SB10001424052970203370604577261343974214110>; Christopher Weaver and Jeanne Whalen, "How Fake Cancer Drugs Entered U.S.", *Wall Street Journal*, July 20, 2012, <http://online.wsj.com/news/articles/SB10001424052702303879604577410430607090226>.

19 Gabriel Levitt, "Scare Tactics over Foreign Drugs", *New York Times*, March 24, 2014, <http://www.nytimes.com/2014/03/25/opinion/scare-tactics-over-foreign-drugs.html>.

20 We note that Mr. Levitt's business, PharmacyChecker.com, for a fee, inspects and promotes

a number of Canadian Internet pharmacies that advertise or sell unapproved medicines. If the pharmacies' acts are criminal, as we allege later in this article, then could PharmacyChecker.com be an accomplice or conspirator? We do not propose to answer this question, but recommend an investigation by both Canadian and American law enforcement authorities.

[21] Health Canada, "Reminder of Obligations with Respect to the Advertising and Sale of Drugs" (October 6, 2006), <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/reminder-rappel_adver-pub_ltr-eng.pdf>.

[22] Government of Canada, *Food and Drug Regulations*, C.R.C., c. 870, "Prescription Drugs", C.01.041 (May 14, 2014), *Justice Laws Website*, <http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/FullText.html>.

[23] *Food and Drugs Act*, R.S.C. 1985, c. F-27.

[24] *Supra* note 22. See, in particular, ss. A.01.062 and C.01.003 to C.01.009 of the Regulations. The labeling requirements in the Regulations are explained at length in Health Canada, *Guidance Document: Labeling of Pharmaceutical Drugs for Human Use*, (January 10, 2014), <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.pdf>.

[25] *Supra* note 22.

[26] *Supra* note 23. *See* s. 31 of the Act for the penalties.

[27] Health Canada, "Drug Identification Number (DIN)" (June 5, 2009), <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/dinfs_fd-eng.php>.

[28] *Supra* note 21.

[29] Health Canada, "Buying Drugs over the Internet" (November 24, 2009), <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/internet-eng.php>.

[30] *Rothmans, Benson & Hedges Inc. v. Saskatchewan*, [2005] S.C.J. No. 1, 2005 SCC 13.

[31] Province of Manitoba, College of Pharmacists of Manitoba, *Pharmaceutical Regulation* (July 2013), <http://mpha.in1touch.org/uploaded/web/New%20Pharmaceutical%20Act/July%203,%202013%20Pharmaceutical%20Regulations.pdf>.

[32] *The Pharmaceutical Act*, C.C.S.M. c. P60, s. 90(1).

[33] "Notice of Discipline Committee Hearing Decision: Mr. Andrew Strempler", *Manitoba Pharmaceutical Association Newsletter* (January 2010): 10, <https://mpha.in1touch.org/document/74/MPhA_January2010_Website.pdf;jsessionid=AC5E487EFD150374DB543526FEDFCCEF>.

[34] For Quebec, see *Prescriptions4us inc. v. Ordre des pharmaciens du Québec*, [2004] Q.J. no. 9014 (Qc. S.C.), aff'd [2004] J.Q. no. 13143 (Qc. C.A.) (in French).

[35] *Ontario College of Pharmacists v. 1724665 Ontario Inc.* (c.o.b. Global Pharmacy Canada), [2013] O.J. No. 2670, 2013 ONCA 381, paras. 1–2.

[36] *Ibid*., paras. 26–41.

[37] *Ibid*., paras.73–76.

[38] *Ibid*., para. 24.

[39] Canada. Parliament. Senate. Standing Senate Committee on Social Affairs, Science and Technology. *Proceedings*" 41st Parliament, 2nd Session. Issue8 – Evidence (March 5, 2014), <http://www.parl.gc.ca/content/sen/committee/412%5CSOCI/08EV-51249-E.HTM>.

[40] Public Prosecution Service of Canada, "Table of Contents (October 2005)", *The Federal Prosecution Service Deskbook*, <http://www.ppsc-sppc.gc.ca/eng/pub/fpsd-sfpg/fps-sfp/fpd/toc.html>.

[41] Canada. Parliament. Senate. Standing Senate Committee on Social Affairs, Science and Technology. *Proceedings*" 41st Parliament, 2nd Session. Evidence (April 30, 2014), <http://www.parl.gc.ca/content/sen/committee/412%5CSOCI/51365-E.HTM>.

[42] *See* PharmacyChecker.com to "compare drug prices among reputable online pharmacies", <www.pharmacychecker.com>.

[43] Canadian International Pharmacy Association", <www.cipa.com>.

[44] Bate *et al*., *supra* note 3.

[45] Some of the Internet pharmacies cannot be fooled so easily. For example, Canada Drug Center, <www.canadadrugcenter.com>, uses a more advanced sort of blocking that keeps pages invisible to Hotspot Shield. But we verified that it is visible to an American truly on U.S. territory.

[46] We confirmed with both Merck and Health Canada via email with replies (on May 9, 2014, and May 22, 2014, respectively) that Vytorin is not approved for sale in Canada.

[47] *Supra* note 35, para. 38.

[48] Canada. Parliament. House of Commons. Standing Committee on Health. *Debates*. 38th Parliament, 1st session (February 3, 2005), <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=1603340&Language=E&Mode=1>.

[49] *Ibid.*, per Réal Ménard (Hochelaga, BQ).

[50] Redekop (March 30, 2013), s*upra* note 5; David Kuxhaus, "An Internet Pharmacy Primer—Manitoba's at Forefront of Billion-Dollar Drug War; Here's What You Should Know", *Winnipeg Free Press*, June 22, 2003, <http://www.winnipegfreepress.com/historic/31347689.html>.

[51] Kuxhaus, *ibid*.

[52] Michael Harris, "Who's the Man between the Prime Ministers?", *iPolitics.ca*, September 28, 2012, <http://www.ipolitics.ca/2012/09/28/whos-the-man-between-the-prime-ministers/>.

[53] *Ibid*. *See also* John Nicol, "Canadian Businessman Gets Bail in U.S. Money-Laundering Case", *CBC News*, August 30, 2013, <http://www.cbc.ca/news/canada/canadian-businessman-gets-bail-in-u-s-money-laundering-case-1.1373582>.

[54] Josh Tapper, "Nathan Jacobson, Fugitive Businessman with Tory Ties, to Appear in Toronto Court", *Toronto Star*, October 31, 2012), <http://www.thestar.com/news/crime/2012/10/31/nathan_jacobson_fugitive_businessman_with_tory_ties_to_appear_in_toronto_court.html>.

[55] *Supra* note 23. *See* s. 31 of the Act at <http://laws-lois.justice.gc.ca/eng/acts/F-27/page-11.html#h-18>. At this writing, Bill C-17 before Parliament seeks to increase this penalty.

[56] Canada. Parliament. House of Commons. *Bill C-17: An Act to Amend the Food and Drug Act*. 41st Parliament, 2nd Session (2013), ss. 8–9. <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6375723&File=24#1>; Health Canada, "Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): Amendments to the *Food and Drugs Act* (Bill C-17)" (December 6, 2013), <http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-eng.php>.

[57] LegitScript.com, "Rogues and Registrars: Top 10 List", October 24, 2012, <http://blog.legitscript.com/2012/10/rogues-registrars-top-10-list-october-2012/>; LegitScript.com, "Rogues and Registrars: Top 10 List", April 29, 2013, <https://blog.legitscript.com/2013/04/rogues-and-registrars-top-10-list-april-2013/>.

[58] *See*, for example, Articles 15(2)(a) and 15(6) of the Convention. The *passive personality principle* is more commonly known in the United States as the *effects doctrine*: *United States v. Aluminum Company of America*, 148 F.2d 416 (2d Cir. 1945).

[59] Gardiner Harris, "Medicines Made in India Set Off Safety Worries", *New York Times*, February 14, 2014, <http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html>.

[60] Matea Gold and Tom Hamburger, "Google Faces New Pressure from States to Crack Down on Illegal Online Drug Sales", *Washington Post*, April 15, 2014, <http://www.washingtonpost.com/politics/google-faces-new-pressure-from-states-to-crack-down-on-illegal-online-drug-sales/2014/04/15/6dfc61fa-be6d-11e3-b195-dd0c1174052c_story.html>.

[61] *Supra* note 18. *See also* David Larkins, "Winnipeg-Based Canada Drugs Lays Off Hundreds of Employees Worldwide", *Winnipeg Sun*, April 18, 2013, <http://www.winnipegsun.com/2013/04/18/winnipeg-based-canada-drugs-lays-off-hundreds-of-employees-worldwide>; CBC News, "Canadadrugs.com's Wholesale Licence Suspended," June 9, 2014, <http://www.cbc.ca/news/canada/manitoba/canadadrugs-com-s-wholesale-licence-suspended-1.2669583>.

[62] *Supra* note 57.

[63] According to the Government of Manitoba, these include "agricultural products, metals and minerals, processed foods, vehicles and transport equipment, machinery and parts, electrical energy, pharmaceuticals, plastics, paper products, chemicals". *See* <http://www.gov.mb.ca/trade/export/qfacts/qf_trade.html>.

• THE RISE OF DATA SHARING IN THE HEALTHCARE SECTOR: TIPS FOR DRAFTING LEGAL AGREEMENTS •

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Sharon Vanin, *Office of the Fairness Commissioner of Ontario*

Simmie Palter, *Barrister & Solicitor*

Introduction

In "The Sign of the Four", Sherlock Holmes—the famous detective created by Sir Arthur Conan Doyle—states, "I never guess".[1] In "A Scandal in Bohemia", Holmes elaborates, "It is a capital mistake to theorise before one has data. Insensibly one begins to twist facts to suit theories, instead of theories to suit facts".[2] As decision making in health policy and management is increasingly evidence based, the need for data[3] to support decision making is becoming more important. Thus, we are seeing growing volumes of data being generated by, and shared between, institutions. In these times of fiscal restraint and increased oversight in Ontario's health care sector, the Ministry of Health and Long-Term Care (the "Ministry"), the Local Health Integration Networks, and the public are demanding more transparency, accountability, and value for money than ever before. It is, therefore, essential to have accurate, time-sensitive, and highly confidential data to influence planning and policy decision making. In fact, one could theoretically separate

the decision making as follows: hospitals and other healthcare institutions will inevitably make decisions based on data showing the value add to the patient or client, healthcare agencies and other crown corporations will make decisions based on data flowing from requirements imparted by the Ministry of Health, and the Ministry of Health will make decisions based on data aiming to close gaps and to highlight societal issues that need to be resolved.

The growing need to have accurate, time-sensitive, and highly confidential data to support any decision making in a healthcare field with multiple players means that data sharing must exist. The sharing of data is a complex process, because each of the players has a different legal personality and, therefore, is subject to varying legal requirements imposed by different pieces of legislation (which may not always fit together nicely). One may speculate that once there has been agreement to the sharing of data and a secure method of transfer has been identified, the next step is to, indeed, "press the button" or "send over the data". However, the reality is much more complex. Not only do legal agreements need to be drafted every time data is shared, but, in addition, there are many pieces of legislation that could be applicable to any type of data-sharing transaction. In fact, identifying the section under the Act(s), in which a public institution, hospital, agency, or Ministry has the legal authority to share the data with one another, requires complex legal rigor.[4]

Central to the data sharing process is a *data sharing agreement* ("DSA"). A DSA must be drafted every time data is shared so that interests are appropriately addressed and risks are managed. This article provides an overview for drafting data sharing agreements for the Ontario health care context, and offers practical considerations for public sector health care organizations involved in data sharing. The following section describes data sharing and data sharing agreements in more detail.

Legislative Framework for Data Sharing

A number of statutes govern data collection in Ontario. The *Freedom of Information and Protection of Privacy Act, 1990* [*FIPPA*][5] applies to the collection of Personal Information ("PI")[6] by all provincial ministries and most provincial agencies, boards, and commissions, as well as universities and colleges of applied arts and technology. The *Municipal Freedom of Information and Protection of Privacy Act, 1992* [*MFIPPA*][7] applies to a broader number of public institutions, including local government organizations, such as municipalities, police, library, health and school boards, and transit commissions. The *Personal Health Information Protection Act, 2004* [*PHIPA*][8] governs the collection, use and disclosure of Personal Health Information ("PHI")[9] within the health care system. Together, these statutes establish a framework for how government organizations and health information custodians[10] may collect, use, and disclose PI and PHI. They also establish a right for individuals to access their own personal information and have it corrected if necessary. All three pieces of legislation are overseen by the Information and Privacy Commissioner of Ontario ("IPC").[11] Among other functions, the IPC has authority to audit public institutions at any time to ensure proper maintenance of data sharing agreements. The IPC defines "data sharing" as

> The exchanging, collecting or disclosing of "personal information" [including personal health information] by an organization with other organizations such as any federal or provincial government ministry, agency, board, or commission, any municipality or local government agency, city, town, village, police service, any private company, or any foreign government.[12]

The IPC also states that "sharing of personal information should be supported by a written 'Data Sharing Agreement'. Such an agreement will clarify the rights and obligations of all parties in a data sharing activity".[13] This means that in addition to having the legal authority to share the data, a DSA must be drafted. A DSA is a contractual arrangement that clarifies the rights and obligations of all parties in a data sharing activity and thereby ensures legal compliance. To clarify, an Act will provide the basis for which the data can be shared, and the DSA will outline the terms and conditions concerning the data sharing (similar to any other legal agreement).

The execution of a DSA is particularly important with respect to PHI. Due to the sensitive and confidential nature of PHI, any sharing of PHI should be supported by a written DSA. This, therefore, implies that in any situation (including research projects) when data, particularly PHI, will be shared with a third party, a legal contract must be executed. The agreement must be drafted precisely to address the relationship of the parties in question as well as to include the details necessary to ensure proper compliance with relevant legislation. The following section provides an overview of complex issues and considerations that must be evaluated before a DSA is drafted.

Before Drafting a DSA: Preliminary Considerations

Determining the Legal Authority

Conducting a legislative analysis to determine whether an institution is able to share data is the first step in drafting a legal agreement. Legal authority to collect,[14] use[15] and disclose[16] data to third parties is central to the legislative analysis and is set out in the aforementioned pieces of legislation. The legislative analysis ensures that the data can be disclosed to an institution and thereby collected and used by a third party. For example, under *PHIPA*, health information custodians (as defined in *PHIPA*) are not permitted to disclose personal health information to non-custodians except in limited circumstances. The terms, *collect*, *use*, and *disclose* are also generally defined terms in a DSA, because they pertain to the actions that must be legally certified by all the parties to the transaction.

It is important to note that should there not be legislative authority for the data sharing, it may be necessary to seek a legislative amendment to the legislation in question. This, however, is a lengthy process and may not be feasible if the timelines for the data sharing are tight. It is also important to note that the legislation may establish hindrances in disclosing data to institutions in jurisdictions outside Ontario, so a thorough legal review must be undertaken.

In addition to conducting a legislative analysis, existing agreements pertaining to the data in question must be reviewed. This is important because institutions may receive data from multiple sources. Due diligence of all applicable agreements ensures that the institution planning to disclose the data can do so freely and is not subject to provisions found within other agreements.

Identifying the Type of Agreement

While the IPC requires the sharing of data to be supported by a legal agreement, the legislation governing the collection, use and disclosure of PI or PHI does not define a DSA.[17] As a result, there are many types of "data sharing agreements" that can be used to share PI or PHI, and a data sharing transaction can be subject to more than one type of agreement.[18] Determining the most suitable type(s) of agreement can be complicated. Types of data sharing agreements could include

- Formally entitled DSAs,
- Statements of Work,[19]
- Health Information Network Provider (HINP) Agreements,[20]
- Funding Agreements and Funding Letters,[21]
- Licence Agreements (for IP),[22]
- Collaboration Agreements,[23]
- Material Transfer Agreements,[24]
- Research Agreements,[25]
- Memoranda of Understanding, and
- Service Provider Agreements.

If a single type of agreement is used for the entire data sharing transaction, detailed data sharing provisions need to be included as schedules to the agreement. The challenge, therefore, is identifying (1) the type (or types) of the agreement to be drafted, based on a particular transaction, and (2) the extent to which detailed data sharing legal provisions are to be included within the body of the agreement or as schedules to the agreement. For the purposes of this article, all agreements in which data is shared are referred to as DSAs.

"Data Elements" Identified during Negotiation

A data element can be defined as the "smallest named item of data that conveys meaningful information or condenses lengthy description into a short code. [It can be] called data field in the structure of a database".[26] Generally speaking, most DSAs will contain an appendix that lists out the data elements to be shared. The list of data elements is generally discussed and agreed to during the negotiation stage. As such, it must be referred to when drafting a DSA. This is important because of the following reasons:

(1) Although a legal agreement governs the relationship between the parties, the actual work conducted pursuant to the agreement (*i.e.*, collecting, using, or disclosing the data) is performed by data analysts or other technical experts. Data analysts must use the information found within the executed agreement to accurately upload, distribute, or store the data elements. The data analysts working on behalf of the institution disclosing the data must ensure that they are providing the correct subset of data. The data analysts working on behalf of the institution collecting and using the data must ensure that they have indeed received the correct data set. This due diligence is particularly important if the institution requires a subset of the data holding and not the entire data set.

(2) It is important to establish parameters on the data set, including the frequency with which the data is to be transferred, the way in which the data is to be utilized, and the required dates in question for each data set. These parameters are known as "Record Selection Criteria". Including the Record Selection Criteria in the schedules as part of the data element list will allow those individuals working with the outgoing data to have proper resources to send over the right data at the right time. The Record Selection Criteria similarly allow those individuals working with the incoming data to create detailed plans for how the data will be utilized.

The following section provides a more thorough list of provisions that must be included in a DSA.

Provisions to Be Included in a DSA

A DSA is a contract, similar to any other type of legal agreement. This means that in addition to standard legal terms and conditions, other specific data sharing terms should be included. The legal terms specific to a DSA include (but are not limited to)[27]

a) the legislative authority for the data sharing and the duties and responsibilities arising from the legal authority;

b) the precise nature of the data subject to the DSA (*i.e.*, data elements to be transferred);

c) a definition of the data that is consistent with relevant legislation (*i.e.*, whether the data is PHI or PI);

d) the party that is responsible for collecting the data and the party that is responsible for disclosing the data pursuant to the DSA;

e) the purposes and authority for collection, use and disclosure (including any restrictions on disclosure);

f) provisions specific to secure transfer, secure retention, secure return/disposal, certificates of destruction, and any breach protocols that must be in place;

g) provisions to ensure that technical, administrative, and procedural safeguards will be employed to ensure the security and privacy of the data;

h) protocols for access to the data by the parties;

i) procedures for handling requests to access the data from the person to whom the data relates; and

j) determination whether threat risk assessment reports or privacy impact assessment reports are required of either or both parties and provisions for the sharing of same.

In addition, it is advisable that the following acknowledgements be included in the DSA:

a) The data collected pursuant to the DSA is necessary for the purpose for which it was collected, and other information (de-identified and/or aggregate information) will not serve the purpose.

b) No more data is being collected and is to be used than is reasonably necessary to meet the purpose.

c) The process of the data collection, use and disclosure subject to the DSA complies with the relevant legislation.

d) An institution's specific policies or procedures that govern the collection, use and disclosure of data that might be relevant to the DSA may be referred to in the agreement as necessary.

It is advisable for DSAs to be drafted when sharing de-identified data (*i.e.*, personal identifiers have been deleted from the data set. If data has been labeled as de-identified, it is important to ascertain that this is indeed the case (this review can be conducted by the privacy expert in the institution) and that the receiving party agrees that it will not re-identify any individuals when the data is collected and used. If data pursuant to the DSA is capable of being linked to other data, then the agreement should state explicitly whether the data will be linked to other information. This point is particularly critical for PHI due to its sensitive nature and possibility of date being re-identified, given the endless linkages available within institutions that have huge data stores.

For those institutions, the IPC has established further requirements deemed Prescribed Entities[28] and Prescribed Registries[29] under *PHIPA*. For such institutions, if PHI will be linked, then the DSA must identify[30]

- the nature of the information to which the PHI will be linked,
- the source of the information to which the PHI will be linked,
- the way in which the linkage will be conducted, and
- the reason for which the linkage is required for the identified purposes.

The following section provides an overview of the legal risks that exist if a DSA is not properly executed.

Liability and Risk

If institutions decide to share data without DSAs, they open themselves to risk and liability. Similarly, if DSAs are not drafted properly, liability can follow. The following discussion highlights some of the more common risks and liabilities.

a) **Privacy breaches**. The last few decades have witnessed a rise in legal proceedings due to privacy breaches and other inadvertent disclosures of sensitive or confidential data. DSAs should explicitly outline the liability associated with breaches so that the parties to the agreement understand their responsibilities. As noted earlier in this article, DSAs should include a provision about breach protocols.[31] In the event of potential or actual breach, DSAs should also state explicitly whether the party to the agreement will be subject to any indemnification should a breach occur as a result of an inadvertent data disclosure. For example, if institution A collects a data set from Institution B, and Institution B may be subject to legal action due to an inadvertent disclosure by Institution A, Institution B may want to clearly state in a DSA that Institution A must indemnify Institution B for any costs incurred as a result of the privacy breach.

b) **Legal action**. Although there have not been many situations in Ontario where parties have sought legal retribution for non-performance of a DSA, it is not unlikely that in a cash-strapped economy, parties will expect provisions within legal contracts to be upheld.

c) **IPC audits**. This can be triggered by an individual filing a complaint with the IPC if he or she believes that a government institution subject to the legislation under the IPC's jurisdiction has failed to comply with the one or more of the privacy protection provisions in the legislation. Alternatively, an audit can be triggered by the IPC itself initiating a complaint, even in the absence of an individual complaint. The IPC's goal in conducting an audit is to make recommendations that will help an organization remediate the situation and prevent similar occurrences in the future. DSAs should be drafted properly to avoid IPC audits. Similarly, detailed records of all executed DSAs should also be maintained in order to be prepared should an audit occur.

d) **Organizational reputation**. Privacy breaches, IPC audits, and possible litigation arising from poor data management and failure to uphold contractual obligations can harm an organization's reputation, resulting in a loss of public trust. This is extremely risky for public sector healthcare organizations whose primary mandate is to serve the public interest. Thus, effective data management and proper fulfillment of contractual organizations are important steps in protecting an organization's reputation that can ultimately affect health care organizations' capacity for delivering on their mandate to serve the public. The bottom line is that an institution needs to decide what level of risk they are willing to incur in order to avoid potential liabilities.

Conclusion

With growing expectations for evidence-based decision making to support health care policy and planning, Ontario's public sector health care organizations will continue to depend on good data, including both PI and PHI. The macro-level utility of this data must be weighed against the individual right of privacy protection. As data sharing may compromise control over PI

and PHI, it is imperative that any sharing transactions be subject to rigorous control mechanisms—including well-executed DSAs. This article has provided a brief overview of proactive steps that Ontario-based public sector health care organizations can take to draft PSAs that will ensure compliance with relevant privacy legislation and organizational protocols. The information in this article is neither exhaustive nor conclusive. Each organization should assess the advantages and disadvantages of data sharing in the context of their unique circumstances. This should be done with the support of legal and privacy experts. Organizations can also avail themselves of the resources of the IPC.

[*Editor's note*: This article does not constitute legal advice, additional considerations may apply in individual situations, and it is advisable to consult a lawyer when writing a data sharing agreement.

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1 Arthur Conan Doyle, "The Sign of the Four", in *The Complete Sherlock* Holmes, (London: CRW Publishing Limited, 2005), 57.

2 *Ibid*., "A Scandal in Bohemia", 218.

3 For the purposes of this article, the term *data* refers only to *Personal Health Information* and *Personal Information* (as defined in the *Personal Health Information Protection Act*, S.O. 2004, c. 3, Schedule A) collected by the public sector. Data collected by private sector organizations are not addressed in this article.

4 In some cases, professional regulators may require the use of data sharing agreements. For example, the College of Physicians and Surgeons of Ontario's policy on medical records (last updated May 2012 and accessible online at <http://www.cpso.on.ca/policies-publications/policy/medical-records#11>) states: "Data sharing agreements incorporating the requirements in this policy must be established among physicians and organizations who will be sharing patient health information with each other".

5 *FIPPA*, R.S.O. 1990, c. F.31.

6 Defined in s. 2 of *FIPPA*.

7 *MFIPPA*, R.S.O. 1990, c. M.56.

8 *PHIPA*, *2004*, S.O. 2004, c. 3, Schedule A.

9 Defined in s. 4(1) of *PHIPA*, *ibid*.

10 Defined in s. 3 of *PHIPA*, *ibid*.

11 It is important to note that in addition to the above-mentioned Acts, there are a variety of other legislations that may be applicable, depending on the Ministry engaged in the data sharing. However, for the purposes of this article, the only Acts discussed are those overseen by the IPC.

12 Information and Privacy Commissioner of Ontario, *Model Data Sharing Agreement* (1995) at 2, <http://www.ipc.on.ca/images/Resources/model-data-ag.pdf>.

13 *Ibid*. at 1.

14 Defined in s. 2 of *PHIPA*, *supra* note 8.

15 *Ibid*.

16 *Ibid*.

17 *PHIPA* does not provide a definition for a DSA; however, *PHIPA* regulation (O. Reg. 329/04, s. 6(3), para, 7) does address the need for an agreement (and sets out guidelines for contents of that agreement) between a health information custodian ("HIC") and an electronic services provider that is not an agent of that HIC. However, this definition is only in a very limited context.

18 See *Model Data Sharing Agreement*, *supra* note 12.

19 A Statement of Work (SOW) is a document that defines the work activities, deliverables, and timeline a vendor must execute in performance of specified work for a client. A Statement of Work usually includes detailed requirements and pricing, with standard regulatory and governance terms and conditions. It overlaps, in concept, with a contract, and, indeed, SOWs are often legally equivalent to contracts, <http://en.wikipedia.org/wiki/Statement_of_work>.

20 *See* s. 10(4) of *PHIPA* and ss. 6 and 6(2) of the Regulation 329/04 to *PHIPA*.

[21] An Agreement that defines the funds to be dispersed, based on performance of a particular project. It can be drafted in the form of a letter.

[22] A licensing agreement is a legal contract between two parties, known as the licensor and the licensee. In a healthcare system, the licensor grants the licensee the right to use technology owned by the licensor. In exchange, the licensee usually submits to a series of conditions regarding the use of the licensor's property and may agree to make payments known as royalties. If an institution has developed technology to upload data from another institution for its benefit, a licence agreement may be utilized.

[23] If two or more institutions join together to create a work, this may involve data sharing.

[24] The University of Toronto, Centre of Research and Innovation, defines a Material Transfer Agreement as

> a contract between the provider of material and the recipient. It grants the recipient a licence to use the proprietary material and ensures that both parties understand how the materials can be used. MTAs govern issues such as ownership of derivatives and modifications of the materials, the transfer of risk, limits on use, confidentiality of information in relation to the materials and rights to inventions, and research results arising out of use of the materials.

See <http://www.research.utoronto.ca/forms/material-transfer-agreements/>. Data may be transferred as part of a Material Transfer Agreement.

[25] A Contractual Agreement between two Parties to conduct research. It also often includes the drafting and publishing of articles and rights related to authorship.

[26] *BusinessDictionary.com,* s.v. "data element", <http://www.businessdictionary.com/definition/data-element.html>.

[27] Information and Privacy Commissioner of Ontario, *Manual for the Review and Approval of Prescribed Persons and Prescribed Entities*, <http://www.ipc.on.ca/images/Findings/process.pdf>.

[28] Defined in s. 45 of *PHIPA*, *supra* note 8.

[29] Defined in s. 39(1)(c) of *PHIPA*, *ibid*.

[30] *Supra* note 27.

[31] *See*, for example, Information and Privacy Commissioner of Ontario, *Privacy Breach Protocol: Guidelines for Government Organizations*, (May 2014), <http://www.ipc.on.ca/images/Resources/Privacy-Breach-e.pdf>.

• *R. v. N.S.*: CASE COMMENT •

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Introduction

This case comment provides an overview of the *R. v. N.S.* matter,[1] which was decided by the Supreme Court of Canada (the "Supreme Court") in December 2012, and which recently received media attention when the Crown decided in July 2014 to withdraw the sexual assault complaint filed by N.S.[2] Writing for the Supreme Court, Chief Justice McLachlin asked the following:

> How should the state respond to a witness whose sincerely held religious belief requires her to wear a niqab that covers her face, except for her eyes, while testifying in a criminal proceeding? One response is to say she must always remove her niqab on the ground that the courtroom is a neutral space where religion has no place. Another response is to say the justice system should respect the witness's freedom of religion and always permit her to testify with the niqab on. In my view, both of these extremes must be rejected in favour of a third option: allowing the witness to testify with her face covered unless this unjustifiably impinges on the accused's fair trial rights.[3]

Although the Supreme Court restricted itself to a question of law on the basis of freedom of religion and right to a fair trial, the decision begs the question of whether the courts have a right to quash women's right to choose how to present their bodies. Although the Supreme Court decision itself is rooted entirely in the context of a criminal proceeding, there are broader issues addressed in this decision that affect Canada's diverse population. Specifically, the outcome of this ruling may impact the way both the courts and Parliament decide whether it is acceptable to legislate issues related to a woman's right to control her body.[4]

The following is an overview of the legal proceedings.

Overview of Legal Proceedings

Facts and Preliminary Inquiry

The case of *R. v. N.S.* began when a woman ("N.S.") pursued charges against her uncle and cousin (collectively, the "accused") for sexual assault when she was a child in the 1980s. N.S. alleged that she was repeatedly sexually abused as a child between the ages of 6 and 12 by the accused. N.S. reported the alleged abuse to a teacher when she was a child, but her father convinced the police not to lay charges. As a result, the sexual assault charges were dismissed. She complained to the police again in 2007, and charges of sexual assault were eventually laid against the accused.

N.S. was called as a witness in 2008 at the preliminary hearing of the sexual assault trial. She made headlines when she refused to remove her niqab while testifying. The niqab is a veil worn by Muslim women that covers the entire face, leaving only the area around the eyes open. The accused sought an order requiring N.S. to remove the niqab while testifying so that the court could see and assess her face and demeanour as she spoke. N.S. argued that demeanour and credibility should be issues left for the trial.

The preliminary inquiry judge held a *voir dire*[5] where N.S. was questioned about her desire to wear her niqab while testifying. Despite the fact that N.S. testified that her religious beliefs prevented her from removing her niqab while in the presence of most men in public, the inquiry judge concluded that N.S.'s religious beliefs were "not that strong" that she was required to wear her niqab while testifying. The preliminary inquiry judge subsequently ordered N.S. to remove her niqab while testifying in court. The decision was based in part on N.S.'s admission that she removed her niqab for a female photographer to take her driver's licence photo and if required, for a security check when crossing the border. When N.S. refused to remove the niqab, the preliminary inquiry was adjourned.

The Superior Court of Justice Decision

The Superior Court of Justice (the "Court") held that N.S. should be allowed to testify wearing a niqab if she asserted a genuine religious reason for doing so but that the preliminary inquiry judge would have the option to exclude her evidence if the niqab were found to have prevented "true cross-examination".[6] The matter was remitted to the preliminary inquiry judge for redetermination. N.S. appealed, and the accused cross-appealed.

The Ontario Court of Appeal Decision

N.S. appealed the decision to the Ontario Court of Appeal (the "Court of Appeal").[7] The Court of Appeal considered whether judges have the jurisdiction to decide whether witnesses should be required to change their attire. The Court of Appeal held that a judge faced with an individual's request to testify wearing a niqab should determine whether the request is the result of a genuine religious belief and if so, whether it contravened the accused's rights to a fair trial.

The Court of Appeal was ultimately satisfied that the preliminary inquiry judge had the statutory power to regulate how a witness would testify, including the power to ask witnesses to change their attire before taking the stand.

The Court of Appeal returned the matter to the preliminary inquiry judge. The matter went to the Supreme Court, which released its judgment in December 2012.

The Supreme Court of Canada Decision

The issue before the Supreme Court was whether, and in what circumstances, a person who wears a niqab for religious reasons could

be required to remove it while testifying as a witness. This legal question triggers two sets of rights in the *Canadian Charter of Rights and Freedoms* (the "Charter"): N.S.'s right to freedom of religion and the accused's right to a fair trial.[8]

The appeal to the Supreme Court was dismissed. In its decision, however, the Supreme Court noted the following:

1. In relying on the freedom of religion protections set out in the Charter, a witness must show that her desire to wear a niqab while testifying is based on "a sincere religious belief".[9]
2. While there is a strong link between seeing a witness's face while testifying and ensuring a fair trial, the risk to trial fairness must be "real and substantial". This depends on the evidence the witness is giving. Evidence that is uncontested and uncontroversial does not trigger the interest of trial fairness. If wearing a niqab due to sincere religious beliefs does not pose a serious threat risk to a fair trial, the witness may wear her niqab while testifying.[10]
3. In seeking a way to accommodate both the freedom of religion and the right to a fair trial, the court must find a "just and proportionate balance" between these two Charter rights in a way that preserves both rights. The courts will seek an available alternative that would respect the witness's religious convictions while preventing a risk to trial fairness.[11]

If no alternative can be found, a woman with sincerely held religious practices who wears a niqab while testifying will be required to remove the niqab if doing so is necessary to prevent a serious risk to the fairness of the trial and if the "salutary effects" of requiring the woman to remove the niqab outweighs "the deleterious effects of doing so".[12] If competing rights cannot be reconciled by accommodation, then there must be a balancing of rights on a case-by-case basis.[13] In this case, the Supreme Court rejected an approach that would prohibit a witness from testifying while wearing a niqab. Salutary effects include preventing the accused from compromising his right to fair trial and preventing the breakdown of the administration of justice. Judges are to consider the nature of the proceedings and, more specifically, examine whether the evidence, credibility assessment, and cross-examination of the witness are central to the case.

Deleterious effects include considering the potential harm caused to the witness when restricting her religious practices, the importance of the religious practice to the witness, the degree and effect of state interference, and the general situation in the courtroom when the witness is testifying. There were other broader societal issues for the Supreme Court's consideration that are worth noting: particularly, the possibility that women who wear niqabs and have sincere Muslim beliefs may be discouraged from reporting offences and participating as witnesses in the justice system if they are required to remove their niqabs.

Justice Abella's Dissenting Opinion in the Context of Women's Rights

Justice Abella provided a dissenting opinion that is notable in its focus on the broader societal issues linked to the discussion of wearing a niqab in court. Justice Abella found that the effects of requiring witnesses to remove their niqabs while testifying created far more harmful consequences than accuseds' not being able to see and assess witnesses' faces and demeanour. She noted that ordering a witness to remove her niqab could deter other women from testifying or bringing charges in the first place. This potential consequence is especially important,

given that the vast majority of sexual assault cases are never even reported to the police.[14] Accordingly, the only circumstance where a niqab should be removed is when the witness's identity is an issue.

Justice Abella likens wearing a niqab to other circumstances where the court has accepted testimonies from witnesses, even though their demeanour cannot be fully observed. These circumstances include cases when a witness uses an interpreter or has speech impairment or physical limitations that may alter facial expressions. Such circumstances have not disqualified witnesses from testifying for fear of compromising a person's right to a fair trial.

N.S., according to Abella J., was a witness who ought not to have been disqualified from testifying. She added that N.S.'s niqab may have concealed her face but did not conceal her tone, inflection, and speech. To require a woman to remove her niqab while testifying means asking her to choose between the religious practice and the desire to participate in the justice system.

Conclusion

The impact that this decision will have on the cultural and religious diversity in Canada remains to be seen. Whether the legal venue is the most appropriate forum in which to grapple with these issues or they are better handled by public opinion, or ultimately the legislature, is a live question.

[*Editor's note*: **Sari Feferman** works in civil litigation, with a focus on health law.]

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1 *R. v. N.S.*, [2012] S.C.J. No. 72, 2012 SCC 72.

2 It is unclear why the Crown determined that there was no reasonable prospect of conviction against N.S.'s uncle and cousin and subsequently dropped all charges against them. As there was no decision reported, it is speculated that the Crown received "additional material" that lead them to this conclusion. The Ministry of the Attorney General has not elaborated on the nature of such additional material. *See* Katrina Clarke, "Crown Dropped Sexual Assault Case by Woman Who Fought to Wear Niqab after Receiving 'Additional Material'", *National Post*, July 22, 2014, <http://news.nationalpost.com/2014/07/22/crown-dropped-sexual-assault-case-by-woman-who-fought-to-wear-niqab-after-receiving-additional-material/>.

3 *Supra* note 1, para. 1.

4 As if to give an example of how diverse Canadian society is, many different intervenors, including the Ontario Human Rights Commission, the Barbra Schlifer Commemorative Clinic, the Criminal Lawyers' Association, the Muslim Canadian Congress, the South Asian Legal Clinic of Ontario, the Barreau du Québec, the Canadian Civil Liberties Association, the Women's Legal Education and Action Fund, and the Canadian Council on American-Islamic Relations, offered their diverging values and opinions. *See* Sean Robichaud, "*R. v. N.S.*: A Person Does Not Have an Absolute Right to Wear a Niqab When Testifying in Court in Canada", *Robichaud's Criminal Defence Litigation*, <http://robichaudlaw.ca/the-case-of-r-v-n-s-supreme-court-rules-on-niqab-in-court/>.

5 Referred to as a "trial within a trial", a *voir dire* can be oral questioning of a witness in order to determine the witness's competence or the admissibility of the evidence. In this case, the preliminary inquiry judge held a voir dire and questioned N.S. on her religious beliefs that required her to wear her niqab in public where men might see her.

6 [2009] O.J. No. 1766, 95 O.R. (3d) 735.

7 [2010] O.J. No. 4306, 2010 ONCA 670.

8 *Canadian Charter of Rights and Freedom*, ss. 2(a) and 11(d).

9 *Supra* note 2, para. 11.

10 *Ibid.*, paras. 27–28.

11 *Ibid*., paras. 31–33.

12 *Ibid*., para. 34.

13 *Ibid.*, para. 52.

14 Samuel Perreault, "Police-Reported Crime Statistics in Canada, 2012", *Statistics Canada* website, <http://www.statcan.gc.ca/pub/85-002-x/2013001/article/11854-eng.htm?fpv=269303>.

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