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Re: AHCA RFI 003-18/19
Date: June 25, 2019
From: Shabbir Imber Safdar, Executive Director
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Identification

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Our response is suitable for release to the public and requires no additional redaction of any portion. We grant permission for the state of Florida to release this RFI response as part of its normal transparency process.

Statement of interest

According to the Request for Information (RFI), the State of Florida, as defined in Section 287.012(22), Florida Statutes (F.S.), is seeking information for “planning purposes.” We believe that our expertise on the issue of counterfeit and substandard prescription drugs is critical for your work in determining if it is possible to develop a program that meets federal standards for safety and cost savings.

Description of our business and experience as it relates to the services outlined in this RFI.

Founded in 2003, the Partnership for Safe Medicines (PSM) is an organization comprised of over 70 nonprofit partner organizations from a variety of facets from within the health care

sector, including pharmacists associations, patient advocates, consumer protection groups, wholesalers, and manufacturers, both branded and generic.

PSM is recognized as a subject matter expert on the topic of counterfeit medicines in America. We have extensively covered counterfeit incidences in America since our founding with the best coverage in the country of the physician in-office wholesale supply chain breaks from 2007-2018. This outbreak included the fake Avastin crisis. You can see a summary of cases from this episode in this report "[Black Market Cancer Drugs in the U.S.](#)"

We were the first organization to identify a nationwide epidemic of counterfeit pills made with fentanyl in our groundbreaking 2017 report, "[40 States And Counting: The Deadly Combination Of Imported Fentanyl And Counterfeit Medicines.](#)"¹ To date, PSM has documented the discovery of counterfeit pills made with fentanyl in 48 states, with confirmed deaths in 33 states.

We recently released, in conjunction with our partners the National Association of Boards of Pharmacy and the National Association of Drug Diversion Investigators, a first-of-its-kind report showing the lack of criminal penalties for counterfeiters who use pill presses. In "[Pill Presses: An Overlooked Threat to American Patients,](#)" we documented that criminals inside and outside America are increasingly getting their hands on industrial quality pill presses and can ship them into the United States, openly bragging about their ability to evade US Customs.²

PSM staff regularly conducts Continuing Education courses for pharmacists and law enforcement all over the United States, teaching them about the state of counterfeit crime in America today.

Estimate of administrative and operational costs

Under "A. Purpose" in the RFI, the state of Florida writes that an RFI may be used for "researching general, special, and/or technical specifications for a solicitation." In the following section, we identify a number of elements that will directly impact the administrative and operation costs of Florida's importation program in regard to patient safety.

Cost of ongoing identification of medicines that yield a "substantial cost savings"

HB19 requires a vendor to:

On an annual basis, develop a list of prescription drugs that have the highest potential for cost savings to State of Florida programs, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs.

¹ <http://www.safemedicines.org/wp-content/uploads/2017/09/40-States-and-Counting.pdf>

² <https://www.safemedicines.org/2019/03/new-report-illegal-pill-presses.html>

Advocates for Canadian importation often like to compare prices of brand name medicine in both the U.S. and Canada to make a point about price savings. However, the direct comparison of a Canadian and U.S. list price is not an accurate depiction of the difference in price a U.S. wholesaler would pay. On average, brand drug manufacturers rebate or discount over one-third of a U.S. drug's list price back to payers, government or the supply chain, including wholesalers, making the net cost of many brand medications much lower than the list price. Conversely, Vermont regulators recently released an analysis assuming that state should mark up the list price of a Canadian drug by 455 for drugs imported through an importation program. This markup is meant to account for supply chain costs and profit margins for entities that may decide to participate.³ When you consider rebates and discounts for FDA-approved drugs coupled with a substantial markup on the list price of Canadian drugs, it is difficult to see how significant savings could be achieved. Furthermore, proponents of importation also conveniently forget that a generic medication is available in the United States for far less money than either the brand drug or generic sell for in Canada.⁴

HB19 works inside a federal legal framework created by the 2003 Medicare Modernization Act (MMA). Limitations in the 2003 MMA restrict what Florida's importation plan can attempt.

Two key components required by the Medicare Modernization Act of 2003 (MMA) of a state's drug importation program is that:

1. patient health and safety must not be compromised; and
2. there must be substantial cost savings to American consumers.

In 2017, 90 percent of prescriptions dispensed in the U.S. were filled with generics,⁵ and generic drugs in the United States are often cheaper than either the Canadian brand-name or generic version of drugs.⁶ Hence, Florida's drug importation plan will need to focus solely on brand-name drugs to find even a possibility of cost savings, severely limiting the number of potential medications that can be imported.

Additionally, the U.S. Food and Drug Administration (FDA) has been approving new generic drugs at a record rate. In 2018, over 1,000 new generics received approval or tentative approval, with 99 being first-time generic drug approvals.⁷ HB 19 only stipulates that the vendor needs to provide a list on an annual basis, which given the rate at which new generics are being

³ P. 4 https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf

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<https://www.benzinga.com/pressreleases/19/05/n13788350/generic-drugs-68-cheaper-in-u-s-than-from-canada>

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<https://www.fda.gov/drugs/2018-office-generic-drugs-annual-report>; <https://www.fda.gov/drugs/first-generic-drug-approvals/2018-first-generic-drug-approvals>

⁶ <https://www.fda.gov/drugs/resources-you/study-us-generic-drugs-cost-less-canadian-drugs>

⁷ <https://www.fda.gov/drugs/2018-office-generic-drugs-annual-report>;

<https://www.fda.gov/drugs/first-generic-drug-approvals/2018-first-generic-drug-approvals>

approved, means that the State of Florida could potentially be paying more than necessary if a generic version of a branded drug comes onto the market at any point during the year.

It's worth noting that strip mall fake Canadian pharmacies in Florida and other states have been caught taking prescriptions for brand name medication and dispensing generics. An ABC News 20/20 investigation documented this practice and found storefronts that claimed to be selling Canadian medicines filling prescriptions for brand-name drugs with foreign, unapproved generics.⁸ The State of Florida will need to ensure that prescriptions written for brand-name drugs are not filled with non-FDA-approved generics, undercutting patient safety and the cost savings benefits of the program.

It is also important to note that the MMA sets restrictions on the drugs allowed to be part of a state's drug importation program. Restricted prescription drugs include controlled substances, biological products, infused drugs, and parenteral drugs (such as insulin and Epi-Pens) that pose a threat to public health.

One of the brand-name prescription drugs cited during the course of legislative hearings in Florida was Lyrica, which the U.S. Drug Enforcement Administration has classified as a Schedule V controlled substance.⁹ Per the MMA, Lyrica cannot be included in a drug importation plan run by the state of Florida.

Failure to adequately instruct the vendor about these limitations on their medicine savings list will add unnecessary administrative costs to the implementation as the eventual vendor researches medicines that can't be imported from Canada due to legal or financial prohibitions, or for which there are already cheaper generic options available.

Cost of testing for authenticity of medicine

HB19 requires the vendor to:

Ensure that eligible importers have documentation that sample testing of the prescription drugs occurred at a qualified laboratory, as required by [21 U.S.C. 384](#).

Proper industry-standard testing for authenticity of a medication is expensive and will be a cost driver for any vendor who is awarded a contract for Canadian importation. The MMA requires that any prescription drugs imported by a state be tested at a testing facility within the U.S. that received approval from the head of HHS. Sec 804: "(4)Qualifying Laboratory--the term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for purposes of this section." The State of Florida will need to have all drugs shipped

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<https://abcnews.go.com/Health/abc-news-investigation-counterfeit-prescription-drug-operations-us/story?id=31077758>

⁹ <https://www.lyrica.com/frequently-asked-questions#why-lyrica-classified-controlled-substance>

directly to the test facility(ies) so that a statistically significant sampling can be tested. If the medicines pass, they can then be shipped to Florida for distribution.

If drugs are not tested thoroughly and consistently, counterfeit and substandard drugs will make their way into Florida's drug supply. When Maine legalized drug importation from Canada in 2013, within 90 days advertisements for cheap "Canadian prescription drugs" were placed in local papers. Mac McCall, the head of the Maine Pharmacists Association, ordered several medications from one of those companies.¹⁰ The pills he received were not from Canada or any of the other Tier One countries as the law required, but were manufactured in Turkey, India, and Mauritius. When he tested the pills, one only contained 77% of the stated API and a second only 58%. The third pill tested contained an unknown contaminant.

It is an industry standard procedure to test prescription drugs against the following four methods to ensure legitimacy:

Assay: assay is a critical component of the Quality Assurance (QA) process used to determine if a pill contains the Active Pharmaceutical Ingredient (API) it is supposed to and if a pill contains the amount of that API. Not having enough or any API would indicate that the pill is subtherapeutic and counterfeit.

Counterfeiters often make sub-therapeutic dose medicines that evade simple testing because there is some but not enough API present. In fact, medicines tested during Maine's disastrous 2013 importation program showed up as sub-therapeutic.¹¹ Such counterfeits would easily fool novices armed with only simple spectrometry equipment.

Patients expecting a therapeutic effect would be at the mercy of their disease. Even worse, their physicians may believe them to require a higher dose to achieve a therapeutic effect. When that patient gets a higher dose from a non-counterfeit, the inappropriately high dose could cause injury or death.

Dissolution rate: dissolution rate is a critical component of QA and Quality Control (QC) that ensures batch-to-batch consistency of the drug's release rate within the body of the patient.¹² An incorrect dissolution rate can significantly affect the bioavailability of a drug, and hence the drug's effectiveness at treating the patient. Should the medicine dissolve too quickly or too slowly, the patient may not be able to receive the full therapeutic effect. Subsequent actions by the physician to raise or lower the dose based upon this effect could be dangerous or fatal to the patient. Dissolution rate is an industry standard testing criteria, and cannot be revealed by simple spectrometry.

¹⁰ <http://www.safemedicines.org/wp-content/uploads/Maine-Importation.pdf>

¹¹ <http://www.safemedicines.org/wp-content/uploads/Maine-Importation.pdf>

¹² <http://www.pharmtech.com/understanding-dissolution-testing>

Content uniformity: content uniformity is a critical quality measure that ensures that a consistent dose of the API is maintained between batches so that the patient receives the correct dose. The API in a pill needs to be evenly distributed throughout the tablet to ensure that if the tablet is split in half, each half of the tablet has an equal dose.

This is a standard measure of quality control in the area of medicine safety.

Sterility: sterility is an essential part of QC and is used to ensure that pharmaceutical and biopharmaceutical therapeutics are sterile and safe for human use. Sterility is one of the most common problems found in counterfeits. Testing from Maine in 2013 found a non-sterile counterfeit blood thinner dispensed as a Canadian medication.

Sterility is challenging to achieve and adds quite a bit to the cost, which is why you see counterfeiters failing sterility tests.

Given the history of counterfeits in importation programs, as well as the promises made by the sponsors of HB19, testing is going to be critical to the safety of any such plan. It is also likely to add to the cost of program administration, reducing possible savings for Florida. As such, any vendor applicant should be required to include a cost estimate for adequate spot checking of imported medications, and any such estimate should come directly from an approved laboratory.

Cost of repackaging, relabeling, new NDC codes, black box warnings, inserts, and serialization

Medicine in Canada is labeled differently than in America and is not suitable for distribution to U.S. patients without relabeling. Labels, warnings, and inserts have evolved to their present state to maximize patient safety and minimize harm. Even experienced healthcare professionals consult product documentation on a regular basis, so it must be compliant with approved labeling, warning, packaging, warnings, and inserts in existing FDA-approved medication.

An Institute of Medicine (IOM) report from July 2006 concludes that labeling and packaging issues are the cause of 33% of all medication errors and 30% of fatalities from medication errors.¹³ Safety advocates constantly study adverse medical events to see if label revisions might avert errors, and recommend label changes as a result.

To that end, it is literally a matter of life or death that any medication brought into the U.S. has the correct labeling and packaging.

¹³ <https://www.nap.edu/read/11623/chapter/1#iv>

Additionally, healthcare professionals or patients used to a specific packaging, dose, or other label may make mistakes if presented with a Canadian version that has a different dose or other usage difference.

The cost of this step, as well as finding a vendor, will not be trivial.

Relabeling and repackaging have to be done in a facility that follows Good Manufacturing Practices to ensure sterility of the medicine. Additionally, the act of repackaging and relabeling is a regulated activity in both Canada and the U.S. In Canada any entity doing this must have this activity approved explicitly by Health Canada as part of their Drug Establishment License (DEL). In America, that activity is regulated and licensed by the U.S. Food and Drug Administration.

Additionally, any medicine brought into the U.S. from another country's regulated supply would require the filing of a new National Drug Code (NDC) number with the U.S. Food and Drug Administration. This change will carry with it both costs in fees as well as responsibilities for maintenance.

Inserts and approved packaging will all have to be affixed to the product.

The product will also have to be serialized, as all drugs sold after November 27, 2018 must be serialized per requirements of the Drugs Security and Supply Chain Act of 2013. As well as being a cost driver, products brought from the Canadian market and then re-serialized will not be as trackable as products in the existing supply chain. See our commentary below on "IMPLEMENTATION CHALLENGE: Promises to implement Track-and-Trace cannot be fulfilled."

Cost of pharmacist, pharmacy, and wholesaler financial liability

Whether covered explicitly or through hidden costs, importing medications from the Canadian drug supply will increase liability for every voluntary participant in the supply chain that handles medication. This is because when a counterfeit is discovered, the entire supply chain is often named in the resulting civil suit, as they were in the case of transplant patient Timothy Fagan¹⁴ who, ironically enough, got his counterfeit from a Florida-based criminal supplier. Timothy Fagan's case was also profiled in *Dangerous Doses*, Katherine Eban's book about the criminal pharmaceutical wholesale underworld in Florida during the late 1990s and early 2000s.

In the Fagan case, nearly every member of the supply chain, from the legitimate manufacturer who had nothing to do with the counterfeit to the Florida wholesalers to the dispensing pharmacy, was named in the civil complaint. Several of them didn't escape liability until the summary judgment phase of the case. The legal representation required to escape liability in

¹⁴ <https://www.safemedicines.org/2018/07/drug-importation-and-liability.html>

these circumstances, even when there is no fault, is still significant. Supply chain entities handling Canadian imported medications will require additional liability insurance that will add to the cost of the program, either explicitly eating up savings, or less explicitly adding to the cost of the medicine before it is sold to the patient by supply chain partners.

Because these products will require separate NDC codes, they will not be able to be mixed with other medical products in supply chain inventories, and the different origin will stick out like a sore thumb to anyone concerned about liability.

Cost of obtaining medication from a fixed size drug supply will result in increased prices and reduced savings for Florida

While Canadian entities that purchase medication within Canada have pre-set negotiated pricing, the state of Florida does not enjoy a right to that pricing structure. The Canadian drug supply is relatively inelastic as well because Canada's pharmaceutical manufacturing sector is so small. This issue can be seen by the increasing number of drugs in shortage in Canada. Essential medications such as the EpiPen have been in shortage in Canada at times for several months. Research into Canadian importation suggests that a state as large as Florida could quickly impact the Canadian drug supply.¹⁵

Any sizable demand on the Canadian drug supply is likely to result in a reminder of the fundamental law of economics: supply and demand. When the supply of a medication is limited and Canadian prices are set, wholesalers in Canada are likely to begin charging Florida more for medication because they have no legal price ceiling and a captive customer. These increased prices will result in reduced savings for the Florida program.

Estimated timeline of the program

No commentary offered on this section.

Description of innovative ideas and strategies in providing services described as well as implementation challenges

The RFI requests that respondents provide information about innovative ideas and strategies as well as implementation challenges to a Canadian importation program. PSM finds that there are several implementation challenges worth discussing.

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<https://www.safemedicines.org/2017/08/u-s-drug-importation-impact-on-canadas-prescription-drug-supply.html>

IMPLEMENTATION CHALLENGE: Florida's Board of Pharmacy cannot regulate foreign pharmacies and wholesalers without a significant corporate presence in Florida.

In Fiscal Year 2017-2018, Florida pharmacy regulatory budget was \$7.2mm.¹⁶ Given the significant cost increases found by Illinois when attempting to inspect Canadian entities dispensing to Illinois residents, we question whether Florida is prepared to outlay the resources required to do repeated inspections of facilities and entities in Canada that they have to do to verify the claims of any non-FDA-approved supply chain. As was found in the early 2000s in Florida and in the last five years in Canada, wholesalers who see a chance to make money with little prosecution risk will happily endanger patient safety to make a buck.

One of the first challenges the State of Florida will face is the logistics of inspecting a business in a foreign country. Given the central role for the vendor in HB 19, one could assume that they will need to play an integral role in the scheduling of all inspections. This presents a clear conflict of interest because the same vendor will be evaluated on how effectively they save money for the state of Florida, and there will be strong pressure not to have failed inspections that disqualify vendors.

The complexity of inspections necessary for a drug importation program may require additional training for Florida inspectors as these activities have typically been performed by FDA staff. The inspection team will need to be alert to process failures, product failures, failures in laboratory tests, and process changes. Microbial test results for all batches, all initial positive sterility test results and reports of investigation, all organisms isolated and source, environmental monitoring results, and investigations, monitoring of Water for Injection (WFI) systems for microbial and endotoxin qualities will need to be examined for all sterile products.

Foreign firms are under no obligation to comply with the U.S. regulations except for their commitments in applications filed with the FDA and/or for their desire to market their products in the U.S. Florida inspectors have no regulatory authority over foreign companies so at best inspectors will be observers. If an inspection team finds significant GMP violations or data integrity problems at the foreign facility that may require additional attention, such findings should be immediately communicated to the vendor, the appropriate person within the State of Florida, and the Secretary of HHS. There is not much that Florida's inspectors can do or say to change how a foreign manufacturer is running their business.

¹⁶ P.46

http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1718.pdf

Even during pre-announced inspections at pharmacies approved by the Canadian Internet Pharmacy Association, inspectors with Minnesota's drug importation program observed dozens of safety problems:¹⁷

- One pharmacy failed to label its products, but instead just shipped the labels unattached in the same shipping container, even when patients received multiple medications in one shipment.
- Drugs requiring refrigeration were being shipped unrefrigerated with no evidence that the products would remain stable.
- Several pharmacies failed to send any patient drug information to patients receiving prescription drugs.

However, safety and quality issues were not the only issue facing the program. Residents simply did not participate in the program anywhere close to the projected numbers. Minnesota originally envisioned filling prescriptions in their Rx Connect drug importation program for as many as 700,000 each month. In January 2005, the program filled 1,100 prescriptions. In December 2009, the month before the program shut down, only 57 prescriptions were filled.¹⁸

Holding foreign entities responsible for selling the State of Florida counterfeit or substandard medication will be a particular challenge. If selling counterfeit or substandard medication is not a crime in that country, the State of Florida will receive no help from any local authorities. If Florida wants to prosecute an individual for their role in the sale of fake or substandard medicine, the best option would be to have that individual come to the U.S. and arrest them once they enter the state of Florida. In the past, individuals charged with selling counterfeit or substandard medication refuse to come into the country to face prosecution; they have just waited until prosecutors cut them a good deal.

According to the U.S. Department of Justice (DOJ), from 2009 through 2014 CanadaDrugs.com sold \$78 million worth of unapproved, mislabeled and counterfeit cancer drugs to doctors across the U.S.¹⁹ On their own website, which has since been seized by the U.S. government, CanadaDrugs.com admitted to selling American patients imported prescription drugs—a practice that the FDA says is illegal—since 2001. The November 2014 indictment of CanadaDrugs and multiple subsidiaries and executives stemmed from the distribution of two lots of counterfeit cancer medications—Avastin and Altuzan—to medical practices in the United States. It alleged that the company tried to conceal the problem rather than reporting the supply chain breach to the FDA. The counterfeit Avastin and Altuzan contained no active ingredient. The DOJ spent years attempting to bring the individuals involved into the U.S. to face justice. In the end, plea deals made in 2018 meant that not a single person spent even a day in jail and

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https://www.safemedicines.org/wp-content/uploads/2019/03/Letter-to-Honorable-Tim-Pawlenty_-February-23-2004-1.pdf

¹⁸ <https://www.safemedicines.org/2019/03/minnesotas-rxconnect-2003-2010.html>

¹⁹ <https://www.safemedicines.org/policymakers-media/canada-drugs-case>

CanadaDrugs.com paid a fine that was less than half of the total amount of counterfeit cancer drugs sold that they sold to U.S. doctors.

IMPLEMENTATION CHALLENGE: Cost of drug product quality testing eliminates Canadian price savings in many cases.

Throughout the legislative debate over HB19, legislative sponsors promised that medication imported under this legislation would be tested thoroughly. Specifically, they promised that:

- Every batch made outside Canada for the Canadian market would be tested upon importation to the United States; and
- Every other batch made in Canada for the Canadian market would be tested upon importation to the United States.

Given the lack of a secure chain of custody for medicine “in Canada,” this is an important safety aspect that Florida legislators were assured of before they could decide to vote for HB19. However, as one counterfeit researcher has shown, the cost of testing is expensive, and testing medicine to a reasonable level of safety can often obliterate the very savings you seek from a Canadian importation program.

This is why the Food and Drug Administration works so hard to secure the entire supply chain: because it costs much less to secure the supply chain than to obtain product from an insecure supply chain and attempt to “test it into safety.”

In a recent paper counterfeit researcher Dr. Kristina Acri née Lybecker identifies 24 medicines that have been discussed for importation.²⁰ She then studies the costs differences of medicine available from three sources that list prices: a U.S. drug search engine (Goodrx²¹), Canadian bricks and mortar pharmacies, and unlicensed and unsafe Canadian online pharmacies.

For the 24 medicines she studies in this research paper, she obtained the cost of testing from a federally regulated lab matching the requirements in the 2003 Medicare Modernization Act that HB19 is based on. She then computes the number of tests that must be done to achieve a determination of safety for a given batch for a “representative state” 1/50th the size of the U.S. conducting an importation program.

In 16 out of 24 cases for the medicines she studied, the cost of testing to a confidence interval of 99.99% confidence and reliability costs more than is saved by buying the medication from Canada. For these drugs, the state would lose money by buying them from Canada and testing them. The state would be better off financially buying them from the existing supply chain in America.

²⁰ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3402784

²¹ Because of the complexity of the U.S. healthcare supply chain, a price on GoodRX.com usually does not reflect what the patient pays.

In fact, Florida would even lose more money because the importation from Canada also requires the infrastructure of the Canadian importation program as described above, which would include additional costs for repackaging and relabeling.

For 99.999% confident and reliability, testing far outweighs any savings a representative state might achieve.

IMPLEMENTATION CHALLENGE: Cost of adverse medical events from even a small amount of counterfeit product eliminates Canadian price savings in many cases.

When one is on a medication to treat a disease, it is easy to forget that there is also a cost for failing to treat the disease. It is a reasonable question to ask: “If I get a counterfeit medicine by buying outside the secure U.S. drug supply chain and my disease runs amok in my body, will the resulting treatment cost me more than I saved?”

This fact is not an abstract hypothetical. Over the past five years, several Americans who went to Tijuana for cheaper weight reduction surgery acquired a treatment-resistant bacteria.²² The medical costs related to this secondary infection have far outweighed the savings they thought to achieve by leaving the regulated U.S. healthcare system and going to Mexico’s poorly regulated healthcare system.²³

Dr. Aciri’s paper also looked at the cost of adverse medical events that might occur should a patient taking this medication discover their medication is counterfeit.²⁴ When studied for a representative state 1/50th the size of the U.S., she found that in many cases (11 out of 24) the cost of a medical adverse event outstrips any savings one might see from Canadian importation rather quickly.

Dr. Aciri’s paper did not attempt to analyze the cost of an adverse medical event of death, though for a medication like an EpiPen, death is a significant risk.

IMPLEMENTATION CHALLENGE: Promises to implement Track-and-Trace cannot be fulfilled.

HB19 states that:

Ensure all participants in the program comply with [Title II of the Federal Drug Quality and Security Act, Pub. L., No. 113-54](#).

²² <https://www.cnn.com/2019/01/10/health/mexico-surgery-antibiotic-resistant-infection-cdc/index.html>

²³

https://www.washingtonpost.com/national/health-science/they-went-to-mexico-for-surgery-they-came-back-with-a-deadly-superbug/2019/01/23/ac0ca280-1dcb-11e9-9145-3f74070bbdb9_story.html

²⁴ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3402784

Repeatedly throughout the legislative life of HB19, sponsors of the legislation made assurances that all drug products imported will comply with Track-and-Trace, the system created by the 2013 federal legislation entitled The Drug Supply Chain and Security Act (DSCSA).

The DSCSA was implemented to facilitate a single system for tracing the manufacture and chain of custody for drug products through all entities in the supply chain.

The promises made to ensure full compliance with Track-and-Trace during the passage of HB19 cannot be fulfilled under any Canadian importation program under any scenario.

*Track-and-Trace requires that the state only do business with Authorized Trading Partners, but Florida cannot authorize trading partners who have no controlling regulatory authority in the United States.*²⁵

A crucial part of the DSCSA is that all entities in the supply chain only do business with Authorized Trading Partners who are licensed and regulated. However for all the reasons identified in “IMPLEMENTATION CHALLENGE: Florida’s Board of Pharmacy cannot regulate foreign pharmacies and wholesalers without a significant corporate presence in Florida,” none of the supply chain partners will be sufficiently licensed.

The Florida Board of Pharmacy can create a special licenses for International Pharmacies and International Pharmacy Wholesalers, but a license from the state of Florida cannot guarantee that the medications provided by these companies are safe. We note that Florida, as a state entity, has neither legal authority in Canada to regulate pharmacies or wholesalers, nor does it have an extradition treaty with Canada to bring egregious cases of criminal negligence into Florida’s courtrooms.

Given Florida’s history as a source of criminal pharmaceutical wholesalers in the early 2000’s as documented in Katherine Eban’s book, *Dangerous Doses*, a more cautious approach should have been taken by Florida legislators. For more information on the crimes committed by the Florida secondary wholesale pharmaceutical industry in the early 2000s, see the Florida Grand Jury report from 2003.²⁶

Canadian medical products are not serialized. Once a product has been made by a manufacturer without serialization for the Canadian market, all of the options to add serialization invalidate the security of the Track-and-Trace system.

As of November 28, 2018, all drug products in America are required to be serialized. Any product brought in through a Canadian importation program would have to be serialized before

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<https://www.pharmacist.com/sites/default/files/audience/Phase%201%20Checklist%20for%20Dispensers%20FINAL.pdf>; <https://www.fda.gov/media/106961/download>

²⁶ <http://www.myfloridalegal.com/interimjury17.pdf>

introduction into the U.S. supply chain. While there a number of ways to attempt this, none of them create compliance either letter or in spirit with the DSCSA. Here is the list of options Florida has available:

Have a relabeler or repackager add a serialized code to the product at the time of importation—fails to fulfill the promise to comply with Track-and-Trace.

This option would allow wholesalers and pharmacies further down the supply chain to trace the chain of custody of the medicine only to the relabeler, but not back to the manufacturer. From the relabeler back to the manufacturer, the authenticity of the medicine would simply be based upon “a web of trust.” The whole point of the DSCSA law and the Florida pedigree law that the DSCSA preempted was that a web of trust and paper pedigrees are insufficient to assure patient safety.

Find a manufacturer that manufactures the same drug product for the American and Canadian markets. Purchase the Canadian product and relabel to add the original manufacturer’s serialized code at the time of relabeling.

An entity is only allowed to label drug product with the labeling codes issued to it by the FDA. This would be a gross compliance violation of the entity involved, as well as fail to provide assurance that no other entity handled the drug product because it could not be traced back to the manufacturer.

The diagrams below show two examples of how Track-and-Trace works, and how it would leave a large portion of the supply chain unprotected under Florida’s Canadian importation law.

Conclusion

Legislative sponsors of HB19 promised that Canadian importation would be cheap, safe, and easy. It is unlikely to be any of these things.

Closed, Secure U.S. Drug Supply Chain

An FDA-regulated manufacturer produces the drug product and affixes a serialized tracking label.



One or more licensed wholesalers and logistics providers buy, sell, and transport the drug product, recording their step in the chain of custody along the way.



The chain of custody records every entity who touched the medicine, and can be confirmed along the entire chain of custody.

The Florida Board of Pharmacy licensed pharmacy dispenses the medication. They can confirm every entity that handled it and their licensing all the way back to the original manufacturer.



Insecure Florida/Canada Drug Supply Chain

A manufacturer produces a product, not originally intended for the American market. It does not affix a serialized barcode to the product.



An unknown number of foreign wholesale and logistics entities in Canada and elsewhere, who cannot be regulated in the state of Florida, buy, sell, and transport the drug product and deliver it to an FDA-regulated labeller who puts U.S.-compliant drug labels and a serialization barcode on it.



All these entities along this chain are unregulated. They won't have a significant corporate presence, staff, or assets in the U.S.

Furthermore we have no way to verify their handling of drug product except paper pedigree which we saw, from Florida in the 2000's, is easy to forge.

Drug product enters U.S. supply.

A U.S.-regulated repackager/relabeler affixes product labels, packaging, and serialization codes to the drug product.



A number of Florida-licensed and regulated entities buy, sell, and transport the drug product.



The Florida Board of Pharmacy licensed pharmacy dispenses the medication. They can only confirm ownership and safety back to the labeller. The foreign entities before the labeller are on the "honor system".



The chain of custody can only be confirmed within the entities licensed in the U.S., no farther.

This is not "Track and Trace".