

Pandemic Could Bring a Reckoning for ‘Canadian Pharmacy’

By Ed Rowland

Francisco de Quevedo, a cynical sharp wit of 16th century Spanish literature’s golden era once commented that “not only are things not what they seem, they are not even what they are called.” The same could be said of the present U.S. situation with imported online prescription medicines. To many, this is called the “Canadian pharmacy.”

The impact on pharmacy pricing to/at U.S. drug chains and independent pharmacy could be immense. It hasn’t happened yet, but COVID-19 might force a reckoning. The pandemic will accelerate the discussion.

The Canadian pharmacy story starts with drug discovery costs. Newly Food and Drug Administration-approved prescription drug molecules enjoy 17 years of market exclusivity in the U.S.; generic versions then appear once the particular drug goes “off patent” or “over the cliff” and can be manufactured anywhere by anyone as long as they adhere to FDA quality standards. Prices to the consumer drop precipitously, sometimes as much as 80% to 90%. There is a huge incentive to jump the legal market exclusivity period. Prescription drugs are not priced by a straightforward cost-of-goods plus a margin model. In fact, the cost of goods in U.S. prescription pricing usually accounts for around 5% of the price. The big money and markups pay for prescription drug creation.

Prescription pricing reflects R&D costs for the successes (and failures) of drug development. The process can cost \$800 million to \$1 billion per drug, with no guarantee of success. By simply copying a successful pharmaceutical molecule, it’s possible to bypass the development-costs-as-part-of-the-value-chain and earn huge profits. An internet search for Viagra and Canada pharmacy will expose obvious price differences. Things such as



safety, “fair” pricing, intellectual property protection and the incentive for further drug research appear differently to consumers and manufacturers and are certainly called by different names. The lines dividing the politics and legal questions are messy and murky.

There are Americans who cross the U.S./Canadian border to buy prescription drugs for lower prices at Canadian pharmacies. Canada has a mostly government-financed single-payer system which controls drug prices still under patent. Canada’s PMPRB, the Patented Medicine Prices Review Board, plays a balancing act. They strive to maintain budgets and support local industry with incentives. In the end, preserving the local pharmaceutical manufacturing base means cheaper drugs. Will Canada continue to allow Americans to purchase subsidized Canadian pharmaceutical products? Meanwhile, many of the U.S. consumers seeking pharmaceutical products overseas are senior citizens. The optics of arresting an elderly person are not good.

But Canadian pharmacy has other meanings as well. The 1987 Prescription Drug Marketing Act clearly sets out that only the original manufacturer can import its pharmaceutical product into

the U.S. It has been loosely enforced at the individual consumer level. The numerous e-commerce Canadian pharmacy websites serving individuals often lead to Russia, India or China. Shut down one e-pharmacy, and another one pops up. It is pharmaceutical whack-a-mole. While the FDA has stated that consumers importing prescription drugs is illegal, the practical side has meant virtually no enforcement. Health Canada, for its part, has investigated these so-called Canadian online pharmacies. A recent study revealed almost 74% of the e-commerce sites were selling pharmaceutical products that were not manufactured in Canada and would not be legal to sell. The study cited India, Hong Kong and Singapore as the main sources. Health Canada concluded that “the likelihood of receiving standard or counterfeit medicine from these countries is considerable.”

The e-commerce flow is almost impossible to control. As some law enforcement will say, it may appear that a crime has been committed but rounding up suspects isn’t feasible, and the case is closed. In prior years, the FDA inspected 10,000 to 20,000 packages, increased to 45,000 in 2019, with plans to increase that to 100,000.

It is still a fraction of the volume.

How big is this? It is hard to tell.

One estimate puts the current number at 2% of U.S. consumers purchasing prescription products overseas via e-commerce. As early as 2017, a Consumer Reports survey estimated 3.4 million U.S. consumers had imported a prescription drug within the last year. The bigger question, especially during the pandemic: Is this now accelerating? When the overall cost of U.S. health care, now at approximately 18% of GDP, politics and legality collide. The collision becomes a high-speed crash as administrative system complexity of various health insurance providers now stands at approximately 33% of total health care costs. Canadian pharmacy is not what it seems and isn’t an apt name to the problem.

In August of 2019, the Trump administration, following up on a campaign promise that enjoys bipartisan support, took a small step towards looking at prescription drug e-commerce imports, but the effort quickly stalled. One industry observer has proposed leveraging trusted brick-and-mortar giants like Walmart or Costco in Canada to serve as the trusted supply houses. For now, e-commerce or slipping across the border is and will remain illegal for consumers.

Safety is an issue. The National Association of Boards of Pharmacy tracks online pharmacy websites and recently found 95% operate outside FDA and state laws. Counterfeit and/or adulterated drugs abound. It is not clear which websites provide “real” prescription products.

The pharmaceutical industry has responded by offering discount coupons to soften the co-pay for those who have coverage. There are patient-assistance programs for those without insurance. Still, the pricing pressure will continue. The move to lower prices will be slowed by regulatory approvals and likely court challenges from industry. Finally, will Canada agree to effectively serve as the U.S.’s pharmacy?

There has been some movement, but



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Pandora’s box is not quite opened yet. The FDA allows consumers to import a 90-day supply of selected prescription products and medical devices if it:

- Provides for a serious condition and no effective U.S. treatment is available.
- Is for personal use/not re-sale.
- Has no “unreasonable risk.”

Health and Human Services Secretary Alex Azar, as reported by the AP, said, “... for the first time in HHS’s history, we are open to importation. We want to see proposals from states, distributors and pharmacies that can help accomplish our shared goal of safe prescription drugs at lower prices.” Interestingly, the FDA has not stopped Florida retail stores from importing since 2003. While there were FDA raids in 2017, these stores have been allowed to continue operations.

Indeed, Canadian pharmacy is not what it seems to be, and it certainly has many names. Health Canada can’t do anything about online Canadian pharmacies because almost all of them aren’t Canadian. What’s in a name?

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Owen Mumford Meets Need

MARIETTA, Ga. — Health care professionals, caregivers and those who are self-injecting using safety pen needles want to know with certainty that the injection was successful, and the full dose was delivered. Owen Mumford Inc. has responded to this need with its next-generation safety pen needle: Unifine SafeControl.

Unifine SafeControl is designed to provide protection from accidental needle stick injuries (NSIs) and provides confidence in delivering the full medication dose, balancing both safety and control during the injection process. The product features an innovative push tab providing one-handed control of the safety mechanism after injection when the health care professional is ready to activate. Unifine SafeControl also offers both visual and audible confirmation as well as dual protection.

Health care professionals who use passive safety pen needles have reported that design flaws often make it difficult to deliver a consistent standard of care to their patients. Hidden needles and premature activation are common concerns. Additionally, a



study in the *Journal of Hospital Infection* revealed that injection pen use correlates with a higher rate of NSIs among health care professionals who give injections. Unifine SafeControl addresses those concerns not only with an improved safety pen needle but with innovation in technology.

“Health care professionals and patients across the country trust Unifine pen needles, and we are thrilled to introduce an innovative safety pen needle unlike anything available today,” said Jim Lanza, vice president of sales at Owen Mumford. “Dual protection on

both ends of the needle and easy safety activation using Unifine SafeControl will offer yet another way for health care professionals to feel safe and confident with injections.”

The addition of Unifine SafeControl rounds out an already comprehensive portfolio of capillary blood sampling and drug delivery devices. “We’ve had conversations with hundreds of health care professionals using first generation safety pen needles, to understand common injection processes and product improvement opportunities, and we incorporated this feedback into our latest innovation,” said Owen Mumford executive vice president Travis Shaw. “Overwhelmingly, they reported that Unifine SafeControl was safe, easy to use, and provided user control. All users felt confident the correct dose was delivered to the patient. We’re proud to be able to help improve health care professionals’ ability to better treat their patients.” Unifine SafeControl is available in two sizes, 5 mm 30G and 8 mm 30G, and samples are available through Owen Mumford. Further information is available at unifinesafecontrol.com.

Pharmabid Seeks to Cut Drug Costs via Auctions

NAZARETH, Pa. — In August, Pharmabid LLC will hold its first auction in what founder Joe Lefebvre hopes will be the beginning of a new pathway to lowering drug costs.

Essentially a pharma version of eBay, Pharmabid works with generic pharmaceutical manufacturers, distributors and warehousing chains by offering an innovative approach to auctions utilizing what Lefebvre calls customized auctions — allowing the manufacturer to determine which bidders are approved to participate in a specific auction and which ones to exclude. Pharmabid runs an auction style platform in an effort to set price for a specific quantity of product, most of which, Lefebvre explains, are tablets and capsules of common prescriptions with short dates, meaning the product is less than 12 months to its expiration date and therefore can be offered at a discounted price.

Once a bid on product is accepted, the product will be shipped directly from the manufacturer to the winning bidder and invoiced accordingly. Because there is no third party or middleman interrupting the delivery straight from the manufacturer to the bidder, prescribers and patients can be confident that the medications secured via Pharmabid’s auction process are both safe and effective, Lefebvre says.

Lefebvre’s goal is to provide the industry with an efficient marketplace for specific types of products. Pharmabid also provides a streamlined experience by offering bidders mobile applications that are currently available for Apple and Android devices.

Bidders may enroll at www.pharma-bid.com and download the mobile application. Interested manufacturers may contact Joe Lefebvre at joe@pharma-bid.com for further information.