COLORADO
Department of Health Care Policy & Financing

Appendices

Colorado's Drug Importation Program - Draft Application

COLORADO
Department of Health Care Policy & Financing
1570 Grant Street
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BY ELECTRONIC FILING (via www.regulations.gov)

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Notice of Proposed Rulemaking, Importation of Prescription Drugs, Docket No. FDA-2019-N-5711, 84 Fed. Reg. 70,796

RE: Importation of Prescription Drugs (Docket No. FDA-2019-N-5711)

Dear Sir or Madam,

Thank you for your request for comments on the Food and Drug Administration's (FDA) Importation of Prescription Drugs Notice of Proposed Rulemaking (the NPRM or proposed rule). The Colorado Department of Health Care Policy & Financing (the Department) is pleased to provide official comment.

The Department appreciates the swift progress on the development of a federal framework for the importation of prescription drugs from Canada. The proposed rule provides a strong foundation and aligns well in many respects with Colorado's draft concept for a successful importation program. However, there are aspects of the proposed rule that would significantly inhibit successful implementation of an importation program. Should the final rule not address these areas of concern, Colorado will struggle to find appropriate partners and realize significant savings for consumers.

The Department is pleased to submit, along with these comments, our draft application for a Section 804 Importation Program (SIP). This draft application is in full compliance with Section 804 of the Food, Drug and Cosmetic Act (FDCA) and addresses many of the provisions outlined in the FDA's Notice of Proposed Rulemaking (NRPM) on Importation of Prescription Drugs. However, certain provisions of the NPRM cannot be addressed in the draft SIP, including the names and contact information of partners including Foreign Seller, Importer, and Repackager/Relabeler and relevant background information as well as specific drug

information including DIN (drug identification number), name and address of NDA (new drug application) or ANDA (abbreviated new drug application) owner, name and address of manufacturer, drug labeling details, etc. These required elements will be included with our final SIP once these draft regulations are made final.

We hope that this draft SIP informs the next steps in the rulemaking process by providing more explicit reasoning for our comments, which aim to improve our ability to maximize consumer savings while ensuring design efficiency, and drug safety. The Colorado draft SIP works to extend the documentation requirements of the Drug Supply Chain Security Act (DSCSA) into the foreign supply chain, incorporate the testing requirements of FDCA Section 804, and includes related audit components. As a result, drugs imported under our SIP, if approved, would be subject to greater regulatory and safety oversight than prescription drugs imported every day by drug companies under the FDA's current regulatory importation program.

To move forward in the implementation of an importation program, we are seeking changes to the NPRM to enhance our ability to successfully implement a SIP to achieve significant cost savings while preserving the safety of the supply chain as required by federal statute. While we have included extensive comments in this letter to address these issues, the Department's priorities for Final Rulemaking include:

- **The final rule should not limit SIP Sponsorship to the state agency or "entity that regulates wholesale drug distribution and/or the practice of pharmacy." Such a limitation would conflict with many state legislative mandates for SIPs, including Colorado's.** We urge HHS and the FDA to issue a Final Rule altering the definition of SIP sponsor to allow for state flexibility to recognize the entity in the state with the appropriate expertise, capability, and capacity to undertake the authority, as well as an ability to collaborate with the entity within the state that regulates wholesale drug distribution and/or the practice of pharmacy.

- **We hope the final rule allows the FDA to conditionally approve SIPs that do not initially specify the Importer(s), Foreign Seller(s), relabeler(s), and repackager(s).** Our preliminary efforts to evaluate partnerships have found that Colorado will struggle to enter into agreements with potential partners as required in the NPRM without some conditional approval of our SIP. The rule should allow the FDA to conditionally approve SIPs and later fully approve the SIP when partner information is provided.

- **The final rule should allow the FDA to approve SIP Proposals that include multiple Foreign Sellers in Canada, both horizontally and vertically.** Limiting SIPs to one Foreign Seller,would allow drug manufacturers to limit sales to the one Foreign Seller specified in a SIP, effectively penalizing them for participating in the program and preventing the SIP from demonstrating to the FDA that they can consistently and

successfully import prescription drugs. Given the purpose of the rule is to realize savings for consumers, it is critical that the rule be modified. Specifically, Colorado has conducted an initial cost savings estimate finding that our program could achieve as much as $36-60 million in savings per year. However, this would require us to partner with multiple Foreign Sellers, in order to import the appropriate prescriptions utilized by Coloradans. If the Final Rule limits our ability to work with multiple entities, our efforts to achieve significant cost savings, as required by Section 804, will be severely limited.

- **The final rule should not automatically terminate SIPs after two years if not proactively extended by the FDA. This sets up SIPs to fail by discouraging investment and participation in the SIP by potential partners.** Colorado has already invested significant time and resources in developing its draft SIP and will continue to do so with stakeholder engagement and partnership development. An automatic program termination not only has the potential to drain state administrative resources without the appropriate return for Colorado, it also threatens our ability to identify and secure partnerships with Foreign Sellers and Importers in developing a final SIP.

While we urge the Administration to make the above outlined issues a priority in final rulemaking, we are also suggesting other significant changes to the NRPM, without which Colorado will be unsuccessful in implementing its SIP. Detailed comments on all of our priorities for final rulemaking are outlined below.

A. State agency SIP Sponsors should not be limited to the state agency that regulates wholesale drug distribution and/or the practice of pharmacy in the state. Such a limitation would conflict with state legislative mandates for SIPs and would be otherwise impractical.

In order to implement a SIP, the proposed rule requires (under both Option 1 and Option 2) that the SIP Sponsor be "a State … entity that regulates wholesale drug distribution and/or the practice of pharmacy" (see the definition of "SIP Sponsor" in proposed § 251.2). Colorado's authorizing legislation places authority with the Department to administer the program. The Department has an annual prescription drug spend of over $1 billion and has authority over the state's All-Claims-Payer-Database, a Pharmacy Office, pharmacy analysts and the capacity and expertise to assume this authority. In Colorado, as in most states, regulating wholesalers and pharmacies is the responsibility of the state Board of Pharmacy (BoP). Colorado's BoP does not have the capacity to serve as the SIP Sponsor. In fact, as far as we know, no state has designated its BoP to be responsible for designing or implementing the state's SIP because BoPs generally do not have the staffing or resource capacity to operate a SIP. States need flexibility to administer their SIP with state agencies that have the capacity to meet the demands of designing and implementing a robust program that can assure safety of the drugs imported and deliver savings to consumers.

Lead agencies have – and should – work in consultation with their state BoP to design and implement their SIPs. However, requiring that the BoP actually *be* the SIP Sponsor is too restrictive, and is, in many cases, unrealistic and contradicts the reasoned judgement of state governments. The FDA should therefore consider altering the definition of SIP Sponsor in the final rule as follows: "a State, tribal, or territorial governmental entity *that has been duly authorized by the State, tribe, or territory (as applicable) to administer a SIP, and which includes in its application a certification that it has the necessary capacity to administer a SIP and that it will collaborate with the State, tribal, or territorial governmental entity or entities* that regulate wholesale drug distribution and the practice of pharmacy."

B. The final rule should allow the FDA to conditionally approve SIPs that do not initially specify Importer(s), Foreign Seller(s), relabeler(s), and repackager(s). The rule should allow the FDA to later fully approve the SIP when that information is provided. Potential SIP partners are less likely to sign on to participate in a SIP framework that has not been, at least conditionally, approved.

Colorado has conducted extensive stakeholder outreach regarding the development of our importation program. Preliminary findings indicate that potential SIP partners are hesitant to sign on to a SIP and undertake the associated obligations if the SIP has not yet been approved, at least conditionally, by the FDA. To address this concern, we recommend the FDA revise the NPRM to allow a SIP Sponsor to submit, and for the FDA to conditionally approve, a SIP proposal that does not specify the Foreign Sellers(s), Importer(s), and relabelers and (if any) repackagers that will participate. The SIP Sponsor would then identify and enroll the Foreign Sellers(s) and Importer(s), and submit the remaining necessary information to the FDA. Such a change in the Final Rule will allow the Department to move forward to establish initial contracts with Foreign Sellers and Importers without compromising the safety of the program. The revision would also enable Colorado to more thoroughly vet necessary prospective commercial participants. We would further encourage the engagement of the Federal government in partnering with states to facilitate these negotiations and discussions with appropriate Canadian officials.

C. FDA approval of SIP Proposals that include multiple Foreign Sellers in Canada, both horizontally and vertically, will allow for more robust and effective SIPs. Not doing so would allow drug manufacturers to discriminate against the one or few Foreign Supplier(s) specified in SIPs, preventing SIPs from demonstrating to the FDA that they can consistently and successfully import prescription drugs.

As proposed, the rule would require that a SIP can initially only designate a single Foreign Seller and a single U.S. Importer. Under this approach, a single specified Foreign Seller would be expected to purchase all prescription drugs intended for importation directly from manufacturers and directly export those prescription drugs to the Importer in the United

States. Based on the Department's research to determine our SIP's cost savings, we believe that this limitation would make it extremely difficult for Colorado to successfully implement a SIP. It would have a significant negative impact on our ability to import all the prescription drugs intended, thereby impeding our ability to realize "significant cost savings" as required in Section 804, reducing our return on investment on the cost of implementation and oversight of the importation program, and reducing our ability to meet the needs of Coloradans seeking lower prices on prescription drugs.

We urge the FDA to allow multiple Foreign Sellers in a SIP and include revisions to the proposed rule that would institute certain additional safeguards to account for changes in the supply chain. We recommend that a SIP specify multiple established Foreign Sellers in Canada who purchase covered drugs directly from the manufacturers for importation under the SIP, and either export those drugs to the U.S. directly or specify a second Foreign Seller in Canada who would purchase the covered prescription drugs from those Foreign Sellers to consolidate for exportation. This proposed rule change does not pose additional risk to the public's health and safety; the Foreign Seller, who is the importer of the drug to Canada, must import the drug directly from the manufacturer of the drug, and the drug would thereafter feature a unique product identifier.

The FDA should also allow a SIP to propose more than one Importer in the U.S., if justified in the SIP proposal. Such an allowance would not impose any additional risk and would be directly overseen by both the FDA and the state. A SIP Sponsor may want to use more than one U.S. Importer under the SIP for a variety of reasons, such as encouraging price competition between two or more Importers.

The FDA should also permit different SIPs to share Foreign Sellers and Importers. This simple revision would enable States to share in the regulatory burdens, audits, and testing required under their respective SIPs, thereby reducing costs and fees associated with the operation and regulation of the programs.

D. Prohibiting the relabeling (and repackaging activities necessary to perform the relabeling) from being conducted in Canada adds unnecessary cost to SIPs without preventing additional risk, and misses a clear opportunity to engender Canadian support for SIPs.

We believe that requiring relabeling of a drug during the importation process rather than in Canada prior to importation poses a significant obstacle to the success of a Colorado importation program. This requirement will significantly increase costs in the supply chain as well as the costs of the FDA's own administrative activities in managing the program, with no noteworthy increase in safety. Accordingly, we ask that the Final Rule permit relabeling (and any limited repackaging required to relabel the drug) to be conducted by a Foreign Seller (or entity under contract with the Foreign Seller). The entity physically conducting the relabeling (and any limited repackaging) would have to be registered as a repackager or

relabeler with the FDA (as is already required under FDA regulations) and would be subject to all FDCA requirements for repackagers and relabelers (e.g., DSCSA obligations and allowing FDA inspections). Further, allowing relabeling to occur in Canada has the potential to engender Canadian support for the Section 804 Importation Program by providing economic opportunities for Canadian relabelers and repackagers. Moreover, in addition to being subject to all applicable FDCA and DSCSA requirements, the repackager or relabeler in Canada would be, as they are today, registered with and regulated by Health Canada.

The proposed rule also appears to require that the relabeling of all drugs imported under a SIP be conducted at a secure warehouse within 30 miles of the authorized port (or, presumably, within the physical confines of the FTZ) (see proposed § 251.17(b), requiring that the covered drugs remain at a secured warehouse from the time they arrive in the U.S. until the FDA issues an admissibility decision). This is highly impractical, would add an unnecessary expense, would upset warehouse storage availability and rates along the border near the ports used for SIPs, and would seriously complicate the FDA's own administrative implementation of the program.

As we note above, the FDA already regulates prescription drug relabelers (and repackagers), as does Health Canada. Much of the drugs imported by drug companies are in bulk, lacking finished packaging and labeling. Drug repackaging and relabeling services are routinely contracted out by drug manufacturers and these operations occur in the U.S. and abroad. The FDA's existing regulatory regime already contemplates repackaging and relabeling of FDA-approved drugs in foreign jurisdictions by third-parties. The recommendation to permit relabeling and repackaging in Canada is consistent with the FDA's current regulatory framework, will keep the costs of drugs imported under a SIP low, and allows for evaluation by the FDA, by Health Canada, or even by the participating states using accredited third-party inspection services.

E. Allowing statutory testing to occur after relabeling, or alternatively, allowing sampling for statutory testing to occur in Canada instead of in the U.S., will result in more viable, efficient, and effective SIPs while not imposing any additional safety risk. Doing so, for example, would allow relabeling of covered drugs to be conducted by qualified Canadian relabeling operations, which would lower relabeling costs for SIPs without undermining quality, and would engender Canadian support for the program.

While the Department acknowledges that statutory testing in the U.S. is required by Section 804, this does not mean that relabeling (and any necessary limited repackaging) must also occur during the course of importation in the U.S. As we note above, prohibiting the relabeling and repackaging from being conducted in Canada misses a key opportunity to engender Canadian support for SIPs without imposing additional risk to Coloradans. By providing opportunities for key activities in the supply chain to occur in Canada, we can

provide financial benefits to the country while also ensuring the safety of imported drugs and limiting unnecessary expenses to SIPs.

To address any concerns regarding failed tests of relabeled drugs, the FDA could require, as a condition of approval of a SIP, that if the FDA tests and/or detains any drug imported under a SIP and the drug fails authenticity or degradation testing or is otherwise determined to not meet the requirements of the FDCA or SIP, then the drugs (if they cannot be reconditioned e.g., via segregation) must be destroyed or be permanently relabeled to show they have failed statutory testing.

Alternatively, relabeling (and any necessary limited repackaging) could still be required to be conducted in Canada after statutory testing if the sampling for statutory testing is permitted to occur in Canada. The FDA could allow importation of the samples for testing purposes and the samples could be destroyed after statutory testing. The FDA's proposed requirement for sampling and relabeling to all occur after the product physically arrives in the U.S. but before the drug is officially admitted into the U.S. sets up an importation regime that is more cumbersome, more burdensome, and more expensive for the FDA to implement. The FDA's proposal also significantly increases federal agencies' and states' costs of implementing Section 804 with no added safety benefit.

F. A blanket prohibition against allowing a SIP to propose, and for the FDA to consider, the importation and repackaging of specified bulk eligible prescription drugs under a SIP will eliminate opportunities to deliver additional savings to U.S. consumers at no additional risk.

It is not uncommon for prescription drugs to be purchased and imported directly into Canada in bulk from the manufacturer; however, under the proposed rule, a SIP could not provide for a Foreign Seller to purchase an eligible prescription drug in bulk. Rather, the Foreign Seller could only purchase the drug after it has been packaged and labeled for the Canadian market. This restriction creates inefficiencies because these labeled drugs would be more expensive to purchase and would have to be stripped of their original Canadian packaging and/or labeling before being relabeled (with any limited repackaging) for the U.S. market.

The Department does not see a reason for a blanket prohibition against bulk purchasing by FDCA-compliant repackagers with positive FDA inspection histories that are also subject to Canadian inspection and stringent common good manufacturing practices (cGMPs). Further, the testing requirements of Section 804 and the proposed rule add additional safeguards for preventing and detecting any degradation. Because repackagers in Canada would be obligated under a SIP to follow cGMPs and are fully qualified to repackage bulk drugs, there's no valid basis to be concerned that repackaging in Canada prior to export would be any more likely to introduce adulterants or to degrade the drug than if the bulk tablets were imported by the drug manufacturer and repackaged in the U.S.

Many drugs imported today by drug manufacturers are imported in bulk and are subjected to contract third-party repackaging and labeling. Many of the drugs imported today in finished packaging were repackaged and relabeled by third-party contract operators abroad. There is no reason to believe that repackaging (and relabeling) in Canada of bulk tablets of a covered drug, after testing, would introduce risk of adulteration or degradation that would not similarly be present when drug manufacturers act as the importer of record. The FDA's regulatory framework is designed to manage bulk drug repackaging and labeling and does so adequately. We recommend applying the existing framework rather than attempting to create a new and different drug importation regulatory system.

G. If the FDA is to require laboratories that conduct statutory testing under a SIP to have an FDA inspection history, the FDA should first demonstrate that a significant number of such laboratories exist throughout the United States. The FDA typically does not inspect independent drug testing laboratories. If few laboratories in the United States meet this requirement, states' ability to find appropriate laboratory partners will be significantly limited and will make successful implementation of a SIP very difficult.

Because of the wide variety of tests that will likely need to be validated and conducted under SIPs, it will be important to have a wide range of laboratories eligible to be Qualified Laboratories. The NPRM proposal to require laboratories that conduct statutory testing under a SIP to have an FDA inspection history could severely limit the laboratories that could conduct statutory testing under a SIP. That, in turn, would significantly increase costs and cause delays for drugs being imported under a SIP. Further, without a wide range of laboratories to partner with, SIPs will be set up to fail.

Imposing this requirement may be an implacable barrier to the successful implementation of Section 804 and state level importation programs. If there *is not* a significant number of such laboratories throughout the U.S. already, that number would not change. A laboratory could not conduct statutory testing without an FDA inspection history, but the FDA would not inspect the laboratory unless it is conducting statutory testing. We do support the FDA's requirement that laboratories conducting statutory testing under Section 804 be accredited to ISO/IEC 17025.

H. Requiring the SIP Sponsor to suspend the entire SIP if they determine any aspect of the SIP does not meet an applicable requirement of the FDCA, FDA regulations, or SIP is unduly burdensome and overbroad. SIP Sponsors should be allowed to tailor their corrective actions to the identified problem.

Proposed § 251.18(a) provides that if at any point a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, Qualifying Laboratory, or other participant in, or element of, the supply chain in the authorized SIP does not in fact meet all applicable requirements of the FDCA, FDA regulations, and the authorized SIP, the SIP Sponsor must immediately stop importation of all drugs under the SIP. This provision is overly broad and is

likely unenforceable because of its vagueness. For example, under this provision a SIP Sponsor's discovery that a single drug capsule is degraded would require the SIP Sponsor to suspend all importation under the SIP, of all drugs and across all supply chains, for some unspecified period of time.

We recommend this provision instead provide that if at any point a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, Qualifying Laboratory, or other participant in or element of a supply chain in the authorized SIP does not in fact meet all applicable requirements of the FDCA, FDA regulations, and the authorized SIP, such that the safety of drugs imported through that supply chain may be adversely affected, the SIP Sponsor must immediately stop importation under the SIP of all drugs so affected by the failure. Under our proposed revision, a SIP Sponsor could, for example, limit the suspension of importation to specific implicated supply chains. Further, the SIP Sponsor would still be required under the rule to notify the FDA and demonstrate to the FDA that importation has in fact been stopped. Under such circumstances it would be illogical for a SIP Sponsor to risk their entire SIP by implementing an inappropriately narrow importation cessation.

Additionally, proposed § 251.18(a) appears to be incomplete because it does not specify under what conditions importation can restart. We recommend this provision specify that the SIP Sponsor may restart the importation when the SIP has reviewed, documented and verified that all such participants and elements of the supply chain in the authorized SIP meet the all applicable requirements of the FDCA, FDA regulations, and the authorized SIP.

I. Categorically excluding drugs subject to Risk Evaluation and Mitigation Strategies (REMS) from being eligible for importation under a SIP ignores the fact that REMS vary widely in their requirements. Many REMS could be implemented effectively under a SIP with no additional risk, thereby providing U.S. consumers with a lower cost drug that the FDA would have otherwise categorically prohibited from importation under a SIP.

Proposed 21 CFR § 251.2 provides that a drug subject to a Risk Evaluation and Mitigation Strategy (REMS) (under Section 505-1 of the FDCA) cannot be imported under a SIP. This would be unnecessary and an unduly burdensome categorical prohibition, as REMS vary widely in their requirements and some could be implemented effectively for a drug imported under a SIP. Many safety concerns addressed by REMS are a function of the drug, not its source or its supply chain. Instead of imposing a blanket prohibition on the importation of drugs subject to REMS, the FDA should determine on a case-by-case basis whether importation of a specific drug subject to a REMS would impose an additional risk to the public's health and safety simply because it would be imported under a SIP. Additionally, many aspects of REMS are implemented at the pharmacy level, and there is no reason to believe a pharmacy would not comply with a REMS just because the drug was imported under a SIP. The process would be agnostic to importation.

J. Default termination of SIPs after two years if not proactively extended by the FDA would set SIPs up to fail by discouraging investment and participation in the SIP.

Proposed § 251.6(2)(a) states that, "unless an extension is granted under this section, authorization for a SIP automatically terminates after 2 years, or a shorter period of time if a shorter period of time is specified in the authorization for the SIP." Proposed § 251.8(e) further provides that the FDA may refuse to grant an extension of the authorization period for a SIP "in its sole discretion." Both of these provisions are unnecessary and would mean that a SIP would terminate in the face of inaction by the FDA. Section 804 and the proposed rule provide the FDA with substantial authorities and tools to assess, monitor, and suspend or terminate a SIP for actual cause at any time. Required default termination of a SIP after two years for no reason other than the FDA's inaction is unreasonable. Although we can see justification for the FDA to require SIP Sponsors to recertify their SIP at some frequency (perhaps every five years), the continuation of the SIP should be presumed unless proactively terminated by the FDA or the SIP Sponsor. Colorado has invested significant time and resources in developing its draft SIP and is concerned that if a program is established just to be discontinued that all of our efforts to bring cost savings to consumers will have been for nothing.

K. The final rule should rely as little as possible on requiring manufacturers to take certain actions and make certain disclosures. Manufacturers are likely to fight these requirements in order to delay implementation of any program that will introduce competition into the U.S. market. The rule should primarily rely on other measures where possible to achieve the same aims.

We recommend the final rule rely as little as possible on mandating drug manufacturers take certain actions and make certain disclosures to SIP participants. In this regard, the proposed rule goes beyond what is required by Section 804 of the FDCA. For example, the proposed rule would require manufacturers to attest that drugs to be imported under a SIP meet all of the requirements of their approved NDA or ANDA, to confirm the manufacture dates of all drugs that will be imported under a SIP, and to provide the U.S. Importer with documentation of the manufacturer's sale of the drug to the Canadian Foreign Supplier. We expect manufacturers will strongly resist such requirements.

We recommend that if the manufacturer has not transmitted a required attestation to the U.S. Importer in a timely fashion, and if such information is available to the FDA, the FDA may transmit information that is necessary for the SIP Sponsor and U.S. Importer to confirm, subject to the FDA's review and verification, whether the drug meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing.

L. The final rule should not include duplicative Adverse Event and ICSR Reporting Requirements and Recall Requirements. Further, it would be inappropriate to establish a novel "medication error" reporting requirement only for SIPs.

1. Duplicative and Ineffective Adverse Event and ICSR Reporting Requirements

Many of the post-importation adverse event, "medication error," and Individual Case Safety Reports (ICSR) reporting requirements in the NPRM unnecessarily duplicate existing adverse event and ICSR reporting requirements or are otherwise inappropriate methods of monitoring and addressing any issues related to supply chains. Such activities will lead to unnecessary costs imposed on SIPs, without additional benefit.

First, we note that requiring SIP participants to submit adverse event reports to identify and address adverse events that were or may have been caused by SIP participants, is an inefficient and ineffective approach to monitoring and researching adverse events. The intent and function of adverse event reporting requirements for drugs, as long recognized by both the FDA and industry, is to "offer further insight into the benefits and risks of the product" and allow for the evaluation of that information "to ensure the safe use of these products".[1] The benefits and risks of the product are wholly related to a drug's development, manufacturing, and the content of the product's approved labeling, not the products' supply chain. SIP participants (e.g., wholesale distributors, importers, and pharmacies) have no control over the development, manufacturing, and the labeling content of drugs.

Second, we are concerned that proposed § 251.18(d) appears to impose the broad and vague requirement that Importers must submit reports of "all adverse events and medication errors associated with the use of their drug products imported under [a SIP]". This would essentially be an impossible requirement, as it assumes the Importer either be omniscient or establish an extremely burdensome reporting requirement framework for all actors in the SIP and in the state (including physicians and patients) who interact with drugs imported under the SIP.

Third, we are concerned that the proposed requirement at § 251.18 to require, in pertinent part, SIP Importers to submit adverse event reports, ICSRs, and field alert reports, to both the FDA and the NDA or ANDA holder, would lead to confusion through excess and duplicative reports and will impose undue costs. FDA regulations already require the NDA or ANDA holder to submit adverse event reports and ICSRs to the FDA and already require the manufacturer, packer, and/or distributor specified on the label to submit to adverse event reports and ICSRs to the FDA, either directly or through the NDA or ANDA holder.

[1] Final Rule: "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements", 79 Fed. Reg. 33072 (June 10, 2014).

Serious adverse events reports and ICSRs are required to specify the drug's National Drug Code (NDC) number (see 21 CFR § 329.100(b)), which would clearly identify the drug as having been imported under a SIP. Further, the labels of all drugs imported under a SIP would feature the proposed statement that the drug was imported under a specific SIP, so any adverse event reports are likely to specify that the drug was imported under a specific SIP (as the FDA recognizes at 84 Fed. Reg. at 70820).

Further, the label or labeling of all drugs imported under a SIP, in accordance with 21 CFR § 209.2, will feature a phone number that consumers can use to report any perceived drug side effects to the FDA. The FDA also provides an easy-to-use portal that health professionals, consumers, and patients can use to voluntarily report observed or suspected adverse drug events. A SIP Sponsor could commit to publicizing this portal as part of its SIP outreach efforts to pharmacists, healthcare providers, and patients.

2. It would be inappropriate to require only SIPs to comply with a novel "medication error" reporting requirement.

The FDA proposes at § 251.18(d) that SIP Importers must submit "medication error" reports to the FDA and importers. The proposed rule at § 251.2 would define "medication errors" as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of a healthcare professional, patient, or consumer" and further provides that the "medication error may or may not result in an adverse event."

There is currently no legal requirement for any entities to report "medication errors" that do not result in an adverse event (as would be required by proposed §§ 251.2 and 251.18(d)). The FDA's proposed definition of a medication error is incredibly broad, would impose undue burdens with little upside, and would encroach into regulation of the practice of medicine.

Further, requiring only SIP participants, and not parties outside of SIPs, to report medication errors would be unfair and arbitrary. The FDA is currently working on revising and re-proposing its 2003 medication error reporting rule, which will address many of the same definitions and standards.[2] If the FDA can establish a comprehensive regulation for reporting medication errors, via that rulemaking, the FDA could apply such requirements in a fair manner to SIP and non-SIP participants alike.

3. Duplicative recall requirements.

We also have concerns that some of the proposed requirements regarding recalls are unnecessarily duplicative.

[2] See the Fall, 2019 Unified Agenda, RIN 0910-AA97, "Safety Reporting Requirements for Human Drug and Biological Products".

First, proposed § 251.18(e) would require the SIP Sponsor to monitor the FDA's recall website for recall or market withdrawal information relevant to the drugs imported under the SIP, with seemingly no allowance for the State to delegate this task to the Importer(s), who will typically already have systems and infrastructure in place to conduct this monitoring (and who would likely already be conducting this monitoring already anyway). Moreover, parties other than the SIP Sponsor (e.g., such as the Importer) are in a better position to immediately recall products in response to a recall announcement. We recommend proposed § 251.18(e) be revised by deleting the phrase "they must also", which would allow for delegation of the monitoring task in accordance with an established procedure. This procedure would be provided to the FDA with the SIP proposal.

Second, the FDA should clarify in the final rule the extent to which the FDA expects to take on a secondary recall coordination role to a primary recall coordination role of the state agency SIP Sponsor. We suspect the FDA will almost always insist on serving as the primary recall coordinator for a recall under a SIP (as the FDA does for most recalls), in which case the proposed recall provisions in proposed § 251.18(e), as currently written, would likely lead to unnecessary duplication and potentially conflicting efforts by the SIP Sponsor and the FDA.

M. The severability provision is too broad, and risks the entire rule being thrown out on a technicality. It should be tailored to specifically address the FDA's underlying concerns.

The NPRM provides that if any provision of the rule is stayed or determined to be invalid, the remaining provisions shall not continue in effect. We propose the severability provision be tailored to reflect the underlying reason for it. For example, proposed 21 CFR § 251.20 would be more appropriately revised to: "If any provision of this part is stayed or determined to be invalid, and the stay or invalidation would cause the rule as a whole to no longer adequately protect public health, the remaining provisions shall not continue in effect."

N. Comments on how to estimate savings under a SIP.

The FDA requested comments on "the factors that should be considered in determining whether a reduction in the cost of covered products is significant". The NPRM mentions the potential approach of comparing the per unit acquisition costs of drugs to be imported from Canada versus the per unit U.S. acquisition costs, in order to establish savings. Although comparing such acquisition costs would provide information about the overall cost differentials between the U.S. and Canadian markets, it would not provide an accurate assessment of savings because states have to account for administrative and supply chain

costs necessary to implement a SIP. In order to do so, SIP proposals should estimate a reasonable mark-up on top of Canadian acquisition costs to more accurately calculate savings after mark-up costs, and how savings would be passed through to consumers. Colorado's draft SIP relies on a markup of 45 percent for supply chain costs such as repackaging, relabeling, and testing. This standard has been recommended by NASHP and other states advancing Canadian drug importation programs.

Thank you again for releasing the prescription drug importation NPRM. We appreciate the great effort of the Administration to advance Section 804 and urge the FDA to make the necessary revisions to the proposed rule to ensure that Colorado can successfully implement its SIP to achieve a significant reduction in the cost of prescription drugs while posing no additional risk to the health and safety of Coloradans. We look forward to continued engagement with the Administration, HHS, and the FDA on this rule.

Sincerely,

Kim Bimestefer
Executive Director
Department of Health Care Policy & Financing

Enclosure(s)
Colorado's Draft Section 804 Importation (SIP) Program Application for a State Importation Program

SENATE BILL 19-005

BY SENATOR(S) Rodriguez and Ginal, Bridges, Crowder, Danielson, Donovan, Fields, Foote, Gonzales, Lee, Pettersen, Story, Todd, Garcia; also REPRESENTATIVE(S) Jaquez Lewis, Bird, Buckner, Buentello, Caraveo, Cutter, Esgar, Froelich, Galindo, Gonzales-Gutierrez, Gray, Hansen, Herod, Hooton, Jackson, Kennedy, Kipp, Lontine, McCluskie, Melton, Michaelson Jenet, Mullica, Singer, Sirota, Snyder, Sullivan, Tipper, Titone, Valdez A.

CONCERNING WHOLESALE IMPORTATION OF PRESCRIPTION PHARMACEUTICAL PRODUCTS FROM CANADA FOR RESALE TO COLORADO RESIDENTS, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) United States consumers pay some of the highest prescription drug prices in the world, and it is estimated that United States consumers pay twice as much as the amount Canadian consumers pay for patented prescription drugs and twenty percent more for generic drugs;

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(b) Federal law, as codified in 21 U.S.C. sec. 384, authorizes the secretary of the United States department of health and human services to allow wholesale importation of prescription drugs from Canada if such importation is shown to be both safe and less costly for United States consumers;

(c) Although importing prescription drugs would be less costly, there may be risks posed to consumer health and safety if the source, quality, and purity of prescription drugs sold by online pharmacies cannot be verified;

(d) Canada has a rigorous regulatory system to license prescription drugs, equivalent to the licensing system in the United States;

(e) In the United States, Title II of the federal "Drug Quality and Security Act", Pub.L. 113-54, referred to as the "Drug Supply Chain Security Act", has significantly improved drug security and safety through a system of pharmaceutical product track-and-trace procedures; and

(f) A wholesale drug importation program for the exclusive benefit of Colorado residents should be designed and implemented to provide Colorado consumers access to safe and less expensive prescription drugs.

SECTION 2. In Colorado Revised Statutes, 25.5-1-201, **amend** (1) introductory portion, (1)(f), and (1)(g); and **add** (1)(h) as follows:

25.5-1-201. Programs to be administered by the department of health care policy and financing. (1) ~~Programs to be administered and functions to be performed by~~ The department of health care policy and financing shall ~~be as follows~~ ADMINISTER THE FOLLOWING PROGRAMS AND PERFORM THE FOLLOWING FUNCTIONS:

(f) The old age pension health and medical care program, as specified in section 25.5-2-101; ~~and~~

(g) Programs, services, and supports for persons with intellectual and developmental disabilities, as specified in article 10 of this ~~title~~ TITLE 25.5; AND

(h) ANY PROGRAM CONCERNING THE WHOLESALE IMPORTATION OF PRESCRIPTION DRUGS PURSUANT TO PART 2 OF ARTICLE 2.5 OF THIS TITLE 25.5.

SECTION 3. In Colorado Revised Statutes, **add** part 2 to article 2.5 of title 25.5 as follows:

PART 2
CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

25.5-2.5-201. Short title. THE SHORT TITLE OF THIS PART 2 IS THE "DR. IRENE AGUILAR CANADIAN PRESCRIPTION DRUG IMPORTATION ACT".

25.5-2.5-202. Definitions. AS USED IN THIS PART 2, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "CANADIAN SUPPLIER" MEANS A MANUFACTURER, WHOLESALE DISTRIBUTOR, OR PHARMACY THAT IS APPROPRIATELY LICENSED OR PERMITTED UNDER CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS TO MANUFACTURE, DISTRIBUTE, OR DISPENSE PRESCRIPTION DRUGS.

(2) "ELIGIBLE IMPORTER" MEANS AN IMPORTER THAT IS DESCRIBED IN SECTION 25.5-2.5-204 (3).

(3) "FEDERAL ACT" MEANS THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT", 21 U.S.C. SEC. 301 ET SEQ.

(4) "MEDICAID PHARMACY" MEANS A PHARMACY REGISTERED PURSUANT TO SECTION 12-42.5-117 THAT HAS A PROVIDER AGREEMENT IN EFFECT WITH THE STATE DEPARTMENT AND IS IN GOOD STANDING WITH THE STATE DEPARTMENT.

(5) "PHARMACIST" MEANS A PERSON WHO HOLDS AN ACTIVE AND UNENCUMBERED LICENSE TO PRACTICE PHARMACY PURSUANT TO SECTION 12-42.5-112.

(6) "PRESCRIPTION DRUG" HAS THE SAME MEANING SET FORTH IN SECTION 12-42.5-102 (34); EXCEPT THAT THE TERM INCLUDES ONLY DRUGS

THAT ARE INTENDED FOR HUMAN USE.

(7) "PROGRAM" MEANS THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM CREATED IN SECTION 25.5-2.5-203.

(8) "VENDOR" MEANS A VENDOR WITH WHICH THE STATE DEPARTMENT CONTRACTS FOR THE PROVISION OF SERVICES UNDER THE PROGRAM PURSUANT TO SECTION 25.5-2.5-203 (1).

25.5-2.5-203. Canadian prescription drug importation program - created - importation process - contract with vendor - vendor duties. (1) THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM IS CREATED IN THE STATE DEPARTMENT. UPON RECEIVING APPROVAL OF THE PROGRAM AS DESCRIBED IN SECTION 25.5-2.5-205 (1), THE STATE DEPARTMENT SHALL CONTRACT WITH ONE OR MORE VENDORS TO PROVIDE SERVICES UNDER THE PROGRAM. FOR THREE YEARS FOLLOWING THE EFFECTIVE DATE OF THIS PART 2, THE SELECTION OF ANY VENDOR PURSUANT TO THIS SUBSECTION (1) IS EXEMPT FROM THE REQUIREMENTS OF THE PROCUREMENT CODE, ARTICLES 101 TO 112 OF TITLE 24.

(2) (a) EACH VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT AND ANY OTHER VENDORS, SHALL ESTABLISH A WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST THAT IDENTIFIES THE PRESCRIPTION DRUGS THAT HAVE THE HIGHEST POTENTIAL FOR COST SAVINGS TO THE STATE. IN DEVELOPING THE LIST, EACH VENDOR SHALL CONSIDER, AT A MINIMUM, WHICH PRESCRIPTION DRUGS WILL PROVIDE THE GREATEST COST SAVINGS TO THE STATE, INCLUDING PRESCRIPTION DRUGS FOR WHICH THERE ARE SHORTAGES, SPECIALTY PRESCRIPTION DRUGS, AND HIGH-VOLUME PRESCRIPTION DRUGS. EACH VENDOR SHALL REVISE THE LIST AT LEAST ANNUALLY AND AT THE DIRECTION OF THE STATE DEPARTMENT PURSUANT TO SUBSECTION (2)(b) OF THIS SECTION.

(b) THE STATE DEPARTMENT SHALL REVIEW THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST AT LEAST EVERY THREE MONTHS TO ENSURE THAT IT CONTINUES TO MEET THE REQUIREMENTS OF THE PROGRAM. THE STATE DEPARTMENT MAY DIRECT A VENDOR TO REVISE THE LIST, AS NECESSARY.

(c) EACH VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT, SHALL IDENTIFY CANADIAN SUPPLIERS WHO ARE IN FULL COMPLIANCE WITH

RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS AND WHO HAVE AGREED TO EXPORT PRESCRIPTION DRUGS IDENTIFIED ON THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST. EACH VENDOR SHALL VERIFY THAT SUCH CANADIAN SUPPLIERS MEET ALL OF THE REQUIREMENTS OF THE PROGRAM AND WILL EXPORT PRESCRIPTION DRUGS AT PRICES THAT WILL PROVIDE COST SAVINGS TO THE STATE. EACH VENDOR SHALL CONTRACT WITH SUCH ELIGIBLE CANADIAN SUPPLIERS, OR FACILITATE CONTRACTS BETWEEN ELIGIBLE IMPORTERS AND CANADIAN SUPPLIERS, TO IMPORT PRESCRIPTION DRUGS UNDER THE PROGRAM.

(d) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT IN DEVELOPING AND ADMINISTERING A DISTRIBUTION PROGRAM WITHIN THE PROGRAM.

(e) EACH VENDOR SHALL ASSIST THE STATE DEPARTMENT WITH THE ANNUAL REPORT DESCRIBED IN SECTION 25.5-2.5-206 AND PROVIDE ANY INFORMATION REQUESTED BY THE STATE DEPARTMENT FOR THE REPORT.

(f) EACH VENDOR SHALL ENSURE THE SAFETY AND QUALITY OF DRUGS IMPORTED UNDER THE PROGRAM, AS FOLLOWS:

(I) (A) FOR AN INITIAL IMPORTED SHIPMENT, ENSURE THAT EACH BATCH OF THE DRUG IN THE SHIPMENT IS STATISTICALLY SAMPLED AND TESTED FOR AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE FEDERAL ACT; AND

(B) FOR ANY SUBSEQUENT IMPORTED SHIPMENT, ENSURE THAT A STATISTICALLY VALID SAMPLE OF THE SHIPMENT IS TESTED FOR AUTHENTICITY AND DEGRADATION IN A MANNER CONSISTENT WITH THE FEDERAL ACT.

(II) CERTIFY THAT EACH DRUG:

(A) IS APPROVED FOR MARKETING IN THE UNITED STATES AND IS NOT ADULTERATED OR MISBRANDED; AND

(B) MEETS ALL OF THE LABELING REQUIREMENTS UNDER 21 U.S.C. SEC. 352.

(III) MAINTAIN QUALIFIED LABORATORY RECORDS, INCLUDING

COMPLETE DATA DERIVED FROM ALL TESTS NECESSARY TO ENSURE THAT THE DRUG IS IN COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION; AND

(IV) MAINTAIN DOCUMENTATION DEMONSTRATING THAT THE TESTING REQUIRED BY THIS SECTION WAS CONDUCTED AT A QUALIFIED LABORATORY IN ACCORDANCE WITH THE FEDERAL ACT AND ANY OTHER APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS GOVERNING LABORATORY QUALIFICATIONS.

(3) ALL TESTING REQUIRED BY THIS SECTION MUST BE CONDUCTED IN A QUALIFIED LABORATORY THAT MEETS THE STANDARDS UNDER THE FEDERAL ACT AND ANY OTHER APPLICABLE FEDERAL AND STATE LAWS AND REGULATIONS GOVERNING LABORATORY QUALIFICATIONS FOR DRUG TESTING.

(4) EACH VENDOR SHALL MAINTAIN A LIST OF ALL ELIGIBLE IMPORTERS THAT PARTICIPATE IN THE PROGRAM.

(5) EACH VENDOR SHALL ENSURE COMPLIANCE WITH TITLE II OF THE FEDERAL "DRUG QUALITY AND SECURITY ACT", PUB.L. 113-54, BY ALL CANADIAN SUPPLIERS, ELIGIBLE IMPORTERS, DISTRIBUTORS, AND OTHER PARTICIPANTS IN THE PROGRAM.

(6) EACH VENDOR SHALL PROVIDE AN ANNUAL FINANCIAL AUDIT OF ITS OPERATIONS TO THE STATE DEPARTMENT. EACH VENDOR SHALL ALSO PROVIDE QUARTERLY FINANCIAL REPORTS SPECIFIC TO THE PROGRAM AND SHALL INCLUDE INFORMATION CONCERNING THE PERFORMANCE OF ITS SUBCONTRACTORS AND VENDORS. THE STATE DEPARTMENT SHALL DETERMINE THE FORMAT AND CONTENTS OF THE REPORTS.

(7) EACH VENDOR SHALL SUBMIT EVIDENCE OF A SURETY BOND WITH ANY BID OR INITIAL CONTRACT NEGOTIATION DOCUMENTS AND SHALL MAINTAIN DOCUMENTATION OF EVIDENCE OF SUCH A BOND WITH THE STATE DEPARTMENT THROUGHOUT THE CONTRACT TERM. THE SURETY BOND MAY BE FROM THIS STATE OR ANY OTHER STATE IN THE UNITED STATES AND MUST BE IN AN AMOUNT OF AT LEAST TWENTY-FIVE THOUSAND DOLLARS. THE SURETY BOND OR COMPARABLE SECURITY ARRANGEMENT MUST INCLUDE THE STATE OF COLORADO AS A BENEFICIARY. IN LIEU OF THE SURETY BOND, A VENDOR MAY PROVIDE A COMPARABLE SECURITY AGREEMENT, SUCH AS AN IRREVOCABLE LETTER OF CREDIT OR A DEPOSIT

INTO A TRUST ACCOUNT OR FINANCIAL INSTITUTION THAT INCLUDES THE STATE OF COLORADO AS A BENEFICIARY, PAYABLE TO THE STATE OF COLORADO. THE PURPOSES OF THE BOND OR OTHER SECURITY ARRANGEMENT ARE TO:

(a) ENSURE PARTICIPATION OF THE VENDOR IN ANY CIVIL OR CRIMINAL LEGAL ACTION BY THE STATE DEPARTMENT, ANY OTHER STATE AGENCY, OR PRIVATE INDIVIDUALS OR ENTITIES AGAINST THE VENDOR BECAUSE OF THE VENDOR'S FAILURE TO PERFORM UNDER THE CONTRACT, INCLUDING BUT NOT LIMITED TO CAUSES OF ACTIONS FOR PERSONAL INJURY, NEGLIGENCE, AND WRONGFUL DEATH;

(b) ENSURE PAYMENT BY THE VENDOR THROUGH THE USE OF A BOND OR OTHER COMPARABLE SECURITY ARRANGEMENT OF ANY LEGAL JUDGMENTS AND CLAIMS THAT ARE AWARDED TO THE STATE, OTHER ENTITIES ACTING ON BEHALF OF THE STATE, INDIVIDUALS, OR ORGANIZATIONS IF THE VENDOR IS ASSESSED A FINAL JUDGMENT OR OTHER MONETARY PENALTY IN A COURT OF LAW FOR A CIVIL OR CRIMINAL ACTION UNDER THE PROGRAM. THE BOND OR COMPARABLE SECURITY ARRANGEMENT MAY BE ACCESSED IF THE VENDOR FAILS TO PAY ANY JUDGMENT OR CLAIM WITHIN SIXTY DAYS AFTER FINAL JUDGMENT.

(c) ALLOW FOR CIVIL AND CRIMINAL LITIGATION CLAIMS TO BE MADE AGAINST THE BOND OR OTHER COMPARABLE SECURITY ARRANGEMENTS FOR UP TO ONE YEAR AFTER THE VENDOR'S CONTRACT UNDER THE PROGRAM HAS ENDED WITH THE STATE DEPARTMENT, THE VENDOR'S LICENSE IS NO LONGER VALID, OR THE PROGRAM HAS ENDED, WHICHEVER OCCURS LAST.

(8) EACH VENDOR SHALL MAINTAIN INFORMATION AND DOCUMENTATION SUBMITTED UNDER THIS SECTION FOR A PERIOD OF AT LEAST SEVEN YEARS.

(9) THE STATE DEPARTMENT MAY REQUIRE EACH VENDOR TO COLLECT ANY OTHER INFORMATION NECESSARY TO ENSURE THE PROTECTION OF THE PUBLIC HEALTH.

25.5-2.5-204. Eligible prescription drugs - eligible Canadian suppliers - eligible importers - distribution requirements. (1) AN ELIGIBLE IMPORTER MAY IMPORT A PRESCRIPTION DRUG FROM A CANADIAN SUPPLIER IF:

(a) THE DRUG THAT IS TO BE IMPORTED MEETS THE FEDERAL FOOD AND DRUG ADMINISTRATION'S STANDARDS RELATED TO SAFETY, EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

(b) IMPORTING THE DRUG WOULD NOT VIOLATE FEDERAL PATENT LAWS;

(c) IMPORTING THE DRUG IS EXPECTED TO GENERATE COST SAVINGS; AND

(d) THE DRUG IS NOT:

(I) A CONTROLLED SUBSTANCE AS DEFINED IN 21 U.S.C. SEC. 802 (6);

(II) A BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC. 262 (i);

(III) AN INFUSED DRUG;

(IV) AN INTRAVENOUSLY INJECTED DRUG;

(V) A DRUG THAT IS INHALED DURING SURGERY; OR

(VI) A DRUG THAT IS A PARENTERAL DRUG, THE IMPORTATION OF WHICH IS DETERMINED BY THE FEDERAL SECRETARY OF HEALTH AND HUMAN SERVICES TO POSE A THREAT TO PUBLIC HEALTH.

(2) A CANADIAN SUPPLIER MAY EXPORT PRESCRIPTION DRUGS INTO THE STATE UNDER THE PROGRAM IF THE SUPPLIER:

(a) IS IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS;

(b) IS IDENTIFIED BY THE VENDOR AS ELIGIBLE TO PARTICIPATE IN THE PROGRAM PURSUANT TO SECTION 25.5-2.5-203 (2)(c); AND

(c) SUBMITS AN ATTESTATION THAT THE SUPPLIER HAS A REGISTERED AGENT IN THE UNITED STATES, WHICH ATTESTATION INCLUDES THE NAME AND UNITED STATES ADDRESS OF THE REGISTERED AGENT.

(3) THE FOLLOWING ENTITIES ARE ELIGIBLE IMPORTERS AND MAY

OBTAIN IMPORTED PRESCRIPTION DRUGS:

(a) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER CONTRACT WITH A MEDICAID PHARMACY, FOR DISPENSING TO THE PHARMACY'S MEDICAID RECIPIENTS;

(b) A PHARMACIST OR WHOLESALER EMPLOYED BY OR UNDER CONTRACT WITH THE DEPARTMENT OF CORRECTIONS, FOR DISPENSING TO INMATES IN THE CUSTODY OF THE DEPARTMENT OF CORRECTIONS;

(c) COMMERCIAL PLANS, AS DEFINED BY RULES PROMULGATED BY THE STATE BOARD AND AS APPROVED BY THE FEDERAL GOVERNMENT; AND

(d) A LICENSED COLORADO PHARMACIST OR WHOLESALER APPROVED BY THE STATE DEPARTMENT.

(4) (a) THE STATE DEPARTMENT SHALL DESIGNATE AN OFFICE OR DIVISION THAT MUST BE A LICENSED PHARMACEUTICAL WHOLESALER OR THAT SHALL CONTRACT WITH A LICENSED PHARMACEUTICAL WHOLESALER LICENSED PURSUANT TO PART 3 OF ARTICLE 42.5 OF TITLE 12.

(b) THE OFFICE OR DIVISION DESIGNATED BY THE STATE DEPARTMENT PURSUANT TO SUBSECTION (4)(a) OF THIS SECTION SHALL:

(I) SET A MAXIMUM PROFIT MARGIN SO THAT A WHOLESALER, DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER PARTICIPATING IN THE PROGRAM MAINTAINS A PROFIT MARGIN THAT IS NO GREATER THAN THE PROFIT MARGIN THAT THE WHOLESALER, DISTRIBUTOR, PHARMACY, OR OTHER LICENSED PROVIDER WOULD HAVE EARNED ON THE EQUIVALENT NONIMPORTED DRUG;

(II) EXCLUDE GENERIC PRODUCTS IF THE IMPORTATION OF THE PRODUCTS WOULD VIOLATE UNITED STATES PATENT LAWS APPLICABLE TO UNITED STATES-BRANDED PRODUCTS;

(III) COMPLY WITH THE REQUIREMENTS OF 21 U.S.C. SEC. 360eee TO 360eee-4 AS ENACTED IN TITLE II OF THE FEDERAL "DRUG QUALITY AND SECURITY ACT"; AND

(IV) DETERMINE A METHOD FOR COVERING THE ADMINISTRATIVE

COSTS OF THE PROGRAM, WHICH METHOD MAY INCLUDE A FEE IMPOSED ON EACH PRESCRIPTION PHARMACEUTICAL PRODUCT SOLD THROUGH THE PROGRAM OR ANY OTHER APPROPRIATE METHOD AS DETERMINED BY THE STATE DEPARTMENT, BUT THE STATE DEPARTMENT SHALL NOT REQUIRE A FEE IN AN AMOUNT THE STATE DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

(5) CANADIAN SUPPLIERS AND ELIGIBLE IMPORTERS PARTICIPATING UNDER THE PROGRAM:

(a) SHALL COMPLY WITH THE TRACKING AND TRACING REQUIREMENTS OF 21 U.S.C. SEC. 360eee ET SEQ.; AND

(b) SHALL NOT DISTRIBUTE, DISPENSE, OR SELL PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM OUTSIDE OF THE STATE.

(6) A PARTICIPATING ELIGIBLE IMPORTER SHALL SUBMIT TO THE VENDOR ALL OF FOLLOWING INFORMATION ABOUT EACH DRUG TO BE ACQUIRED BY THE IMPORTER UNDER THE PROGRAM:

(a) THE NAME AND QUANTITY OF THE ACTIVE INGREDIENT OF THE DRUG;

(b) A DESCRIPTION OF THE DOSAGE FORM OF THE DRUG;

(c) THE DATE ON WHICH THE DRUG IS RECEIVED;

(d) THE QUANTITY OF THE DRUG THAT IS RECEIVED;

(e) THE POINT OF ORIGIN AND DESTINATION OF THE DRUG; AND

(f) THE PRICE PAID BY THE IMPORTER FOR THE DRUG.

(7) A PARTICIPATING CANADIAN SUPPLIER SHALL SUBMIT TO THE VENDOR THE FOLLOWING INFORMATION ABOUT EACH DRUG TO BE SUPPLIED BY THE CANADIAN SUPPLIER UNDER THE PROGRAM:

(a) THE ORIGINAL SOURCE OF THE DRUG, INCLUDING:

(I) THE NAME OF THE MANUFACTURER OF THE DRUG;

(II) THE DATE ON WHICH THE DRUG WAS MANUFACTURED; AND

(III) THE COUNTRY, STATE OR PROVINCE, AND CITY WHERE THE DRUG WAS MANUFACTURED;

(b) THE DATE ON WHICH THE DRUG IS SHIPPED;

(c) THE QUANTITY OF THE DRUG THAT IS SHIPPED;

(d) THE QUANTITY OF EACH LOT OF THE DRUG ORIGINALLY RECEIVED AND THE SOURCE OF THE LOT; AND

(e) THE LOT OR CONTROL NUMBER AND THE BATCH NUMBER ASSIGNED TO THE DRUG BY THE MANUFACTURER.

(8) THE STATE DEPARTMENT SHALL IMMEDIATELY SUSPEND THE IMPORTATION OF A SPECIFIC DRUG OR THE IMPORTATION OF DRUGS BY A SPECIFIC ELIGIBLE IMPORTER IF IT DISCOVERS THAT ANY DRUG OR ACTIVITY IS IN VIOLATION OF THIS SECTION OR ANY FEDERAL OR STATE LAW OR REGULATION. THE STATE DEPARTMENT MAY REVOKE THE SUSPENSION IF, AFTER CONDUCTING AN INVESTIGATION, IT DETERMINES THAT THE PUBLIC IS ADEQUATELY PROTECTED FROM COUNTERFEIT OR UNSAFE DRUGS BEING IMPORTED INTO THIS STATE.

25.5-2.5-205. Federal approval. (1) ON OR BEFORE SEPTEMBER 1, 2020, THE STATE DEPARTMENT SHALL SUBMIT A REQUEST TO THE UNITED STATES SECRETARY OF HEALTH AND HUMAN SERVICES FOR APPROVAL OF THE PROGRAM UNDER 21 U.S.C. SEC. 384. THE STATE DEPARTMENT SHALL BEGIN OPERATING THE PROGRAM NOT LATER THAN SIX MONTHS AFTER RECEIVING SUCH APPROVAL. THE REQUEST MUST, AT A MINIMUM:

(a) DESCRIBE THE STATE DEPARTMENT'S PLAN FOR OPERATING THE PROGRAM;

(b) DEMONSTRATE HOW THE PRESCRIPTION DRUGS IMPORTED INTO THE STATE UNDER THE PROGRAM WILL MEET THE APPLICABLE FEDERAL AND STATE STANDARDS FOR SAFETY, EFFECTIVENESS, MISBRANDING, AND ADULTERATION;

(c) INCLUDE A LIST OF PRESCRIPTION DRUGS THAT HAVE THE HIGHEST

POTENTIAL FOR COST SAVINGS TO THE STATE THROUGH IMPORTATION AT THE TIME THAT THE REQUEST IS SUBMITTED;

(d) ESTIMATE THE TOTAL COST SAVINGS ATTRIBUTABLE TO THE PROGRAM; AND

(e) INCLUDE A LIST OF POTENTIAL CANADIAN SUPPLIERS FROM WHICH THE STATE WOULD IMPORT PRESCRIPTION DRUGS AND DEMONSTRATE THAT THE SUPPLIERS ARE IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS.

(2) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE CONTRARY, THE STATE DEPARTMENT MAY EXPEND MONEY FOR THE PURPOSE OF REQUESTING APPROVAL OF THE PROGRAM AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION BUT THE STATE DEPARTMENT SHALL NOT SPEND ANY OTHER MONEY TO IMPLEMENT THE PROGRAM UNTIL THE STATE DEPARTMENT RECEIVES APPROVAL OF THE PROGRAM AS DESCRIBED IN SAID SUBSECTION (1).

(3) UPON RECEIPT OF FEDERAL APPROVAL OF THE PROGRAM, THE STATE DEPARTMENT SHALL NOTIFY THE PRESIDENT OF THE SENATE AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AS WELL AS THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES. AFTER APPROVAL IS RECEIVED AND BEFORE THE START OF THE NEXT REGULAR SESSION OF THE GENERAL ASSEMBLY IN WHICH THE PROPOSAL COULD BE FUNDED, THE STATE DEPARTMENT SHALL SUBMIT TO ALL PARTIES SPECIFIED IN THIS SUBSECTION (3) A PROPOSAL FOR PROGRAM IMPLEMENTATION AND PROGRAM FUNDING.

25.5-2.5-206. Reports. (1) NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), ON OR BEFORE DECEMBER 1, 2021, AND ON OR BEFORE DECEMBER 1 EACH YEAR THEREAFTER, THE STATE DEPARTMENT SHALL SUBMIT A REPORT TO THE GOVERNOR, THE PRESIDENT OF THE SENATE, AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES CONCERNING THE OPERATION OF THE PROGRAM DURING THE PREVIOUS FISCAL YEAR. THE REPORT MUST INCLUDE, AT A MINIMUM:

(a) A LIST OF THE PRESCRIPTION DRUGS THAT WERE IMPORTED UNDER THE PROGRAM;

(b) THE NUMBER OF PARTICIPATING CANADIAN SUPPLIERS AND ELIGIBLE IMPORTERS;

(c) THE NUMBER OF PRESCRIPTIONS DISPENSED THROUGH THE PROGRAM;

(d) THE ESTIMATED COST SAVINGS DURING THE PREVIOUS FISCAL YEAR AND TO DATE;

(e) A DESCRIPTION OF THE METHODOLOGY USED TO DETERMINE WHICH PRESCRIPTION DRUGS SHOULD BE INCLUDED ON THE WHOLESALE PRESCRIPTION DRUG IMPORTATION LIST ESTABLISHED PURSUANT TO SECTION 25.5-2.5-203 (2)(a); AND

(f) DOCUMENTATION DEMONSTRATING HOW THE PROGRAM ENSURES THAT:

(I) THE VENDOR VERIFIES THAT CANADIAN SUPPLIERS PARTICIPATING IN THE PROGRAM ARE IN FULL COMPLIANCE WITH RELEVANT CANADIAN FEDERAL AND PROVINCIAL LAWS AND REGULATIONS;

(II) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE NOT SHIPPED, SOLD, OR DISPENSED OUTSIDE OF THE STATE ONCE IN THE POSSESSION OF THE ELIGIBLE IMPORTER;

(III) PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM ARE PURE, UNADULTERATED, POTENT, AND SAFE;

(IV) THE PROGRAM DOES NOT PUT CONSUMERS AT A HIGHER HEALTH AND SAFETY RISK THAN IF THE PROGRAM DID NOT EXIST; AND

(V) THE PROGRAM PROVIDES COST SAVINGS TO THE STATE ON IMPORTED PRESCRIPTION DRUGS.

25.5-2.5-207. Importation program authorized - rules. (1) UPON APPROVAL BY THE SECRETARY, IN ACCORDANCE WITH SECTION 25.5-2.5-206, THE STATE DEPARTMENT SHALL ADMINISTER AN IMPORTATION PROGRAM.

(2) THE STATE DEPARTMENT SHALL APPROVE A METHOD OF FINANCING THE ADMINISTRATIVE COSTS OF THE IMPORTATION PROGRAM,

WHICH METHOD MAY INCLUDE IMPOSING A FEE ON EACH PRESCRIPTION PHARMACEUTICAL PRODUCT SOLD THROUGH THE IMPORTATION PROGRAM OR ANY OTHER APPROPRIATE METHOD DETERMINED BY THE STATE DEPARTMENT TO FINANCE ADMINISTRATIVE COSTS. THE STATE DEPARTMENT SHALL NOT REQUIRE A FEE IN AN AMOUNT THAT THE STATE DEPARTMENT DETERMINES WOULD SIGNIFICANTLY REDUCE CONSUMER SAVINGS.

(3) THE EXECUTIVE DIRECTOR SHALL PROMULGATE RULES, IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24 AND SECTION 25.5-1-108, AS NECESSARY FOR THE ADMINISTRATION OF THIS PART 2.

SECTION 4. In Colorado Revised Statutes, **amend** 25.5-2.5-101 as follows:

25.5-2.5-101. Short title. THE SHORT TITLE OF this ~~article shall be known and may be cited as~~ PART 1 IS the "Colorado Cares Rx Act".

SECTION 5. Appropriation - adjustments to 2019 long bill. (1) For the 2019-20 state fiscal year, $1,041,802 is appropriated to the department of health care policy and financing. This appropriation is from the general fund. To implement this act, the department may use this appropriation as follows:

(a) $469,293 for use by the executive director's office for personal services, which amount is based on an assumption that the department will require an additional 4.1 FTE;

(b) $27,790 for use by the executive director's office for operating expenses;

(c) $134,719 for legal services; and

(d) $410,000 for general professional services and special projects.

(2) For the 2019-20 state fiscal year, $134,719 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of health care policy and financing under subsection (1)(c) of this section and is based on an assumption that the department of law will require an additional 0.7 FTE. To implement this act, the department of law may use this appropriation to provide legal services for

the department of health care policy and financing.

(3) The appropriation in subsection (1)(a) of this section is based on the assumption that the anticipated amount of federal funds received for the 2019-20 state fiscal year by the department of health care policy and financing for personal services will decrease by $70,000.

SECTION 6. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 2, 2019, if adjournment sine die is on May 3, 2019); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless

approved by the people at the general election to be held in November 2020 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Leroy M. Garcia
PRESIDENT OF
THE SENATE

KC Becker
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED May 16, 2019 at 10:06 A.M.
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

Appendix C - Report for the Colorado Department of Health Care Policy and Financing

The Canadian Framework for Drug Distribution System Oversight of Safety and Price

March 2020

Submitted by: Mara Baer, Founder & President, AgoHealth, LLC

Report Purpose and Findings

As the State of Colorado advances its effort to establish a Section 804 Importation Program (SIP) to allow for the importation of Canadian prescription drugs, the Department of Health Care Policy and Financing (the Department) contracted with AgoHealth, LLC to conduct an independent research project regarding the Canadian drug distribution system. Such information has informed the development of the state's initial SIP framework thus far and will continue support further development of this work, including the exploration of potential partners in Canada.

This report provides a detailed overview of how the Canadian government, quasi-governmental entities, and local provincial and territorial governments provide oversight of the safety and pricing of prescription drugs in Canada. This analysis finds that Canada has a very extensive oversight framework for prescription drugs, providing comparable safeguards to those found in the United States. Further, Canada has additional oversight mechanisms in place to critically evaluate drug prices.

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Canadian Health System Overview

The Canadian health care system provides universal coverage for basic health services (provided by hospitals and outpatient providers) through a division of responsibilities between the federal government and provinces and territories. Health Canada is the overarching governmental body that provides oversight and organizes health care priorities[1]:

The federal government sets the standards for coverage and delivery, and provinces and territories implement the programs and standards largely through publicly funded health care. This coverage is financed with federal and local taxes with a mandate to cover hospital, diagnostic and physician services. Drugs are specifically excluded from the national health program making the country unique compared to other nations with national health care programs. There are discussions underway across the country regarding this with some ministries and policy experts advocating for a national "pharmacare" program yet these discussions have been divisive.[2]

Most provincial and territorial governments offer and fund supplementary benefits not required by federal rules to certain groups including low-income individuals and seniors. This

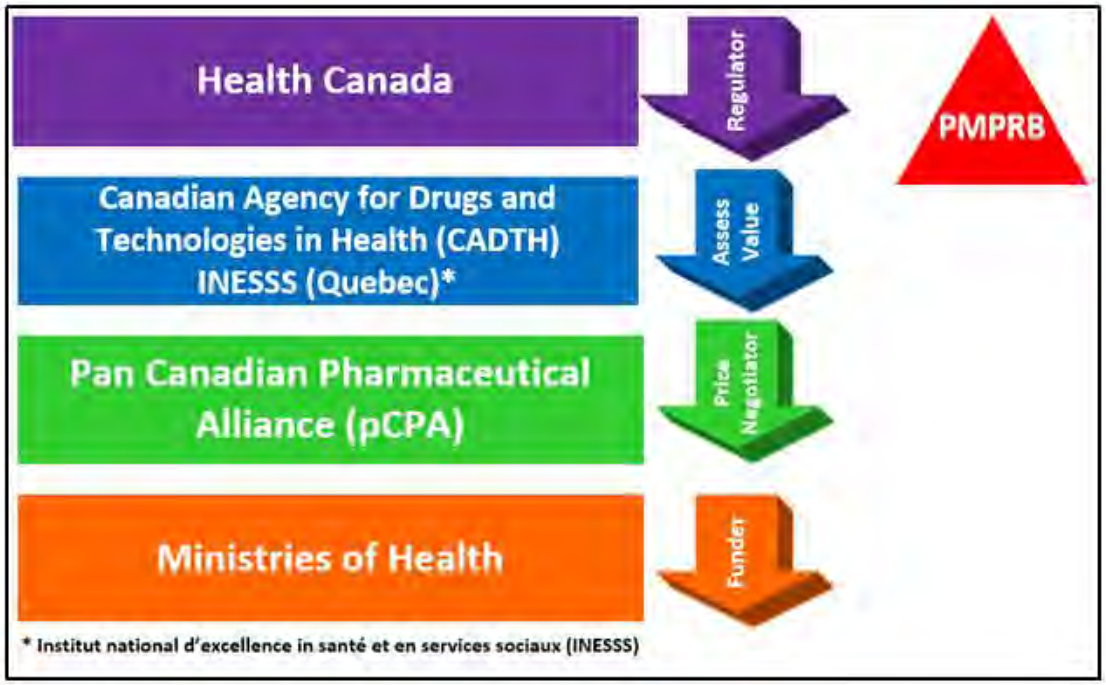
1 https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/partner-health-canadians.html

2 https://news.ontario.ca/mohltc/en/2018/01/statement-by-minister-of-health-and-long-term-care.html

includes drugs prescribed outside hospitals, ambulance costs, and hearing, vision and dental care. Similar supplemental coverage is also provided through employer-based group coverage or through individually purchased coverage. One estimate indicates that about two-thirds of Canadians have supplemental coverage.[3] Such coverage is generally restricted to supplemental benefits and may not duplicate what is offered in the publicly funded provincial or territorial plan. About 30 percent of healthcare spending comes from private sources due to services not covered through the public insurance program.[4]

Drug Review Entities & Key Steps

Canada has an extensive drug review and pricing process which requires evaluation across numerous entities:



· *Health Canada* – Sets the federal standards and rules for clinical drug trials, and application review, approval, and ongoing monitoring of safety and quality.

[3] https://www.washingtonpost.com/news/wonk/wp/2012/07/01/everything-you-ever-wanted-to-know-about-canadian-health-care-in-one-post/?utm_term=.af3f7b9c6c5b

[4] https://www.huffingtonpost.ca/john-have/private-health-insurance-canada_b_12032150.html

- *Patented Medicines Price Review Board (PMPRB)* – A price regulator, PMPRB is an independent quasi-judicial entity established by Parliament to ensure prices for patented drugs are not excessive.

- *Canadian Agency for Drugs and Technologies in Health (CADTH)* – Provides non-governmental impartial reviews of drugs through the Common Drug Review (CDR).

- *Institut national d'excellence in sante et en services sociaux (INESSS)* – Quebec does not participate in CADTH and has its own independent review to assess the value of drugs.

- *Pan Canadian Pharmaceutical Alliance* – pCPA conducts joint negotiations for drugs across participating jurisdictions. A negotiated agreement between the manufacturer and the pCPA does not have to be accepted by participating local provinces or territories.

- *Ministries of Health* – Provincial and territorial ministries of health administer public health plans and have the ultimate decision regarding whether to offer supplemental drug coverage and what to include in such coverage. Private supplemental drug coverage can be offered as well and is overseen by these ministries.

Each of these entities roles in drug oversight and price decisions are described in detail in the following sections.

Health Canada Drug Trial Application and Drug Review/Authorization

Health Canada's Health Products and Food Branch (HPFB) has oversight of drug trial reviews, product applications, and ongoing oversight.[5] [6] The HPFP's Therapeutic Products Directorate (TPD) is the chief regulator of therapeutic and diagnostic products available in Canada and is tasked with managing oversight of health products and food to protect and promote health safety.[7] The Directorate's Bureau of Pharmaceutical Sciences (BPS) reviews drugs for quality

[5] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drugs-reviewed-canada.html
[6] https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch.html
[7] https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html

and chemical composition as part of the approval process. This review also includes analysis of studies regarding bioequivalence.

Clinical Trial Application Process

Before a drug can be reviewed for sale by Health Canada, the Food and Drugs Act and related regulations require a Clinical Trial Application (CTA). This application is submitted to the TPD Office of Clinical Trials. Specific requirements regarding the CTA are found in Part C, Division 5 of the regulations and in the *Guidance Document for Clinical Trial Sponsors.*[8] Sponsors must submit a CTA for all Phase I through III trials. The CTA contains information on the goals of the proposed trial and safety, clinical and quality aspects of the application are reviewed by Health Canada. This review can be followed up with an inspection (only 2% of trials a year receive this). Within 30 days a response is provided. Local ethics board approvals must also be obtained before a trial can begin.[9]

National Drug Approval Process

At HPFB a drug application is reviewed to evaluate the safety and efficacy of the drug before it can enter the Canadian market. HPFB's engagement begins prior to a clinical trial when the entity reviews information in a clinical trial application. If a trial demonstrates a possible therapeutic value, a sponsor may file a New Drug Submission application with HPFB. Clinical study data, packaging and labeling information are reviewed during the initial filing as well as review of therapeutic claims and side effects. HPFB's drug approval evaluation steps include a deeper dive into drug data with a focus on evaluating safety, efficacy and quality. Laboratory testing may also occur at this step. If a drug is deemed to have benefits outweighing any risks the drug is issued a Notice of Compliance (NOC).[10] This process and all the drug approval requirements are governed by the Food and Drugs Act and the corresponding regulatory framework under Part C, Division 8 of the Food and Drug Regulations.[11] [12]

[8] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html
[9] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/links.html
[10] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance.html
[11] https://laws-lois.justice.gc.ca/eng/acts/f-27/
[12] https://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 870/index.html

Ongoing Oversight

HPFB monitors all drugs once on the market and conducts investigations as needed regarding any reported complaints and manages recalls. Complaints are reported through the Food and Drugs Act Liaison Office.[13] The HPFB requires reporting by distributors of any drug issues including serious side effects. Any additional studies post-market must also be reported. The agency also licenses production sites and conducts regular inspections.

Patented Medicine Prices Review Board

Background/Overview

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial tribunal with the mandate to regulate the prices of patented medicines sold in Canada, ensuring that they are not excessive. This oversight focuses on the "factory gate" ceiling price which is the price patentees sell their drugs to wholesalers, distributors and through direct channels (hospitals and pharmacies).[14] The PMPRB's policies and guidelines are outlined in *the Compendium of Policies, Guidelines and Procedures.*[15]

Patentees are required to submit information on the drug product upon offering it for sale in Canada and then throughout the year. Information must include price and sales for each class of customer by province and territory, revenues from sales and expenditures on research and development of the drug product, and the price sold to each class of customer in other countries.[16]

Scientific and Price Review

The first PMPRB step for patentees with a new drug product is a scientific review, which measures the level of therapeutic improvement of the new product and determines the comparable drug products as well as comparable dosage regimens.[17] The scientific review is

[13] https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/food-drugs-act-liaison-office.html
[14] http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2018/2017_Annual_Report_Final_EN.pdf
[15] http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492
[16] www.pmprb-cepmb.gc.ca/view.asp?ccid=528&lang=en
[17] http://www.pmprb-cepmb.gc.ca/en/regulating-prices/scientific-review

carried out by the Human Drug Advisory Panel, a group of independent scientific and medical experts.

The PMPRB also reviews the average price of each strength of an individual dosage form of each patented medicine. The board uses five factors for determining whether a drug product is excessively priced:

- Prices at which the medicine has been sold in the relevant market,
- Prices at which other medicines in the same therapeutic class have been sold in the relevant market,
- Prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada,
- Changes in the Consumer Price Index, and
- Any other factors that may be set out in regulations.[18]

The guidelines limit price increases to changes in the CPI, calculated over a three-year period. Additionally, the increase cannot exceed the Highest International Price Comparison test.[19] The PMPRB also published data regarding pricing information such as the Foreign-to-Canadian ratios below:

TABLE 9 Average Foreign-to-Canadian Price Ratios, Bilateral Comparisons, 2017

	Canada	France	Italy	Germany	Sweden	Switzerland	United Kingdom	United States
At Market Exchange Rates								
Average price ratio 2017	1.00	0.75	0.95	1.12	0.93	1.12	0.94	3.36
Average price ratio 2016	1.00	0.77	0.92	1.09	0.95	1.09	0.99	3.08
At Purchasing Power Parities								
Average price ratio 2017	1.00	0.79	1.12	1.20	0.83	0.88	0.98	3.25
Average price ratio 2016	1.00	0.83	1.09	1.22	0.84	0.87	0.97	3.15
Number of patented medicines 2017	1,381	675	775	1,016	845	889	991	1,100
Sales ($millions)	16,784.86	9,679.62	12,611.57	14,379.87	12,960.85	14,183.17	13,567.44	15,575.41

Source: PMPRB

Source: PMPRB Annual 2017 Report

[18] http://www.pmprb-cepmb.gc.ca/en/regulating-prices/price-review

[19] http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#1645 (Schedule 8-10)

The Role of Independent Reviews

Once Health Canada approves a drug for sale, independent reviews to assess the value of a drug are conducted by the Canadian Agency for Drugs and Technologies (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec. These entities support local governments in decision making regarding drug formulary development.

CADTH

The Canadian Agency for Drugs and Technologies in Health (CADTH) is an independent nonprofit organization that provides health care stakeholders with objective evidence to help make informed decisions about the best use of drugs and other medical tests and procedures. It was created by Canada's federal, provincial, and territorial governments to take a coordinated approach to assessing drugs, devices, and tests. Eighteen drug plans, including all provinces and territories other than Quebec, participate in CADTH and each has their own pricing and eligibility approval processes.[20]

The CADTH Common Drug Review (CDR) process evaluates the clinical, economic, and patient evidence on drugs, and uses this evaluation to provide reimbursement recommendations and advice to Canada's federal, provincial, and territorial public drug plans, with the exception of Quebec.[21] As a part of this process, CADTH considers studies on drug effectiveness, economic assessments as well as feedback from patients, clinicians, and manufacturers through a formalized process. CADTH also has a process specific to evaluation of cancer drugs called the pan-Canadian Oncology Drug Review (pCODR).[22] This program is designed to ensure consistency and clarity to the assessment of cancer drugs.

The Health Canada, CADTH, and INESSS approval processes operate independent of one another, but there have been recent efforts to better align the processes. The goal of this effort is to reduce the time between Health Canada's market approval and the funding recommendations to federal, provincial and territorial drug plans.

[20] https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/common-drug-review-submissions/participating-drug-plans
[21] https://cadth.ca/sites/default/files/cdr/process/Procedure_and_Guidelines_for_CADTH_CDR.pdf
[22] https://www.cadth.ca/pcodr/guidelines-procedures-and-templates

Institut national d'excellence en santé et en services sociaux (INESSS)

Quebec does not participate in CADTH, instead issuing its own drug evaluation process at INESSS whose mission is to promote clinical excellence and the efficient use of resources in the health and social services sector. Quebec's decisions on drug approval have often been different than the decisions made by the CDR, and some attribute this to the large pharmaceutical industry presence in that province.[23]

INESSS issues recommendations for use and coverage of drugs by the public plan, and it develops guides to clinical practice to ensure proper use. An economic evaluation is included in the assessment which informs decisions on whether a drug may be placed on Quebec's official List of Medications.[24]

Pan Canadian Pharmaceutical Alliance (pCPA)

Once the federal government and national advisory bodies conduct their reviews of drugs, the Pan Canadian Pharmaceutical Alliance (pCPA) conducts a price review and possible negotiation with manufacturers on selected drugs. Local health ministries in provinces and territories may also conduct independent analyses and then make the ultimate decision on what drugs to include in their supplemental public drug plans.

The pan-Canadian Pharmaceutical Alliance (pCPA) or "Alliance" was established in 2010 to conduct joint provincial, territorial, and federal negotiations for drugs in Canada to achieve better value through combined negotiations. Participants include public drug plan and/or cancer agencies from: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Québec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, Northwest Territories, Nanavut, Non-Insured Health Benefits, Correctional Services of Canada, and Veterans Affairs Canada. When pCPA was founded in 2010, Québec was not a member, but they joined in 2015 and the federal government joined in 2016.[25] Private plans are not a part of pCPA.

Negotiation Process

The Alliance selectively determines whether to jointly negotiate a specific drug after the drug plans decide if it is eligible for reimbursement. First, a drug must be approved by Health

[23] https://www.cadth.ca/sites/default/files/pdf/early_history_of_CDR.pdf
[24] http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2019/liste_med_2019_03_07_en.pdf
[25] https://www.canada.ca/en/health-canada/news/2016/01/government-of-canada-partners-with-provinces-and-territories-to-lower-cost-of-pharmaceuticals.html

Canada. Once the drug has been approved, the drug plans look to the recommendations by the Canadian Agency for Drugs and Technologies in Health (CADTH) as a result of its Common Drug Review (CDR) or pan-Canadian Oncology Drug Review (pCODR).

If the plans conclude that the drug is eligible for reimbursement, pCPA decides if they would like to negotiate with the manufacturer and they select a jurisdiction to serve as the lead negotiator. If an agreement is reached, the lead jurisdiction and the manufacturer sign a letter of intent, and then the individual jurisdictions ultimately decide if they will fund the drug through its public plan. These joint negotiations are especially helpful to smaller provinces that would not otherwise have leverage in negotiations with drug manufacturers.[26] Details on the status of negotiations are found on the pCPA website.[27]

Procurement and Distribution

Most distribution in Canada is indirect, relying on wholesalers and distributors. This process consolidates ordering, purchasing, and delivery and the entities serve as middle-men between manufacturers and front-line delivery organizations. While Health Canada has primary responsibility for the initial prescription drug safety and efficacy review, the distribution process is primarily overseen by each of the provinces and territories.

Distributors/Wholesalers

Canadian distribution involves the acquisition, warehousing, storage, and delivery of drugs to community pharmacies and other entities that are front-line users. Canada has numerous entities that distribute prescriptions and most have distribution centers across the country. While there is no publicly available database of all wholesalers and distributors, the Health Canada Drug and Health Product Inspections tracker system is available to search for these entities and their inspection data.[28]

Group Purchasing Organizations (GPOs) which may also serve as wholesalers negotiate directly with drug makers to achieve discounts through bulk purchases. Wholesalers purchase drugs directly from drug manufacturers and importers and sell them to pharmacies in Canada with community pharmacies representing the majority of front-line users. Like in the U.S., wholesalers consolidate shipments to pharmacies to lower costs.

[26] http://canadaspremiers.ca/wp-content/uploads/2013/12/pan_canadian_drugs_negotiations_report_march22_2014.pdf
[27] http://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/
[28] http://www.healthycanadians.gc.ca/apps/gmp-bpf/index-en.html

Licensure and Regulatory Oversight

Before distribution can occur, an entity must comply with both national and provincial government regulatory requirements. A Drug Establishment License (DEL) must be obtained from Health Canada in order to establish a wholesale entity. The direct regulation of the wholesale process is governed by provincial governments including in some cases Colleges of Pharmacy or pharmacy boards.[29] A DEL must be held in order to obtain approval to sell a drug by wholesale in a province and local governmental bodies provide ongoing oversight of wholesale activities yet at varied levels depending on the province or territory. An additional license and/or registration may be required at the provincial or territorial level as well.

The DEL ensures that all distribution activities have complied with good manufacturing practices (GMP).[30] [31] [32] The Canadian Minister of Health can conduct inspections or require additional information as part of annual reviews. The DEL can be suspended or canceled if there are issues with the license renewal application. Wholesalers and distributors receive federal inspections every three years.[33]

Provincial Oversight

Regulatory oversight varies between provinces but in general wholesalers must register with the province and meet requirements regarding who they may sell their drugs to. Provincial regulations govern who may be approved to sell and dispense drugs. While limited provincial oversight information was publicly available to inform this report, available preliminary information for three provinces (Ontario, British Columbia and Quebec) regarding this oversight role in the distribution chain is outlined below:

Ontario - According to Ontario's Drug and Pharmacies Regulation Act, drug wholesalers are required to register with the Ontario College of Pharmacists and provide a signed statement

[29] https://ca.practicallaw.thomsonreuters.com/0-618-6695?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1
[30] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html
[31] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/annual-review-documents/frequently-asked-questions-drug-establishment-licensing-fees.html#a2
[32] https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html
[33] https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections/about-drug-inspections.html#s1

with information about the wholesaler as well as information about the businesses to which they are selling. The final regulation in the Act says that pharmacists can only purchase drugs from wholesalers in the location most appropriate for patients.[34]

British Columbia- Regulation in the Pharmacy Operation and Drug Scheduling Act states that wholesalers and manufacturers of limited access drugs must maintain a record of all sales of those drugs and allow an inspector to inspect the record or inventory of those drugs at any time during normal business hours without the requirement of a court order.[35] Wholesalers of limited access drugs must register with the College of Pharmacists of British Columbia in the manner specified in the bylaws.

Quebec Distribution Regulation- Quebec has a regulation governing the accreditation of manufacturers and wholesalers of medications as it relates to prescription drug insurance.[36]The regulation defines a drug wholesaler as an intermediary between drug manufacturers and pharmacists, holds a license under the federal Controlled Drugs and Substances Act, and be an authorized distributor under that Act.[37] The wholesaler must also conduct business in the drug distribution field, including purchase and sale, receipt, storage, transport and delivery of the drugs on the List of Medications, maintaining a drug inventory including not less than 50% of the drugs on the List of Medications.[38]

Provincial/Territorial Drug Coverage

Local provinces and territories ultimately decide the benefits and pricing framework for their supplemental drug coverage programs. Summarized below are several examples of how local governments (Ontario, British Columbia and Québec) organize their health and drug coverage programs, each having a unique approach. Territories are not included in this analysis due to their very small population sizes.

Ontario

Overview

Ontario is located in east-central Canada and is the most highly populated of the provinces having 38 percent of the country's population. The province provides its residents with health

[34] https://www.ontario.ca/laws/statute/90h04#BK35
[35] http://www.bclaws.ca/civix/document/id/complete/statreg/03077_01#section28
[36] http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/A-29.01%2c%20r.%202
[37] https://www.canlii.org/en/ca/laws/stat/sc-1996-c-19/latest/sc-1996-c-19.html
[38] http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2019/liste_med_2019_04_11_en.pdf

coverage through the Ontario Health Insurance Plan (OHIP) which pays for the services required by the Canada Health Act including provider visits, hospital services and diagnostics when determined medically necessary. Like other local ministries, Ontario does not include prescription drug coverage in its health plan for all its citizens but offers a supplemental public drug program for some qualifying citizens.[39]

Drug Approvals

The Health Ministry of Ontario requires that brand name drug manufacturers receive approval from Health Canada and CADTH before a drug can be sold in the province. Once this approval occurs, the Ontario Ministry of Health and Long-Term Care (OMHLTC) may conduct additional reviews of a drug to be funded by the Ontario Drug Benefit (ODB) plan. In general, the OBD relies on national review bodies to inform decisions about the formulary including CADTH and pCPA and will evaluate drugs on a case-by-case basis.

When evaluating a drug for coverage, the OMHLTC reviews clinical evidence, patient comments, and the impact on health services. The entity also relies on an advisory committee to make a recommendation to the Executive Officer of drug programs which then makes a final coverage and pricing decision.[40] [41] In making a final funding determination the Executive Officer considers the committee's recommendation and input from other advisory bodies, as well as impact to patients and the public interest.[42]

British Columbia

Overview

British Columbia (B.C.) is the most western province in Canada with an estimated population of 4.75 million. Residents receive health care from the Medical Services Plan (MSP). Under the province's Medicare Protection Act, enrollment in the MSP is mandatory for all eligible citizens.[43] B.C. residents participating in the MSP are eligible for drug coverage through one of several "PharmaCare" plans.

[39] https://www.ontario.ca/page/apply-ohip-and-get-health-card#section-1
[40] http://www.health.gov.on.ca/en/public/programs/drugs/approval/approval_mohltc.aspx
[41] http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/drug_submissions.aspx
[42] http://www.health.gov.on.ca/en/public/programs/drugs/approval/approval_mohltc.aspx
[43] http://www.bclaws.ca/civix/document/id/complete/statreg/96286_01

Drug Approvals

PharmaCare conducts a review of each drug through its Drug Benefit Council (DBC) which makes an evidence-based recommendation on whether the drug should be added to the formulary. The DBC examines prior national reviews as a first step and then decides whether there is enough information to accept an existing recommendation (for example from the CADTH Common Drug Review) or conduct an additional review. The DBC is considered an independent advisory committee and is made up of a variety of experts.[44] Most recent data indicate that PharmaCare has approved over 5,200 drugs for its formulary (2016/2017).[45] A formulary search is available on the PharmaCare website and includes maximum unit price information.[46]

In making a final decision, PharmaCare evaluates; the DBC recommendation, existing policy for the type of drug, other Ministry programs that could cover the drug, and available resources to cover the drug's costs. A drug can be fully approved as a regular benefit or as a "limited coverage drug" requiring a pre-approval.[47]

Québec

Overview

Québec is located in eastern Canada and is bordered to the west by Ontario, to the east by the province of Newfoundland and Labrador, and to the south by the province of New Brunswick and the U.S. state of Maine. Québec is Canada's largest province by area and the second largest by population, after Ontario. It is the only province to have a predominantly French-speaking population, and French is the provincial official language. Over 8 million people live in the province.

Régie de l'assurance maladie du Québec (RAMQ) was established in 1969 to set up the Québec Health Insurance Plan and today it administers both the public health insurance plan and the public prescription drug insurance plan. The official RAMQ data and statistics are only available in French.[48] The Public Health Insurance Plan is available to people a) born in Québec, b) from another Canadian province taking up residence in Québec, c) from another country taking up

[44] https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/drugrevproc.pdf
[45] https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/pharmacare-trends-2016-17.pdf
[46] https://pharmacareformularysearch.gov.bc.ca/faces/Search.xhtml
[47] https://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/drug-coverage/drug-review-process-results
[48] http://www.ramq.gouv.qc.ca/en/data-statistics/Pages/data-statistics.aspx

residence in Québec, and d) from another country staying in Québec temporarily. Once deemed eligible, each person receives a Health Insurance Card and they use it for covered medical, dental, optometric, and pharmaceutical services. According to RAMQ data, 8 million people were a part of the Public Health Insurance Plan and 3.6 million people were covered by the Prescription Drug Plan in 2017-2018.[49]

List of Medications

Institut national d'excellence en santé et en services sociaux (INESSS) is responsible for assessing the clinical effectiveness of drugs and making recommendations to the Minister of Health and Social Services as to which drugs should go on the List of Medications,[50] INESSS's process requires that drug manufacturers submit a registration application, and if it meets the requirements, it posts it online to solicit feedback from consumer and professional groups. A scientific committee reviews the application and issues a report to the INESSS Board of Directors, who then decides approval and forward to the Minister of Health for final approval. If approved, the product is added to the List of Medications.

The List of Medications includes the prices of the drugs that are covered as part of the public plan. It also includes information on the pricing methodology and the drug wholesalers that are accredited by the Minister and the allowable markup for each wholesaler. The List of Medications also includes exceptional medications with detailed indications under which the drug would be provided to the patient. The list is updated, on average, once a month.

Conclusion

This analysis has provided an in-depth review of the policy framework governing the Canadian drug distribution system which highlights the extensive nature of the oversight role Canadian federal and local governments play in ensuring drugs are safe and affordable. As Colorado continues to pursue its efforts to establish a Section 804 Importation Program or SIP, this report can serve as a guide in support of next steps including development of a strategy to pursue potential Foreign Seller partners in Canada.

About the author:

[49] http://www.ramq.gouv.qc.ca/fr/donnees-et-statistiques/Pages/la-regie-en-quelques-chiffres.aspx

[50] www.ramq.gouv.qc.ca/SiteCollectionDocuments/liste_med/2019/liste_med_2019_03_07_en.pdf

AgoHealth, LLC is a boutique health care policy consulting firm located in Denver, Colorado. The firm serves government, non-profit, and private sector health care organizations. Mara Baer, AgoHealth's Founder & President brings over 25 years of health care experience to her clients including deep expertise in federal and state health policy. For more information about this report please contact: mara@agohealth.com.

Appendix D - Request for Information - Pharmacy Questions

Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. For additional background about the Colorado bill, please see the bill in its entirety here:

The Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384. For additional information, click here. This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply.

For additional background about importation, please see the FDA's Safe Importation Action Plan released 7.31.19:

Purpose:
The primary goal of this Request for Information (RFI) is for Colorado to assess interest among pharmacies whether they would consider participation in a prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Pharmacy compensation:
The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For pharmacies considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the pharmacies capture positive margins.

1. What are your general thoughts on importing drugs from Canada or another country?

2. What positive outcomes could result from foreign drug importation?
    a. For consumers?

    b. For businesses?

3. What factors would prohibit your participation or decrease your interest in participating?

4. What drugs would you like to see included in Canadian importation? (Excluded drugs include controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs). Please explain your reasoning for each drug/drug class

5. What specific recommendations do you have to ensure safety as required by federal law?

6. What payment models would work for you?

7. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate shelf space for Canadian drug stock
    b. Separate file for Canadian drug invoices
    c. Separate file for Canadian drug hard copies
    d. Additional inspections by the state and potentially federal level
    e. Obtaining a separate license for importation
    f. Using a separate wholesaler just for Canadian drugs
    g. What other potential requirements would influence your decision?

8. What are your thoughts on limiting distribution of Canadian imported drugs to a defined set of pharmacies or a single pharmacy, for example, a mail order only option?

9. What other support would you need from the State of Colorado?

10. What other information do you want to share with the State of Colorado?

COLORADO
Department of Health Care Policy & Financing

Request for information
Wholesaler Questions

Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. For additional background about the Colorado bill, please see the bill in its entirety here:

The Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384. For additional information, click here. This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply.

For additional background about importation, please see the FDA's Safe Importation Action Plan released 7.31.19:

Purpose:
The primary goal of this Request for Information (RFI) is for Colorado to assess interest among prescription drug wholesalers, distributors, repackers, relabelers, logistics providers, and importers (collectively, wholesalers) for participation in a wholesale prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. Such wholesalers may be in the U.S. or in Canada. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Wholesaler role:
The exact role may vary but could entail the following:

- Establishing a relationship with a Canadian wholesaler
- Performing or subcontracting for repacking and relabeling
- Performing or subcontracting for batch testing
- Record keeping, including pedigree and track and trace obligations
- Recall management
- Responsiveness to state audits

Wholesaler compensation:
The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For wholesalers considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the wholesalers capture positive margins.

Questions:

1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?

2. What factors would encourage your participation?

3. What factors would prohibit your participation or decrease your interest in participating?

4. Do you have locations in Canada?

5. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?

6. Do you already purchase medications from Canadian or other foreign sources?

7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?

8. Do you have direct relationships with manufacturers?
    a. All manufacturers
    b. No manufacturers
    c. Mix of some manufactures and other wholesalers

9. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate warehouse space for Canadian stock?
    b. Creating a separate invoice/file for Canadian drugs?
    c. Requirement to obtain a separate license from the state for importation?
    d. Audit of financial records to ensure “substantial cost savings” to the consumer
    e. Additional inspections by the state and potentially federal level
    f. What other requirements not listed above could be a barrier?

10. What payment models would work for you?

11. Would you be reluctant to participate in a wholesale importation program from Canada out of concern that it could impact your existing contracts with drug manufacturers or expose you to risks of retaliation from opposing market actors?

12. What other support would you need from the State of Colorado?

13. What other information do you want to share with the State of Colorado?

Appendix E - Drug Importation Survey

Responses Question 1: Please select all that apply:

	Number of Response(s)	Response Ratio
I purchase prescription drugs for myself or someone else.	25	64.1%
I am a physician, nurse, or other health care provider who has direct contact with patients.	5	12.8%
I am a pharmacist.	6	15.3%
I work in health care in an administrative capacity.	7	17.9%
I am a stakeholder.	7	17.9%
I am a lobbyist, lawmaker, or policy maker.	4	10.2%
Other	8	20.5%
Total	39	100%

"Other" responses include:

Healthcare policy consultant
Consumer advocate
I am a former pharmaceutical industry analyst
Family member used Canadian pharmacy
Insurance Broker
I am a volunteer lobbyist
Insurance Broker
Consultant

Question 2: Please explain your interest in a Canadian drug importation program.

reduce costs for high-cost diseases such as certain cancers, to avoid the health effects of "financial toxicity." High drug costs result in patient noncompliance or dropout from therapeutic regimens, resulting in unnecessary morbidity and mortality.

The National MS Society is committed to stopping MS in its tracks, restoring what's been lost, and ending MS forever. Until that happens, we help people living with MS live their best lives. Evidence shows that early and ongoing treatment of MS with a disease modifying therapy is the best way to prevent disability in the brain and body. However, these MS drugs are exorbitantly expensive. The first drug came to market at approx. $10,000 a year- that same drug, no changes to formula, is now over $80,000 a year. People with MS struggle to afford these life changing drugs, which can literally be the difference between walking and using a wheelchair. The National MS Society has no position on Canadian Importation and neither supported nor opposed SB19-005. However, we are interested in seeing how this program can bring relief to people living with MS in terms of lowering drug costs.

cheaper prices, less finagling with insurance copays and coinsurance

We should not pay more for same drugs than Canada or any country in the world, due to various price-fixing, negotiating that pharma is engaging in to monopolize their market share, prevent generics from coming on the market, or basically preventing good health in their profit motivation.
Competition from Canada, like any threat to the market, should bring down prices for all consumers as well as for public programs paid for by the taxpayer.
Lowering premiums.
would like to see any program that would help reduce cost
It feels like the Pharma charges prices that aren't justified and beyond the scope of doing business.
Worried about drug re-labeling and FDA's ability to oversee in cases of drug adverse effects.
I would like to understand what is possible from a legal and logistics point of view, the savings a program would be expected to achieve (both for the State and for consumers), and what response the State anticipates will come from the Federal government, industry and the domestic supply chain. I hope to be helping develop policy for Colorado, and this is information germane to my interests.
Anything we can do to keep medicine affordable is a good thing. Also with the large profits pharmaceutical companies make it doesn't seem fair to the people, these companies do have the ability to do research and provide medicines at affordable rates, they choose not to. Maybe more competition will help even out our market. Plus I'm also in support of price transparency so consumers can make educated choices
i have concerns with quality control issues that may arise from importing medications. i do not believe it is possible to have qualified oversight necessary to ensure safety and ingredients
Our health-system is currently opposed to general importation of drugs from Canada due to concerns with logistics, costs of importation, safety, and overall feasibility given the limited supply of drugs in Canada. In addition, these drugs may not comply with NDC standards and will not be available in drug databases (FDB, Medispan, etc.) to allow for appropriate charging & drug interaction checking.
In cases where US approved product is not available, we would support importation. However, we do not support importation based solely on cost and strongly recommend that cost/contracting issues be addressed with a cost/contracting strategy."
Not interested
I like the lower cost option.
I'm skeptical as to whether or not this will work. The pharmaceutical companies will just reduce the supply into Canada to drove prices back up.
My regular birth control (Seasonique) is incredibly expensive in Colorado, and I cannot take generic (it messes up my body too much).
When living in Boston, MA, I belonged to a community health center which participated in the Federal 340B drug pricing program. The difference in price (cash pay) - $50 in Boston, $450 in Colorado for the same drug. This is a huge cost savings due to negotiation, so I can only assume what the price would be for the Rx if imported from Canada.

My interest is both professional and personal. I have several medical conditions that require me to be on medications to maintain my health and quality of life. Recently I was prescribed a medication that is still hundreds of dollars a month even with my private insurance. This is not an option for me so I have to go with out. I'm not sure how sustainable this decision is. But I have no choice. That is one example of how prescription drug prices impact my life and health. I also am a psychotherapist and work with clients that have to choose to pay rent, buy food, pay utilities, pay medical bills etc. over getting a prescription they need. Unfortunately having to forego taking a medication keeps my clients sick. Both physically and mentally. We need help. We need a better way.

Families, and individuals, across Colorado are cost-burdened with the high cost of medication... especially for diabetes, stroke prevention, and cancer treatment.

Recommend Canada to some of my Medicare clients and they have found Canada a viable option.

None I do not want to Canadian drugs. If industry and the Goverment can not come t some agreement then would should not go to other countries for supplies

Most of the cost of medicine is paid for through our taxes several of the drugs were developed at NIH A lot of the cost of the drugs we buy goes to pay for advertising, lobbying in DC and local government. So many people as they get older have to choose between their medicine or food. There is just to much greed and waste in this country

I need for life lengthening and life saving drugs to be available, safe and within the payment ability of all of those who need them.

Some of these drugs are manufactured in the US and shipped to Canada. To solve the problem by then purchasing from Canada and shipping back to US seems a very convoluted way to solve a problem that resides here in the US.

Seems like a way for politicians to avoid solving this directly here at home in an attempt to avoid lose of donations by big pharma"

I am actively involved in all matters related to bringing down the cost of care.

Put pressure on Big Pharma to behave in consumer interest.

People are having difficulty purchasing prescription drugs because of cost. Canadian drugs are more reasonable. People living on Social Security cannot afford needed drugs in the U.S. where pharmaceutical companies are out of control. We need to find a solution, and importation would be a first important step.

I want to purchase cheaper drugs

It is important to lower the increasingly high cost of prescription medications so everyone can afford the treatments they need. Most of the US pharmaceutical manufacturers have plants in Canada. FDA inspects these plants as the US pharma imports from Canada and sells here or labels for export. Thus I believe Canadian drugs are safe. The current problem with carcinogens in some products are not from Canadian sourced prescription drugs. If this action encourages the US HHS to formulate regulations for direct importation, we could broaden the scope and use any FDA approved product source in our effort to lower prices.

Well...I need a prescription for Xifaxin and it costs 1600 for a 2nweek treatment...300 from Canada. My daughters epi pen was over 300. I have patients everyday that without.
If it can be safe and efficient, it would disrupt the current system that gives drug companies too much power. That could have both positive and negative impacts, but would change the dynamics of policy and negotiations.
Drug prices are a huge burden on our communities. It's unfair that we are mandated to bear such a burden when our neighbor to the North has better options.
why reimport meds that are already available in America. I struggle to understand why drug companies sell to other nations at such reduced prices and charge extremely high prices to Americans...?
If market share is what these companies seek, sell at the same AWP worldwide.
At this point Americans are subsidizing other nation's health care costs as well as our own which is completely unfair.
The result is people are not compliant with their medication regimens and health care costs accelerate as a result.
It would certainly drive the cost of prescriptions downward a little bit and help to reduce the cost of health insurance including the federal government's cost of Medicare and Medicaid insurance which would help us all in the long run.
Save my patients money on certain prescription drugs and possibly make a profit for a change.
I do not understand the point of the entire industry jumping through the hoops to comply with the DSCSA track and trace laws just to allow people to get their drugs from another country outside of the US supply chain.
I am interested in a short term project centering around a pharmaceutical issue. I am very interested in the Canadian Prescription Drug Importation legislation. I am a pharmacist with experience as Director of Pharmacy for BCBS of Wyoming, Vice President of Sales for Prime Therapeutics (PBM), Perform Cost Management (PBM). Vice President of Sales for ComCoTec (Prescription Processing software). Owner of Haraseks Pharmacy in Berwyn Illinois. Pharmacy Manager Banner Health Greeley Colorado. I would like to focus on a single project like Canadian Drug Importation. A project of one year or less would be ideal. I can work as a contract employee. Can you direct me to the appropriate person or agency?
As a matter of public health, access to prescription drugs is very important to the population. Not all individuals are able to afford the prescriptions that they need, therefore they place not only themselves, but others around them at risk for increased illness. Many individuals are forced to choose between putting food on their tables or taking necessary medications, thus the high costs of prescription drugs contributes to nutritional deficits that can lead to increased illnesses. Reducing prescription drug costs will help increase access and ultimately lead to a healthier population.
I am curious to see if it will actually help patients. The drug industry has been aggressively raising prices and entering into exotic lobbying arrangements for years in order to unethically extort patients and public entities. I am hopeful this will present an actual threat to these practices.

The current state of the prescription marketplace in Colorado is oligopolistic and profit-driven. The exorbitant prices paid for prescription drugs in this country is an outrage. This needs to change. We need additional sources of supply, and we need actors who are not driven by profit. This law is a good step in that direction.

Question 3: I think the quality and safety of drugs imported from Canada would be:

	Number of Response(s)	Response Ratio
More safe	2	5.1%
Less safe	5	12.8%
The same	25	64.1%
I'm not sure	7	17.9%
No responses	0	0.0%
Total	39	100%

Question 4: Tell us what you would expect from a Canadian prescription drug importation program.

Lower prices.

The ability to acquire therapeutically equivalent drugs at a significantly lower cost.

cheaper prices, less finagling with insurance copays and coinsurance

Have every belief that Canada exercises the same oversight over pharmaceuticals as the U.S. does through the FDA. Quality would remain the same. US residents would not be prompted to go across the border and purchase expensive medications and bring them back to the U.S. as is happening now, even though technically against the law.

I would expect more open market in Canada to have an effect on US drug prices by bringing them down.

assurance that the medications were equal want to was available domestically.

An easy process for patients to obtain medications via mail

Lower costs

Tampering

For cash pay customers, the cost of drugs obtained in Canada ought to be lower. If Colorado is the only state (or one of just a few) to engage in a formal importation program, it's possible supply/access would be reliable. However, I believe manufacturers would respond by restricting supply to Canada as well as upping the paperwork quotient for persons obtaining pharmaceutical products (especially those in the "specialty" category) while covered by health insurance. I worry that important customer service functions will be impacted adversely as well. If there's a side effect and the lot is Canadian, how will the manufacturer work with the patient, physician and FDA to remedy the situation?

I would expect a third choice at the pharmacy: name brand, generic or imported or something similar to that.

the same scrutiny as medications allowed within US
We are generally opposed to importation due to the complex logistics. I would support a program when drugs are on shortage in the US. Ideally, these drugs would be available through our standard wholesalers and distribution channels to minimize the potential for diversion and adulteration.
Not interested
Monitored.
I would expect it to bring additional competition to the market, more reasonably priced prescription drugs and a safe option to Colorado.
To begin, Timeliness and education.
Lower cost and potentially increased selection.
There are companies in Canada that people can currently use to fill their prescriptions. Expanding the education of state side clients could prove to a cost savings for everyone and PBM's companies would have to learn to accept they need to become competitive to stay in business.
No I am not in favor
I would expect the program to start with some of the most prescribed drugs high blood pressure, simvastatins, depression medicine, if all goes well then slowly expand the program to include more medications
Please see #2 above. I would expect that we proceed in full agreement with Canada. I don't think it is wise to move forward without Canadian (policy makers and general population) agreement.
The program should provide protections to physicians and other clinicians from lawsuits that could stem from supply chain, quality, and safety issues.
The buyer of the medications should have a choice and be well informed from where the medications originate. Once the information obligation has been met then responsibility is transferred to the buyer/patient since they are making an informed choice.
Hopefully lower prices without sacrificing quality and safety.
Lower costs directly from Canada and pressure on Big Pharma.
Lower costs for people of all ages. Relief for parents of children who have diabetes and other life-threatening diseases.
cheaper drugs
Colorado would be able to offer considerable savings to patients for some medications that are 40-60% cheaper in Canada than in the US. I would expect a Board, a State office and a contractor to ensure that the products are FDA approved, purchased from a reliable source and that state-wide pharmacies could provide savings to their pockets as well as to consumers.
Cheaper prices
Lower costs
No impacts on access
Equivalent or better safety than current system
Flexibility for policy discussions

Consideration of impacts on US pharmacies, especially in small, rural,or underserved communities
Cheaper prescriptions that sent to my home
Nothing. Keep the products here so that the consumer can be confident in pedigree, no tampering or storing meds in poor conditions - either in actual storage (climate control) or transporting.
Most of it would be run through mail order programs of course.
Be able to buy and dispense band name medication below current wholesale costs.
It's going to complicate things more in the US. I do not understand how Canada would be able to sustain all the extra products being shipped out of their country to the US. How will DEA regulate for controlled substances?
Competition for U.S. pharmaceutical companies and lower costs to the consumer.
I hope the state will choose the classes of drugs that have seen the greatest increases in price without new innovation, such as insulins, doxycycline or other ancient drugs that have seen absurd price increased. Then purchase vast quantities, return those to retail in the state and depress the price of similar medications. Drug companies function as cabals and hide behind claims of innovation and caring for patients, by targeting older drugs with inflated prices the state can both save lives and lay bare industry lies.
Lower prices for the identical or chemically identical product.

Question 5: How many prescriptions does your household purchase each month?

8 - 10
People living with MS may use upwards of 10 symptom management drugs in addition to a disease modifying therapy.
6
8
1
2
2
8
2-3
2-3
11
2
5
2
0
I purchase one. I have cut back on others due to the cost.
6 approx
5
None
4

Eight per month
5
2
3
2
Seven.
6
one
2
6
4
none due to the cost
4
N/A
2
12
2
It's around 7 different products.

Question 6: How much does your household pay each month for prescription medicine?

$100 more or less
People living with MS pay anywhere from $200-$3000 per month for their prescriptions.
$100
approx $70
$8
100
$100+
$80
$100
Not a huge amount but I have paid over $100 for antibiotics in the past and that is a terrible burden when you are already sick and choice would help.
$200
$5 - Our drugs are very cheap - $1-2 per prescription typically....
$100
$25.00
O
I am currently lucky that after 4 months of appeals, phone calls, and paperwork, my insurance company now covers part of the cost of my RX, so $20/month.
$100 aprox
369
Nothing
Insurance and co pays

I am Medicare so I have reached catastrophic cost by March
About $80
100
Under $30
$15
We are very fortunate because my husband who is disabled vet gets his medications from the VA. We pay about $80 a month on average.
$400
$15
200
usually about $50, but one drug (intermittently filled) can cost upwards of $100 per month alone
$180
we would pay over $2,500 in unreimbursable cost or pay exorbitant premiums to cover these meds.
450
Business purchases $150,000 per month for resale.
20
$75-$100 as co-pays to medical insurance. We are among the lucky ones that can afford good health insurance coverage.
$8
After insurance coverage, somewhere in the range of $400.

Question 7: How much does your most expensive prescription cost?

During my spouse's bouts with cancer, we often faced COPAYS of $600 / week
Some people living with MS have a 40% coinsurance, meaning their therapy can cost $2500 a month.
$27
$20 for 90 days
$8
60
$100/month
$10 (with insurance.)
$100/mo.
The cozy fluctuates with insurance and that is a separate and equally problematic issue. If not for chp I would not be able to afford my sons asthma medicine
"cost to me: $35
actual cost $1,200"
$3
$25
$35.00
O

$450 for 3 months at full retail price in Colorado (which I would be paying if I didn't convince Anthem to cover it).
$250
280
50.00
The most expensive drug cost is 7246 dollars.Per month.
New prescription is $50 out of pocket. Retail price is $600, at least that is what is printed on the packaging.
50
$15
$15
$60 copay
$350/month
Epipen for $148/year OOP, after deductible or $370 if deductible not met.
The antibiotic I need is $1600
when filled, $80-100/month, per above, but routinely $20-25/month.
$180
$1,800 for biologicals
200
N/A
Not sure due to my copay costs
Without insurance coverage, the most expensive prescription would cost just over $600 per month.
$4
Several thousand dollars before insurance, for a three-month supply.

Question 8: What's the most you have ever had to pay out of pocket for a prescription drug?

$600 per dose for Neupogen
$2500/month on the extreme end.
$189
$45
$70
200
none of our prescriptions are covered in our drug plan, so we plan full price
$90
$100/mo.
Something around $100
$50
$40
$80
Over $100.00.
500

$450
I cant remember
480
Can’t recall
Yes
$2578 dollars, I am still paying on that charge card for this years first months co pay for it. I will have to add 2020 first months on to the same charge card it charges me 28% interest.
As far as I remember, this new drug at $40 is the most expensive one that I paid for. I did not fill the one with a co-pay of $200.
1000
A couple hundred.
$100
$60
$350
$370
Trying not to pay the above. Epi pens 430
$100
$675
$1,800
600
N/A
125.00
$435.
$50-60
One time I had to pay full retail for one of these extremely expensive drugs, something like $30 or more per DAILY DOSAGE.

Question 9: What type of pharmacy do you use today? Please select all that apply.

	Number of Response(s)	Response Ratio
Chain drug store (Walgreens, CVS, Rite Aid, etc.)	21	53.8%
Independently owned pharmacy	7	17.9%
Grocery store pharmacy (King Soopers, City Market, Safeway, etc.)	13	33.3%
Kaiser Permanente (outpatient or mail order)	6	15.3%
Mail order	11	28.2%
Hospital outpatient (Denver Health, UCHealth, Children's Hospital, etc.)	3	7.6%
I get samples from my doctor	3	7.6%
Other	3	7.6%

Total	39	100%

Question 10: How important is it for you to be able to continue using the pharmacy you use today for all of your prescriptions?

Top number is the count of respondents selecting the option. Bottom % is percent of the total respondents selecting the option.	I Don't Care	Not Important	Neutral	Important	Very Important
	5	7	12	9	5
	13%	18%	32%	24%	13%

Question 11: Would you be willing to change where you get your prescriptions if it meant you could purchase cheaper Canadian drugs?

	Number of Response(s)	Response Ratio
Yes	22	56.4%
No	9	23.0%
I'm not sure	7	17.9%
No Responses	1	2.5%
Total	39	100%

Question 12: Would having a choice of pharmacy influence your decision whether to purchase Canadian imported drugs? Please explain your answer.

	Number of Response(s)	Response Ratio
I want to be able to choose my pharmacy	10	25.6%
I don't care what pharmacy I use	16	41.0%
I'm not sure	12	30.7%
No Responses	1	2.5%
Total	39	100%

17 Comment(s)

Comments include:

I don't understand the question.

Pharmacies are irrelevant to me. I use goodrx.com as drug/price vetting comparison site to see who is charging what for a drug. Apps and online access to information is what is now key to drug purchases, not pharmacies.

Ours are only oral meds. For brand, the pharmacy is just a distribution node. For generics, the manufacturer can be important, but we monitor that.
I'd be willing to change my pharmacy but I don't want to go to a pharmacy that I feel takes advantage of people like Walgreens or to king Soopers who has the worst customer ser Also what would systems like kaiser do? They don't give their members a choice and I would hope if it saved the people money they would have to participate.
not likely to purchase Canadian imported drugs
I may avoid pharmacies that preferably import Canadian drugs due to cost only.
Choice is always good.
With different insurance plans over my lifetime, I have been bounced around among many different pharmacies/mail order options. If you wanted your Rx, you did what the insurance company says.
Would US pharmacy's control the use of Canadian pharmacy's, if so then the process could become a very cumbersome mess. Clients could become confused, frustrated and discouraged, not wanting to use the program.
As I ride the bus, it needs to be somewhere I can get to easlily
My concern is that the drugs be quality drugs, safe, affordable and available.
Just as long as the drugs are as safe as US drugs.
Since we live in a rural area, the choices are limited. However, we could drive which is fine now, but question is will it always be okay.
I would be willing to use mail order for a 90 day supply of my current medication, assuming the source is reliable and considers shipment time for keeping me stocked.
For acute care needs, I'd like to go to the closest and cheapest location that I can purchase my prescription.
There is some value to convenience. We don't pay huge amounts, so the savings may not be worth the hassle of less convenient access.
Some medications laying in the mailbox can be frozen or become damaged
Choice of pharmacy is not my first concern. Affordability and quality are primary, area proximity to pharmacy is secondary.

Question 13: If Canadian imported drugs were only available through a mail order pharmacy, would you be willing to switch if it meant those drugs were less expensive?

	Number of Response(s)	Response Ratio
Yes	21	53.8%
No	9	23.0%
I'm not sure	8	20.5%
No Responses	1	2.5%

Total	39	100%

Question 14: Do you have anything else you would like to share with us regarding a Canadian prescription drug importation program?

Canadian drug importation should look for the most bang for the buck. Vermont made a list of the most expensive drugs to the consumer, to employers (in self-insured health plans) and to the taxpayer (for Medicaid and other public programs).

Clearly there needs to be some reason/advantage for Canadian wholesalers to sell to the U.S., in the way of expansion of their markets as well.

Drugs become more of a commodity sale, like generics are, than a branded drug.

Absolutely the ludicrousness of on TV ads from drug companies, spending huge amounts of our precious health care dollars on marketing, needs to be stopped. And let's stop it by importing from Canada.

Interestingly, the Consumer is not very influenced by brands, as they most undoubtedly will be by their premium and out of pocket costs.

Do it

thanks for all you are doing to try to bring down the cost of health care in colorado

Really hope this doesn't happen.

Personally, I believe that there are far more sustainable programs Colorado could consider to alleviate the cost pressures we face v/v Rx.

I think we need to be careful to be respectful of Canada and their health system and I would like to know why their drugs are so much cheaper, maybe we need to look into some significant system changes.

While there may be a limited role for importation during shortages, I generally feel importation is a work around that is not solving the key issue which is primarily a cost and contracting problem. Canada has limited resources and interested in participating in importation programs due to the concerns with supply, cost, and logistics. I strongly suggest that government agencies pursue expansion of 340B and other discount/contracting programs to address the issue of cost. Please refer to the ASHP statement on drug importation for additional concerns related to importation.

After my mother passed, it was very hard to discontinue services from Canadian pharmacy. It seemed at though we were put on unnecessary holds on the phone, lasting for over an hour.

Hell Yes please go for this!

As a health insurance agent I listen to client express their concerns of the cost of prescription medication. This becomes more of a concern for those clients on Medicare, as doctors continue to prescribe more new expensive medication and the client is making some very interesting decisions regarding their medications.

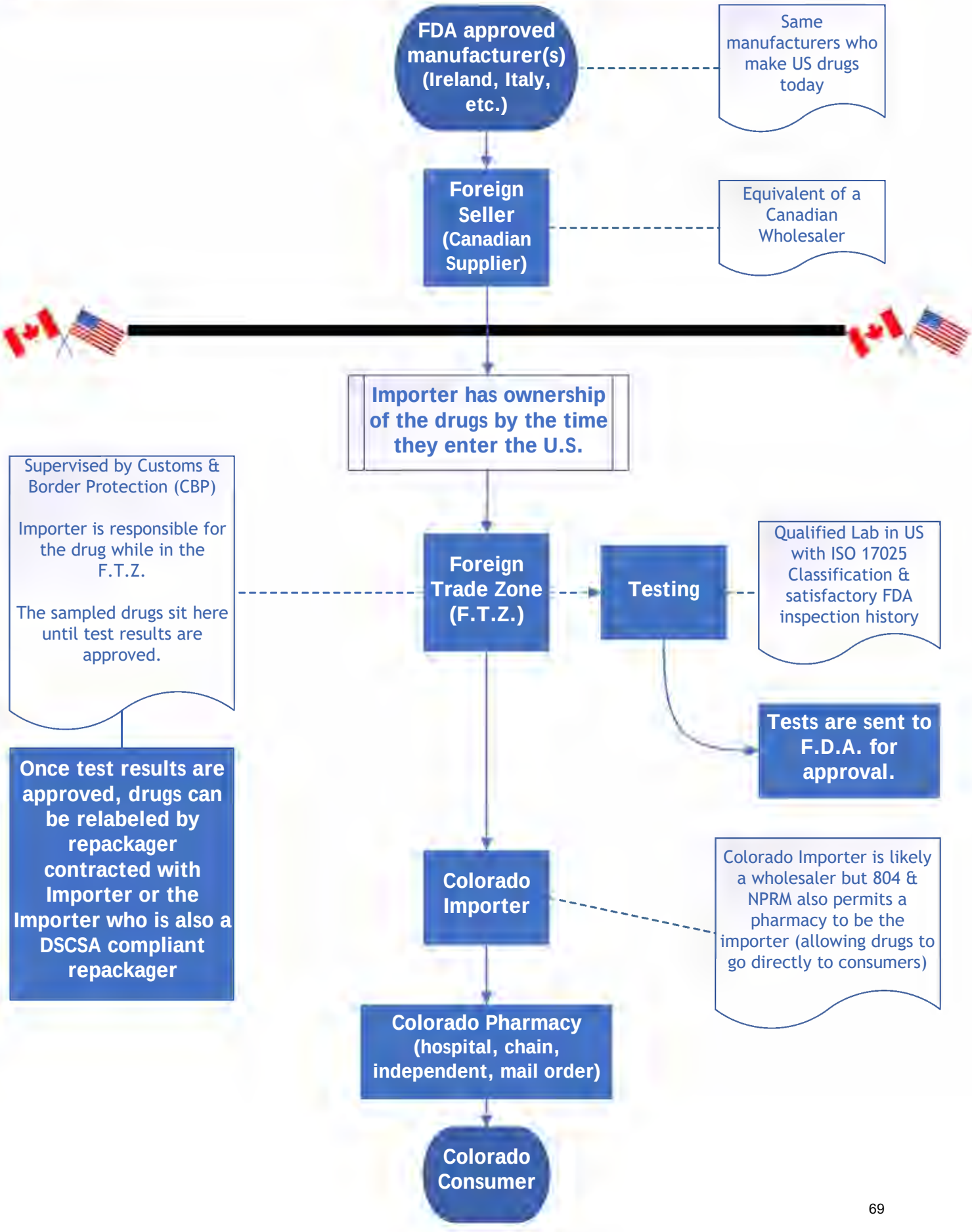
Just get it done,please.

I have used a mail order pharmacy before. For me it was not convenient and felt less reliable than going to my corner pharmacy.

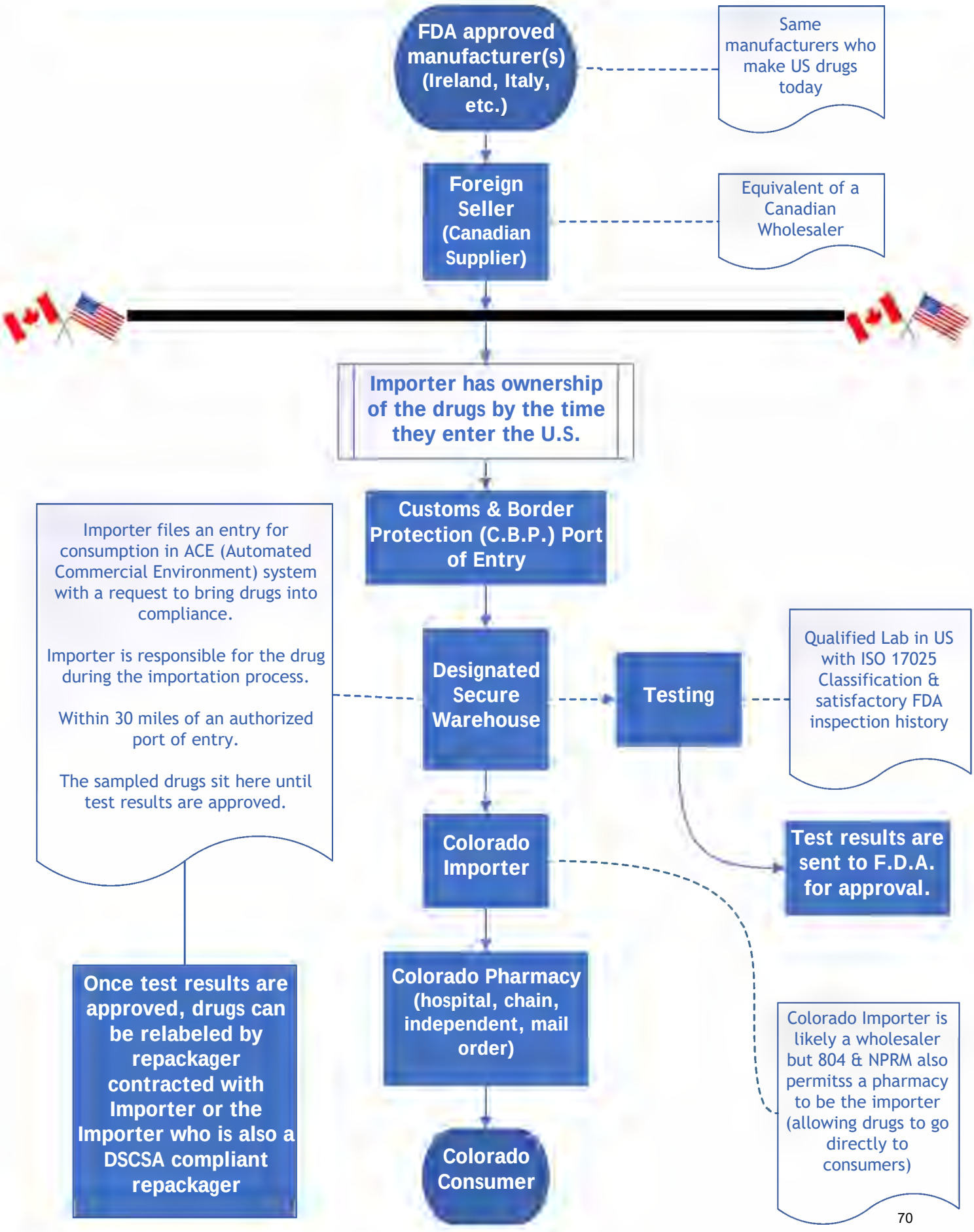
mail order pharmacies have been problematic for some of my patients due to delayed delivery and disagreement between insurance and pharmacy as to # of months supplied.

Safety and quality are very important. If Canadian drugs are not as safe or have the same quality, I would not put safety and quality over cost.
let all pharmacies do this! don't limit it.
I would like to see transparency on costs and the process. I am concerned that politics might interfere with successful execution of the program once HHS Sec approval and regulations are achieved. I would like visible accounting of the drugs selected and the average cost savings.
Get on it!
Only allow independent pharmacies to dispense them.
How can we be sure that the medications are not going to be counterfeit?
My spouse and I have both good and bad experiences with mail-order pharmaceuticals. The answer to question #13 would have to depend upon the mail-order pharmacy policies and procedures, and comparative local pharmacy choices.
My particular prescriptions are inexpensive. I am more concerned for my patients, and society in general.
Mail order pharmacies are problematic, as there is no real connection between the pharmacist and the customer.

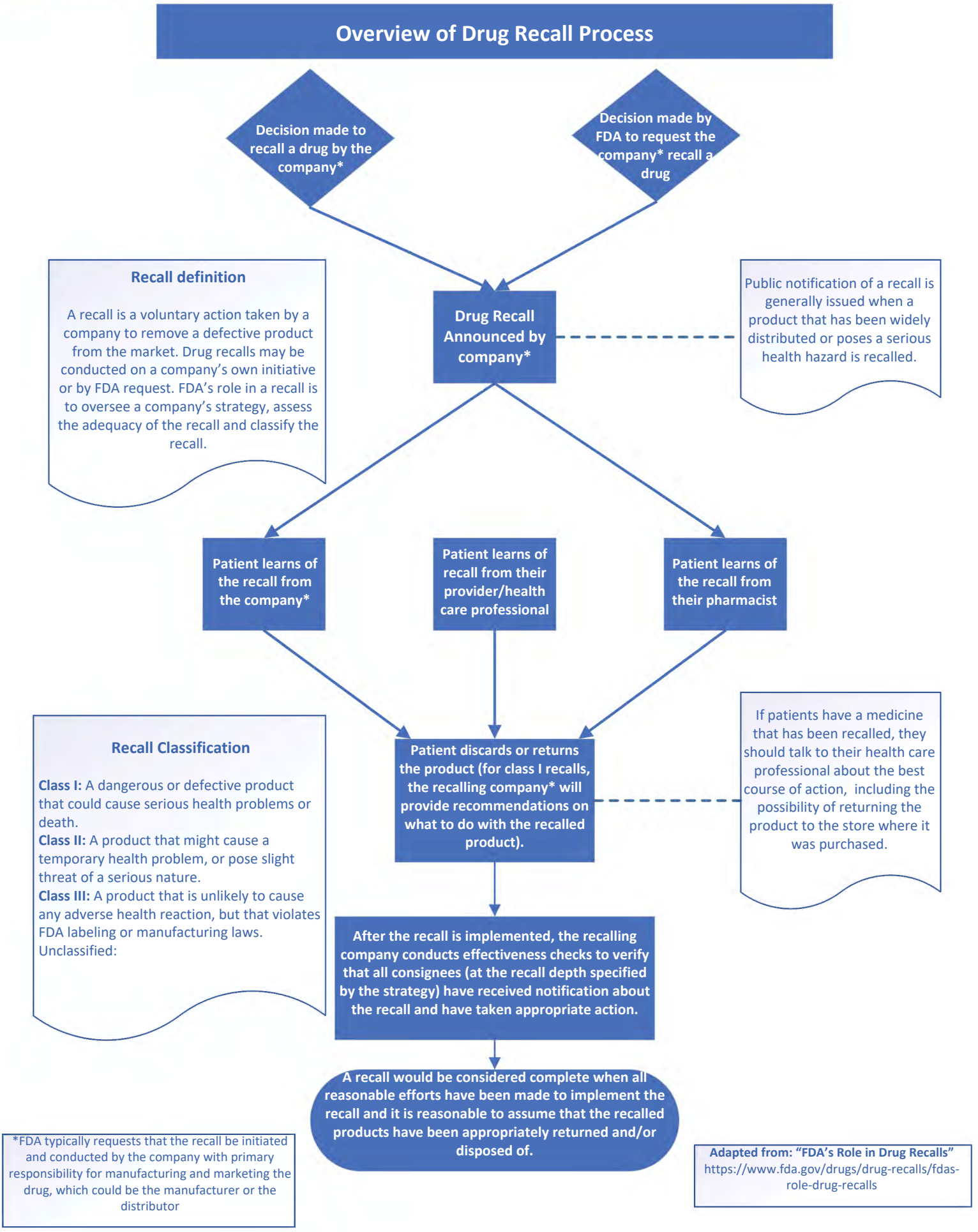
Colorado/Canadian Drug Importation NPRM Pathway #1



Colorado/Canadian Drug Importation NPRM Pathway #2



Appendix H - Drug Recalls Process Map



Appendix I - Adverse Events Reporting Process Map

Adverse Event Reporting Overview by Consumers, Health Care Professionals, and Industry

Industry Pathway (Mandatory)

Drug manufacturers, packers & distributors, and applicants with FDA-approved drug applications, and firms who market prescription drugs without an FDA-approved application.

Use Medwatch form FDA3500A

Non-Industry Pathway (Voluntary)

Healthcare professionals, etc. report to the FDA

Use Medwatch form FDA3500

Non-Industry Pathway (Voluntary)

Consumers report to the FDA

Use Medwatch form FDA3500B

Report goes into FAERS

Based on FDA's evaluation of potential safety concerns, FDA may take regulatory action.

What is FAERS?

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

What to report in MedWatch:

Report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use/medication error, product quality problems, and therapeutic failures for:

- **Prescription**
- **Over-the-counter medicines**
- **Biologics**
- **Medical devices**
- **Combination products**

What happens to a report?

A report may be critical in notifying the FDA of new or potential safety information. When problems with FDA-regulated products occur, the agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the agency to take prompt action. The agency evaluates each report to determine how serious the problem is, and, if necessary, may request additional information from the person who filed the report before taking action.

Adapted from: FDA website regarding FAERS and Medwatch

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.faqs
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers

COLORADO
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Appendix J - Colorado's Draft Drug Importation List
Summary of Savings

SAVINGS AT 15 PERCENT REPLACEMENT*				
SAVINGS ESTIMATES ON TOP 168 DRUGS ON DRAFT LIST				
	CO Price	**Importation Price****	**Estimated Savings**	**Percent Savings**
CIVHC Commercial Data	$39,917,194	$15,002,942	$24,914,252	**61%**
Self-funded (ASO) Data	$19,344,486	$8,078,507	$11,265,979	
TOTAL COMMERCIAL	$59,261,680	$23,081,449	$36,180,231	

SAVINGS AT 25 PERCENT REPLACEMENT*				
SAVINGS ESTIMATES ON TOP 168 DRUGS ON DRAFT LIST				
	CO Price	**Importation Price****	**Estimated Savings**	**Percent Savings**
CIVHC Commercial Data	$66,528,656	$25,004,903	$41,523,754	**61%**
Self-funded (ASO) Data	$32,240,810	$13,464,178	$18,776,632	
TOTAL COMMERCIAL	$98,769,467	$38,469,081	$60,300,386	

SAVINGS AT 100 PERCENT REPLACEMENT*				
SAVINGS ESTIMATES ON TOP 168 DRUGS ON DRAFT LIST				
	CO Price	**Importation Price****	**Estimated Savings**	**Percent Savings**
CIVHC Commercial Data	$266,114,625	$100,019,610	$166,095,014	**61%**
Self-funded (ASO) Data	$128,963,241	$53,856,713	$75,106,528	
TOTAL COMMERCIAL	$395,077,866	$153,876,324	$241,201,542	

* Replacement (market shift) assumes that a percentage of Colorado's drug supply will be replaced by imported drugs.
**The Importation Price is the Canadian (provincial) price, as of February 5, 2020, converted to USD and including a 45% markup for the costs of the supply chain.

COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Importation Drug List

Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Adcirca	20mg	Pulmonary Hypertension	$13.23	$61.09	14450	7781	22231	$1,310,544.97	$294,221.45	$1,016,323.52	78%
Advair Diskus	250/50	Respiratory	$1.64	$4.54	1848883	995552	2844435	$12,461,754.45	$4,675,557.91	$7,786,196.54	62%
Advair Diskus	500/50	Respiratory	$2.33	$5.12	946340	509568	1455908	$7,193,348.08	$3,397,232.90	$3,796,115.18	53%
Advair Diskus	100/50	Respiratory	$1.37	$4.67	567013	305315	872328	$3,931,190.04	$1,198,311.61	$2,732,878.43	70%
Afinitor	10mg	Cancer	$202.28	$543.12	3097	1668	4765	$2,497,186.38	$963,762.58	$1,533,423.80	61%
Afinitor	5mg	Cancer	$202.28	$556.65	938	505	1443	$775,173.66	$291,898.38	$483,275.28	62%
Alecensa	150mg	Cancer	$45.86	$65.32	27862	15003	42865	$2,702,089.48	$1,965,607.41	$736,482.07	27%
Anoro Ellipta	62.5-25 mcg	Respiratory	$2.28	$6.64	123670	66591	190261	$1,218,915.82	$434,509.22	$784,406.59	64%
Apri 28 Day	.15mg	Contraceptive	$0.30	$0.41	683365	367966	1051330	$416,437.27	$317,271.78	$99,165.49	24%
Aptiom	800mg	Anticonvulsant	$10.40	$30.59	3859	2078	5937	$175,252.94	$61,720.81	$113,532.13	65%
Atripla	600, 200, 300mg	HIV	$42.25	$83.93	18161	9779	27940	$2,262,853.44	$1,180,343.76	$1,082,509.68	48%
Aubagio	14mg	Multiple Sclerosis	$55.42	$238.86	26592	14319	40910	$9,429,588.46	$2,267,101.46	$7,162,487.00	76%
Banzel	400mg	Anticonvulsant	$3.40	$23.77	19129	10300	29430	$675,060.08	$100,168.19	$574,891.88	85%
Breo Ellipta	100/25	Respiratory	$2.98	$5.65	362505	195195	557700	$3,041,962.54	$1,661,807.92	$1,380,154.62	45%
Breo Ellipta	200/25	Respiratory	$4.24	$5.63	338917	182494	521410	$2,835,285.24	$2,209,541.34	$625,743.89	22%
Brilinta	90mg	Anticoagulant	$1.61	$6.01	146243	78746	224989	$1,304,488.99	$362,120.54	$942,368.45	72%
Cayston	75mg	Antibiotic	$46.11	$103.15	7151	3851	11002	$1,095,105.71	$507,298.69	$587,807.02	54%
Climara	0.05mg/day	Menopause	$5.71	$12.93	17342	9338	26680	$332,810.12	$152,398.66	$180,411.46	54%
Climara	0.025mg/day	Menopause	$5.35	$12.79	8974	4832	13806	$170,394.76	$73,832.29	$96,562.47	57%
Combivent Respimat	20mcg/20mcg	Respiratory	$32.63	$95.98	7151	3850	11001	$1,018,931.27	$358,900.35	$660,030.92	65%
Complera	200/25/300mg	HIV	$42.65	$72.66	3148	1695	4843	$339,596.85	$206,586.30	$133,010.55	39%
Copaxone	20mg	Multiple Sclerosis	$46.98	$238.08	3057	1646	4703	$1,080,602.09	$220,966.43	$859,635.66	80%
Cuprimine	250mg	Wilson's Disease	$0.92	$262.15	1260	678	1938	$490,376.98	$1,791.87	$488,585.12	100%
Dexilant	60mg	GERD	$0.39	$8.97	204298	110006	314304	$2,720,294.99	$124,007.05	$2,596,287.94	95%
Dexilant	30mg	GERD	$0.39	$9.07	26816	14440	41256	$361,264.41	$16,277.26	$344,987.15	95%
Diclegis Dr	10/10mg	Morning Sickness	$1.38	$6.80	29019	15625	44644	$292,812.44	$61,755.85	$231,056.59	79%
Dificid	200mg	C.diff	$86.13	$185.64	1710	921	2631	$471,240.97	$226,573.69	$244,667.28	52%
Dulera	200/5mg	Respiratory	$8.03	$29.90	36123	19451	55574	$1,603,521.97	$446,302.09	$1,157,219.88	72%
Dulera	100/5mg	Respiratory	$6.53	$26.91	23714	12769	36484	$947,433.36	$238,057.00	$709,376.36	75%
Eliquis	5mg	Anticoagulant	$1.74	$6.93	825823	444674	1270496	$8,495,548.60	$2,210,663.66	$6,284,884.94	74%
Eliquis	2.5mg	Anticoagulant	$1.74	$6.87	104820	56442	161262	$1,069,174.13	$280,595.05	$788,579.08	74%
Elmiron	100mg	Bladder pain	$1.43	$8.92	129504	69733	199236	$1,714,586.48	$284,703.88	$1,429,882.60	83%
Enstilar	0.005/0.064%	Psoriasis	$1.53	$16.71	22337	12028	34365	$554,157.54	$52,458.00	$501,699.55	91%
Entresto	24/26mg	Heart Failure	$3.94	$7.93	34162	18395	52557	$401,980.00	$206,902.86	$195,077.14	49%

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Importation Drug List

Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Entresto	49/51mg	Heart Failure	$3.94	$8.00	19769	10645	30413	$234,657.68	$119,729.31	$114,928.37	49%
Entresto	97/103mg	Heart Failure	$3.94	$7.88	18628	10030	28658	$218,038.77	$112,820.74	$105,218.03	48%
Epi Pen	0.3mg/0.3mL	Anaphylaxis	$88.09	$267.30	829	446	1275	$328,919.36	$112,324.09	$216,595.27	66%
Epi Pen Jr	0.15mg/0.3mL	Anaphylaxis	$88.09	$259.19	642	346	988	$247,029.00	$86,998.86	$160,030.14	65%
Erivedge	150mg	Cancer	$319.97	$402.01	702	378	1080	$418,977.54	$345,565.62	$73,411.92	18%
Estring		Menopause	$68.26	$439.16	2643	1423	4066	$1,723,072.29	$277,546.88	$1,445,525.41	84%
Farxiga	10mg	Diabetes	$2.66	$15.18	98295	52928	151223	$2,215,380.43	$402,914.28	$1,812,466.15	82%
Farxiga	5mg	Diabetes	$2.66	$15.24	34596	18629	53225	$782,657.67	$141,812.15	$640,845.52	82%
Finacea	15%	Inflammation	$0.65	$6.83	24312	13091	37403	$246,372.15	$24,405.33	$221,966.82	90%
Firazyr	10mg/1mL / 30mg/3mL	Hereditary Angioedema	$2,936.25	$3,699.59	1074	578	1652	$5,898,916.36	$4,851,588.46	$1,047,327.90	18%
Forteo	250 mcg/mL	Osteoporosis	$880.58	$1,526.19	2405	1295	3700	$5,449,943.89	$3,258,561.51	$2,191,382.38	40%
Genvoya	150, 150, 200, 10mg	HIV	$47.63	$92.79	234760	126409	361169	$32,340,301.82	$17,203,517.07	$15,136,784.75	47%
Gilenya	0.5mg	Multiple Sclerosis	$92.62	$256.06	61793	33273	95066	$23,490,701.76	$8,804,699.25	$14,686,002.51	63%
Gleevec	400mg	Cancer	$115.36	$334.84	2301	1239	3539	$1,143,658.53	$408,290.08	$735,368.45	64%
Gleevec	100mg	Cancer	$28.84	$94.13	1050	565	1615	$146,727.02	$46,585.69	$100,141.33	68%
Glucagon Kit	1mg	Hypoglycemia	$93.17	$284.48	3032	1632	4664	$1,280,440.46	$434,541.38	$845,899.09	66%
Ibrance	125mg	Cancer	$276.13	$591.34	7890	4249	12139	$6,926,988.85	$3,351,901.30	$3,575,087.55	52%
Ibrance	100mg	Cancer	$276.13	$570.00	5571	3000	8571	$4,714,677.28	$2,366,823.26	$2,347,854.02	50%
Ibrance	75mg	Cancer	$276.13	$592.79	1743	939	2682	$1,534,276.14	$740,613.19	$793,662.95	52%
Imbruvica	140mg	Cancer	$98.58	$137.05	11063	5957	17020	$2,250,951.81	$1,677,864.75	$573,087.06	25%
Incruse Ellipta	62.5mcg	Respiratory	$1.81	$10.57	41754	22483	64237	$655,225.42	$116,430.28	$538,795.15	82%
Inlyta	5mg	Cancer	$101.14	$251.37	450	242	692	$167,934.50	$70,020.00	$97,914.50	58%
Intelence	200mg	HIV	$11.85	$22.02	11129	5993	17122	$363,781.19	$202,961.99	$160,819.19	44%
Invokana	300mg	Diabetes	$2.85	$15.39	94019	50626	144645	$2,148,185.56	$411,768.41	$1,736,417.16	81%
Invokana	100mg	Diabetes	$2.85	$15.47	51992	27995	79987	$1,194,268.93	$227,703.11	$966,565.82	81%
Isentress	400mg	HIV	$12.51	$25.14	61537	33136	94673	$2,296,911.68	$1,184,003.54	$1,112,908.13	48%
Jadenu	360mg	Iron Overload	$47.39	$167.95	4241	2284	6525	$1,057,440.17	$309,173.06	$748,267.11	71%
Jakafi	10mg	Myelofibrosis	$89.38	$211.63	4581	2467	7048	$1,439,267.02	$629,947.99	$809,319.03	56%
Jakafi	20mg	Myelofibrosis	$89.38	$221.06	4080	2197	6277	$1,338,998.10	$561,053.87	$777,944.23	58%
Jakafi	5mg	Myelofibrosis	$89.38	$224.02	3590	1933	5523	$1,193,950.73	$493,672.40	$700,278.33	59%
Jakafi	15mg	Myelofibrosis	$89.38	$222.29	2960	1594	4554	$976,854.89	$407,039.08	$569,815.81	58%
Janumet	50/1000mg	Diabetes	$1.49	$6.90	112081	60351	172432	$1,148,420.18	$256,902.41	$891,517.76	78%
Janumet	50/500mg	Diabetes	$1.49	$7.01	21164	11396	32560	$220,312.47	$48,509.80	$171,802.67	78%
Janumet XR	50/1000mg	Diabetes	$1.49	$7.07	38908	20950	59858	$408,219.82	$89,181.06	$319,038.76	78%

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

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Janumet XR	100/1000mg	Diabetes	$2.98	$14.55	11030	5939	16969	$238,267.29	$50,563.04	$187,704.25	79%
Januvia	100mg	Diabetes	$2.85	$14.08	217062	116879	333941	$4,538,628.93	$950,646.53	$3,587,982.40	79%
Januvia	50mg	Diabetes	$2.85	$14.11	22948	12356	35304	$480,559.33	$100,502.12	$380,057.20	79%
Jardiance	25mg	Diabetes	$2.85	$15.06	216910	116798	333708	$4,850,621.89	$949,982.22	$3,900,639.67	80%
Jardiance	10mg	Diabetes	$2.85	$14.99	119360	64271	183631	$2,655,868.31	$522,752.46	$2,133,115.85	80%
Jentadueto	2.5/1000mg	Diabetes	$1.29	$6.76	30906	16642	47548	$310,383.10	$61,206.90	$249,176.21	80%
Keppra	500mg	Epilepsy	$1.06	$7.50	16469	8868	25337	$183,368.65	$26,865.40	$156,503.25	85%
Kombiglyze XR	2.5/1000mg	Diabetes	$1.38	$6.61	21410	11528	32938	$209,953.68	$45,492.13	$164,461.55	78%
Kuvan	100mg	Hyperphenylalaninemia	$35.89	$38.67	19623	10566	30190	$1,126,674.29	$1,083,441.10	$43,233.19	4%
Lamictal	100mg	Epilepsy	$1.56	$11.94	40022	21550	61573	$709,377.23	$95,820.21	$613,557.02	86%
Lamictal	150mg	Epilepsy	$2.28	$11.95	19355	10422	29777	$343,325.24	$67,911.76	$275,413.48	80%
Latuda	40mg	Schizophrenia, bipolar	$3.88	$40.21	44226	23814	68040	$2,639,821.10	$264,156.70	$2,375,664.40	90%
Latuda	20mg	Schizophrenia, bipolar	$3.88	$39.74	33722	18158	51880	$1,989,392.25	$201,418.83	$1,787,973.41	90%
Latuda	80mg	Schizophrenia, bipolar	$3.88	$40.14	31826	17137	48964	$1,896,691.51	$190,094.72	$1,706,596.79	90%
Latuda	60mg	Schizophrenia, bipolar	$3.88	$40.82	30964	16673	47638	$1,876,699.96	$184,947.05	$1,691,752.91	90%
Latuda	120mg	Schizophrenia, bipolar	$3.88	$60.64	15747	8479	24226	$1,417,753.19	$94,055.51	$1,323,697.69	93%
Lonsurf	20/8.19mg	Cancer	$82.92	$218.94	2683	1444	4127	$871,960.46	$342,222.64	$529,737.82	61%
Lumigan	0.01%	Inflammation	$58.78	$71.16	6280	3381	9661	$663,446.01	$567,859.57	$95,586.43	14%
Myrbetriq ER	50mg	Overactive Bladder	$1.59	$11.96	28554	15375	43929	$506,989.28	$69,748.06	$437,241.22	86%
Myrbetriq ER	25mg	Overactive Bladder	$1.59	$11.39	22219	11964	34183	$375,881.07	$54,274.03	$321,607.04	86%
Nexavar	200mg	Cancer	$50.03	$160.64	3350	1804	5154	$798,946.10	$257,870.48	$541,075.62	68%
Noxafil	100mg	Antifungal	$50.81	$67.96	26453	14244	40697	$2,668,974.67	$2,067,884.61	$601,090.06	23%
Nuvaring		Contraceptive	$16.01	$154.70	44576	24002	68578	$10,237,567.86	$1,097,798.68	$9,139,769.18	89%
Ofev	100mg	Pulmonary Fibrosis	$29.56	$155.99	1920	1034	2954	$444,635.88	$87,310.52	$357,325.36	80%
Onglyza	5mg	Diabetes	$2.50	$13.06	36178	19480	55658	$701,705.69	$139,215.73	$562,489.96	80%
Otezla	30mg	Psoriasis	$20.56	$53.07	107499	57884	165383	$8,469,045.72	$3,399,986.47	$5,069,059.25	60%
Otezla	10, 20, 30mg kit	Psoriasis	$20.56	$56.85	2425	1306	3731	$204,680.84	$76,695.04	$127,985.80	63%
Portia 28	0.03/0.15mg	Contraceptive	$0.28	$0.91	1015631	546878	1562510	$1,364,918.77	$441,799.60	$923,119.17	68%
Premarin	0.625mg	Menopause	$0.38	$5.25	22741	12245	34986	$177,405.91	$13,438.16	$163,967.75	92%
Premarin Cream	0.625mg/g	Menopause	$0.68	$10.82	95396	51367	146763	$1,531,806.36	$100,231.46	$1,431,574.90	93%
Prezcobix	800/150mg	HIV	$27.39	$53.88	20084	10814	30898	$1,606,514.04	$846,322.52	$760,191.51	47%
Prezista	800mg	HIV	$21.30	$48.21	21270	11453	32723	$1,522,258.07	$697,083.64	$825,174.43	54%
Prezista	600mg	HIV	$18.69	$23.11	10376	5587	15963	$355,975.73	$298,382.13	$57,593.60	16%
Prograf	1mg	Transplant	$2.72	$6.16	55208	29728	84936	$505,199.29	$230,873.17	$274,326.13	54%

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Importation Drug List

Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Relpax	40mg	Migraines	$14.35	$52.36	2380	1282	3662	$185,034.52	$52,552.74	$132,481.77	72%
Retin-A	0.025%	Acne	$0.39	$1.71	212957	114669	327626	$541,409.40	$126,840.23	$414,569.18	77%
Retin-A	0.05%	Acne	$0.38	$1.96	121900	65638	187538	$353,932.77	$70,423.27	$283,509.50	80%
Revatio	20mg	Pulmonary Hypertension	$11.63	$48.29	3960	2132	6092	$283,925.45	$70,873.06	$213,052.38	75%
Rexulti	3mg	Schizophrenia, MDD	$3.81	$38.82	2835	1527	4362	$163,388.90	$16,617.46	$146,771.44	90%
Rexulti	2mg	Schizophrenia, MDD	$3.81	$35.66	17034	9172	26206	$901,733.43	$99,744.83	$801,988.60	89%
Rexulti	1mg	Schizophrenia, MDD	$3.81	$36.75	13503	7271	20774	$736,624.93	$79,069.97	$657,554.96	89%
Rexulti	0.5mg	Schizophrenia, MDD	$3.81	$37.18	4648	2503	7150	$256,523.92	$27,215.54	$229,308.38	89%
Sabril	500mg	Epilepsy	$0.96	$140.15	1170	630	1800	$243,433.36	$1,736.30	$241,697.06	99%
Sensipar	30mg	Hyperparathyroidism	$11.73	$24.75	5493	2958	8450	$201,859.69	$99,103.14	$102,756.55	51%
Sensipar	60mg	Hyperparathyroidism	$21.38	$51.94	1989	1071	3060	$153,385.53	$65,424.56	$87,960.97	57%
Serevent diskus	50mcg	Respiratory	$0.95	$6.16	18617	10024	28641	$170,169.41	$27,326.52	$142,842.89	84%
Spiriva Handihaler	18mcg	Respiratory	$1.88	$12.84	95562	51457	147019	$1,822,025.20	$276,598.02	$1,545,427.18	85%
Sprycel	100mg	Cancer	$159.14	$442.91	9733	5241	14974	$6,400,114.97	$2,383,038.23	$4,017,076.74	63%
Sprycel	50mg	Cancer	$79.57	$253.52	947	510	1457	$356,425.62	$115,928.93	$240,496.69	67%
Sprycel	70mg	Cancer	$87.75	$251.66	690	372	1062	$257,796.42	$93,151.32	$164,645.10	64%
Stivarga	40mg	Cancer	$78.97	$208.51	3304	1779	5083	$1,022,791.86	$401,432.19	$621,359.67	61%
Stribild	150/150/200/300mg	HIV	$47.85	$102.92	5994	3228	9222	$915,865.10	$441,251.14	$474,613.95	52%
Sutent	50mg	Cancer	$274.71	$633.58	448	241	689	$421,397.73	$189,340.09	$232,057.64	55%
Sutent	25mg	Cancer	$137.36	$367.26	623	335	958	$339,506.92	$131,581.77	$207,925.15	61%
Synthroid	100mcg	Hypothyroidism	$0.07	$1.18	263066	141651	404717	$459,902.57	$27,288.07	$432,614.50	94%
Synthroid	75mcg	Hypothyroidism	$0.09	$1.17	245550	132219	377769	$425,850.79	$34,344.89	$391,505.90	92%
Synthroid	50mcg	Hypothyroidism	$0.05	$1.18	221186	119100	340286	$386,852.91	$17,318.87	$369,534.04	96%
Synthroid	112mcg	Hypothyroidism	$0.10	$1.19	221658	119354	341012	$390,846.51	$32,783.16	$358,063.35	92%
Synthroid	125mcg	Hypothyroidism	$0.10	$1.19	216372	116508	332880	$382,517.94	$32,544.40	$349,973.54	91%
Synthroid	88mcg	Hypothyroidism	$0.09	$1.19	208644	112347	320991	$370,033.79	$29,182.93	$340,850.87	92%
Tagrisso	80mg	Cancer	$320.46	$509.47	7305	3933	11238	$5,525,245.94	$3,601,470.31	$1,923,775.63	35%
Tagrisso	40mg	Cancer	$320.46	$511.02	390	210	600	$295,879.88	$192,276.35	$103,603.53	35%
Tarceva	150mg	Cancer	$87.00	$281.56	1605	864	2469	$670,897.14	$214,823.08	$456,074.07	68%
Tarceva	100mg	Cancer	$58.00	$264.81	665	358	1023	$261,441.35	$59,338.42	$202,102.92	77%
Tasigna	150mg	Cancer	$29.66	$118.49	14338	7720	22058	$2,522,076.66	$654,257.81	$1,867,818.85	74%
Tasigna	200mg	Cancer	$38.33	$119.15	8598	4630	13227	$1,520,862.14	$506,948.12	$1,013,914.01	67%
Tecfidera	240mg	Multiple Sclerosis	$27.71	$125.49	106817	57517	164334	$19,900,768.63	$4,553,528.12	$15,347,240.52	77%
Tivicay	50mg	HIV	$20.12	$48.07	127927	68884	196811	$9,128,830.10	$3,959,596.04	$5,169,234.06	57%
Tracleer	125mg	Pulmonary Hypertension	$69.79	$189.04	2705	1456	4161	$759,089.43	$290,428.66	$468,660.77	62%

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COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Importation Drug List

Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Tradjenta	5mg	Diabetes	$2.45	$13.24	114441	61622	176064	$2,249,715.16	$430,805.69	$1,818,909.47	81%
Triumeq	600/50/300mg	HIV	$44.12	$87.50	98177	52865	151042	$12,752,982.07	$6,663,347.29	$6,089,634.78	48%
Truvada	200/300mg	HIV (PrEP)	$28.39	$53.87	378909	204028	582937	$30,304,085.00	$16,547,200.25	$13,756,884.75	45%
Uloric	80mg	Gout	$1.73	$10.89	24202	13032	37234	$391,254.07	$64,381.93	$326,872.14	84%
Uptravi	1200mcg	Pulmonary Hypertension	$69.78	$292.34	1260	678	1938	$546,850.76	$135,268.34	$411,582.42	75%
Uptravi	400mcg	Pulmonary Hypertension	$69.78	$288.49	540	291	831	$231,278.97	$57,972.15	$173,306.82	75%
Uptravi	200mcg	Pulmonary Hypertension	$69.78	$185.10	938	505	1443	$257,761.25	$100,699.76	$157,061.49	61%
Vesicare	10mg	Overactive Bladder	$1.63	$11.42	17903	9640	27543	$303,631.42	$44,929.90	$258,701.51	85%
Victoza	6mg/mL	Diabetes	$74.48	$94.31	59460	32017	91477	$8,325,466.89	$6,813,488.14	$1,511,978.76	18%
Vimovo DR	500/20mg	Arthritis Pain	$1.00	$41.80	3360	1809	5169	$208,535.30	$5,171.82	$203,363.48	98%
Vimpat	100mg	Epilepsy	$3.61	$14.06	79711	42922	122633	$1,664,330.42	$442,766.31	$1,221,564.11	73%
Vivelle-Dot	0.05mg	Menopause	$2.91	$16.05	18256	9830	28086	$434,890.82	$81,857.10	$353,033.72	81%
Vivelle-Dot	0.1mg	Menopause	$3.25	$16.08	15779	8496	24275	$376,669.13	$78,802.45	$297,866.68	79%
Vivelle-Dot	0.0375mg	Menopause	$2.72	$16.01	10680	5751	16431	$253,778.57	$44,760.50	$209,018.07	82%
Vivelle-Dot	0.075mg	Menopause	$3.13	$16.10	9592	5165	14757	$229,257.81	$46,138.44	$183,119.37	80%
Wellbutrin XL	300mg	Depression	$1.15	$14.47	33221	17888	51109	$713,493.80	$58,615.79	$654,878.01	92%
Wellbutrin XL	150mg	Depression	$0.57	$13.83	12225	6583	18807	$251,064.84	$10,782.78	$240,282.06	96%
Xalkori	250mg	Cancer	$141.38	$300.42	1730	932	2662	$771,599.97	$376,275.00	$395,324.97	51%
Xarelto	20mg	DVT Treatment	$3.09	$13.79	564085	303738	867823	$11,546,088.45	$2,680,271.61	$8,865,816.84	77%
Xarelto	10mg	DVT Treatment	$3.09	$14.02	63897	34406	98303	$1,329,602.09	$303,609.35	$1,025,992.74	77%
Xarelto	15mg	DVT Treatment	$3.09	$13.98	53674	28901	82576	$1,114,222.63	$255,034.75	$859,187.87	77%
Xeljanz	5mg	Arthritis	$25.12	$65.81	46696	25144	71840	$4,562,549.99	$1,804,449.28	$2,758,100.71	60%
Xeloda	500mg	Cancer	$6.63	$45.63	11543	6215	17758	$782,024.14	$117,805.19	$664,218.94	85%
Xifaxan	550mg	Hepatic Encephalopathy	$8.35	$37.13	95911	51644	147555	$5,286,320.12	$1,231,981.45	$4,054,338.67	77%
Xigduo	5/1000mg	Diabetes	$1.33	$8.20	12654	6814	19468	$154,047.85	$25,892.03	$128,155.82	83%
Xtandi	40mg	Cancer	$30.83	$87.86	37699	20300	57999	$4,917,630.83	$1,787,829.09	$3,129,801.73	64%
Yasmin 28	3/0.03mg	Contraceptive	$0.46	$3.96	59976	32295	92271	$352,188.73	$42,431.37	$309,757.36	88%
Yaz 28	3/0.02mg	Contraceptive	$0.46	$4.80	114128	61454	175582	$814,013.37	$80,742.42	$733,270.94	90%
Zelboraf	240mg	Cancer	$37.12	$47.97	7073	3809	10882	$503,732.49	$403,948.35	$99,784.15	20%
Zomig	5mg	Migraines	$15.06	$73.99	3802	2047	5849	$417,576.74	$88,092.51	$329,484.23	79%
Zytiga	250mg	Cancer	$30.81	$86.22	33078	17811	50889	$4,234,059.97	$1,568,022.58	$2,666,037.39	63%
								$395,077,866.22	**$153,876,323.80**	**$241,201,542.41**	**61%**

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

Appendix K - Colorado's Draft Biologics Importation Analysis

Summary Savings

SAVINGS AT 15 PERCENT REPLACEMENT*				
TEN SELECTED BIOLIGICS				
	CO Price	Importation Price**	Estimated Savings	Percent Savings
CIVHC Commercial Data	$19,677,414	$5,505,396	$14,172,018	71%
Self-funded (ASO) Data	$9,535,977	$2,964,444	$6,571,533	
TOTAL COMMERCIAL	$29,213,391	$8,469,840	$20,743,551	

SAVINGS AT 25 PERCENT REPLACEMENT*				
TEN SELECTED BIOLIGICS				
	CO Price	Importation Price**	Estimated Savings	Percent Savings
CIVHC Commercial Data	$32,795,689	$9,175,660	$23,620,029	71%
Self-funded (ASO) Data	$15,893,296	$4,940,740	$10,952,556	
TOTAL COMMERCIAL	$48,688,985	$14,116,400	$34,572,585	

SAVINGS AT 100 PERCENT REPLACEMENT*				
TEN SELECTED BIOLIGICS				
	CO Price	Importation Price**	Estimated Savings	Percent Savings
CIVHC Commercial Data	$131,182,758	$36,702,640	$94,480,117	71%
Self-funded (ASO) Data	$63,573,183	$19,762,960	$43,810,222	
TOTAL COMMERCIAL	$194,755,940	$56,465,600	$138,290,340	

*Replacement (market shift) assumes that a percentage of Colorado's drug supply will be replaced by imported drugs.
**The Importation Price is the Canadian (provincial) price, as of February 5, 2020, converted to USD and including a 45% markup for the costs of the supply chain.

COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Biologics Importation Analysis

Drug Name	Dose	Indication	Canadian Unit Cost in USD with 45% Markup	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization in Units	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Cimzia	200mg/mL	Chronic Inflammatory Conditions	$687	$4,112	1199	645	1844	$7,317,396	$1,265,865	$6,051,531	83%
Enbrel	50mg/mL	Rheumatoid Arthritis	$391	$1,244	6369	3429	9798	$11,765,572	$3,828,422	$7,937,150	67%
Humalog	100U/mL	Diabetes	$3	$20	805078	433503	1238581	$23,896,173	$3,524,986	$20,371,186	85%
Humalog KwikPen	100U/mL	Diabetes	$4	$30	236334	127257	363590	$10,394,228	$1,355,973	$9,038,255	87%
Humira	40mg/0.8mL	Chronic Inflammatory Conditions	$777	$2,234	27656	14892	42548	$91,721,385	$33,048,893	$58,672,492	64%
Lantus	100U/mL	Diabetes	$6	$21	146652	78967	225619	$4,464,525	$1,424,809	$3,039,716	68%
Lantus Solostar	100U/mL	Diabetes	$6	$25	171898	92561	264459	$6,256,829	$1,689,547	$4,567,282	73%
Levemir	100U/mL	Diabetes	$7	$28	167672	90285	257957	$7,048,920	$1,845,686	$5,203,234	74%
Rebif	44mcg/0.5mL	Multiple Sclerosis	$475	$1,243	1438	774	2213	$2,653,756	$1,050,715	$1,603,041	60%
Stelara	90mg/mL	Chronic Inflammatory Conditions	$4,689	$19,119	1030	555	1585	$29,237,158	$7,430,705	$21,806,453	75%
								$194,755,940	**$56,465,600**	**$138,290,340**	**71%**

*APCD data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to the APCD and other sources). In order to derive a cost savings estimate for the self-funded lives not included in APCD data, we assumed similar utilization rates to APCD claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

COLORADO
Department of Health Care Policy & Financing

Colorado's Draft Insulin Analysis

Drug Name	Dose	Indication	Canadian Unit Cost in USD with 45% Markup	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization in Units	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Humalog	100U/mL	Diabetes	$3	$20	805078	433503	1238581	$23,896,173	$3,524,986	$20,371,186	85%
Humalog KwikPen	100U/mL	Diabetes	$4	$30	236334	127257	363590	$10,394,228	$1,355,973	$9,038,255	87%
Lantus	100U/mL	Diabetes	$6	$21	146652	78967	225619	$4,464,525	$1,424,809	$3,039,716	68%
Lantus Solostar	100U/mL	Diabetes	$6	$25	171898	92561	264459	$6,256,829	$1,689,547	$4,567,282	73%
Levemir	100U/mL	Diabetes	$7	$28	167672	90285	257957	$7,048,920	$1,845,686	$5,203,234	74%
								$52,060,674	**$9,841,001**	**$42,219,673**	**81%**

*APCD data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to the APCD and other sources). In order to derive a cost savings estimate for the self-funded lives not included in APCD data, we assumed similar utilization rates to APCD claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

Appendix L - Englarged Figure Library

Figure 1: High Level Process Map of Colorado's Proposed Importation Program

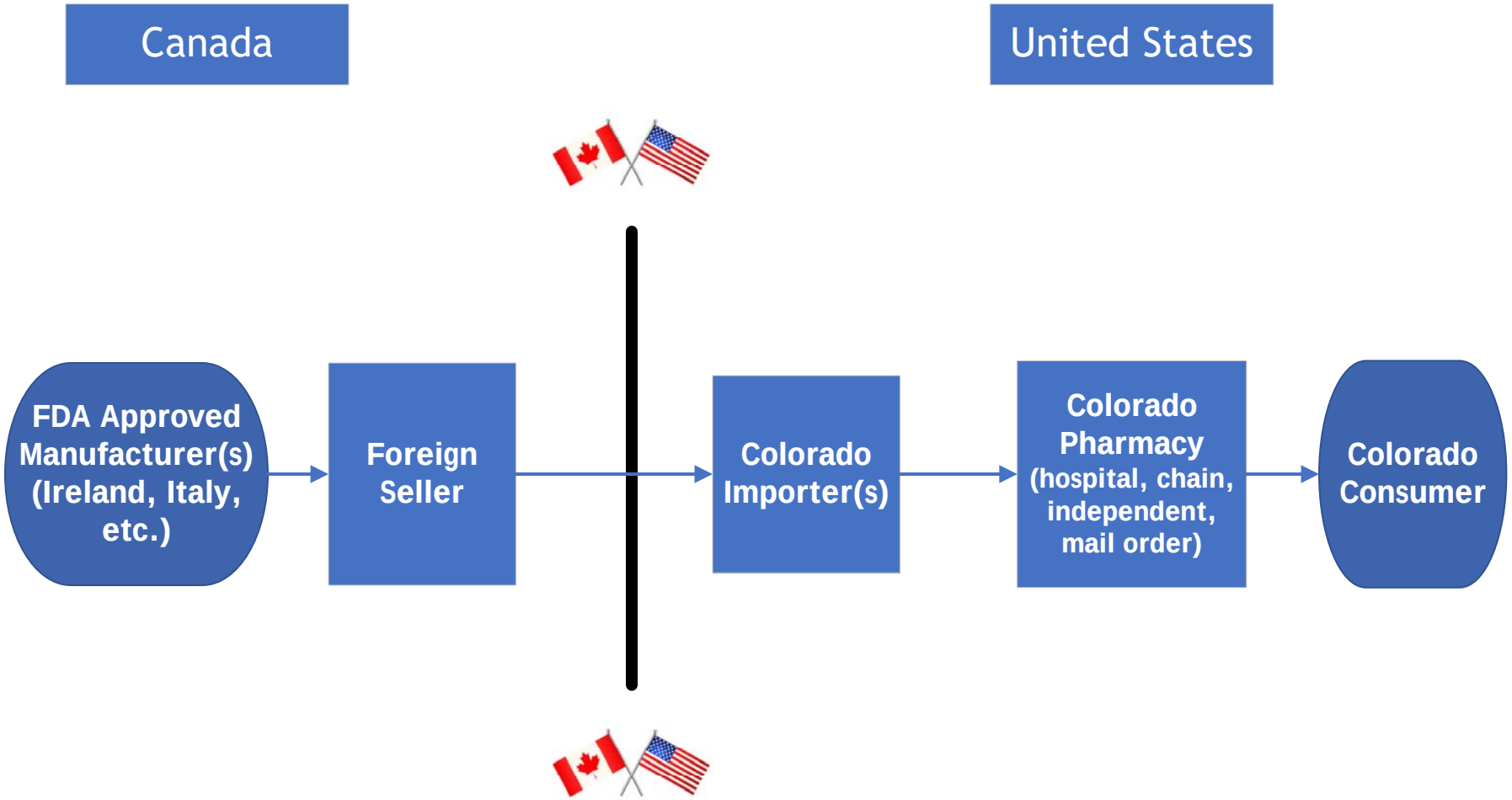


Figure 3::

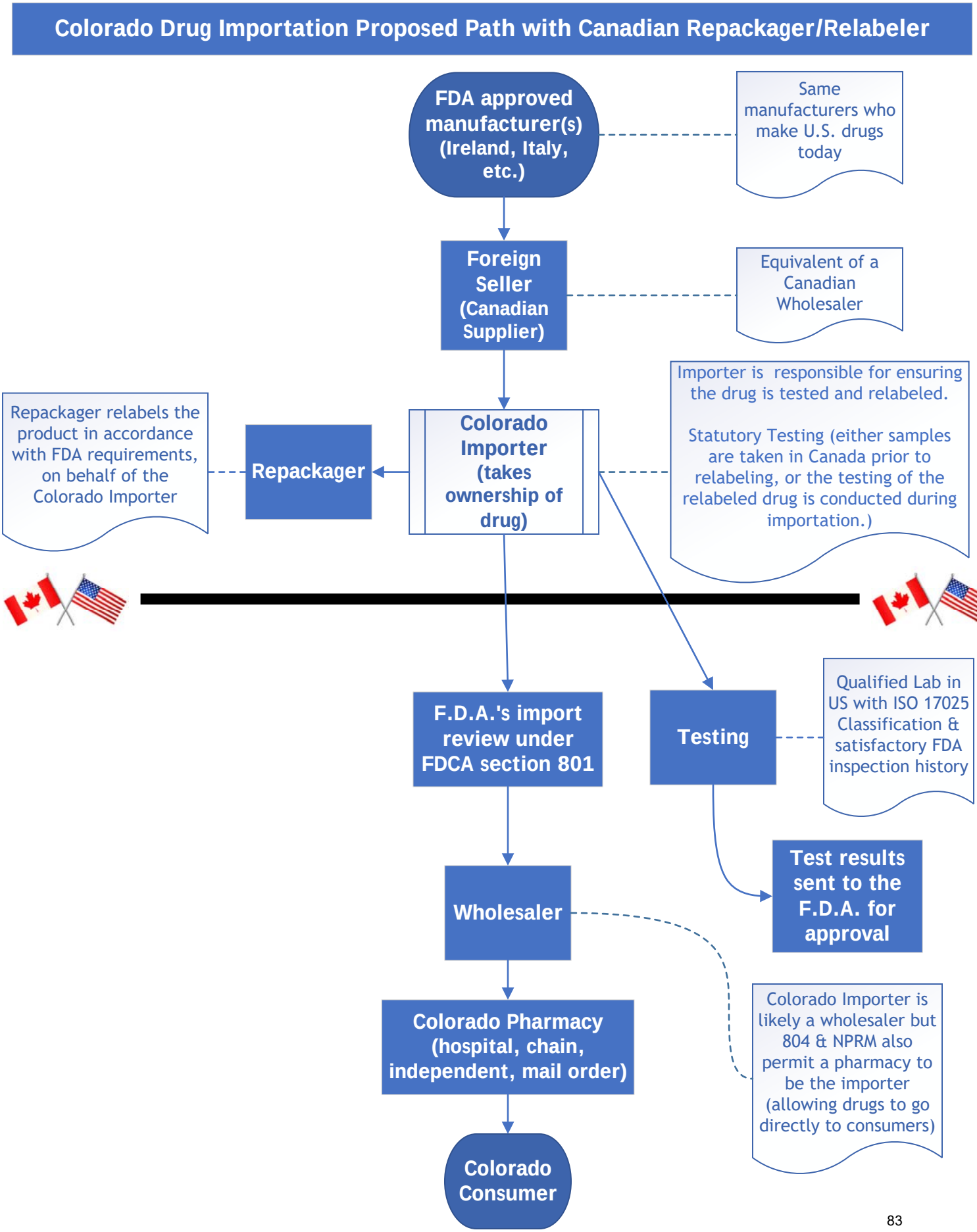
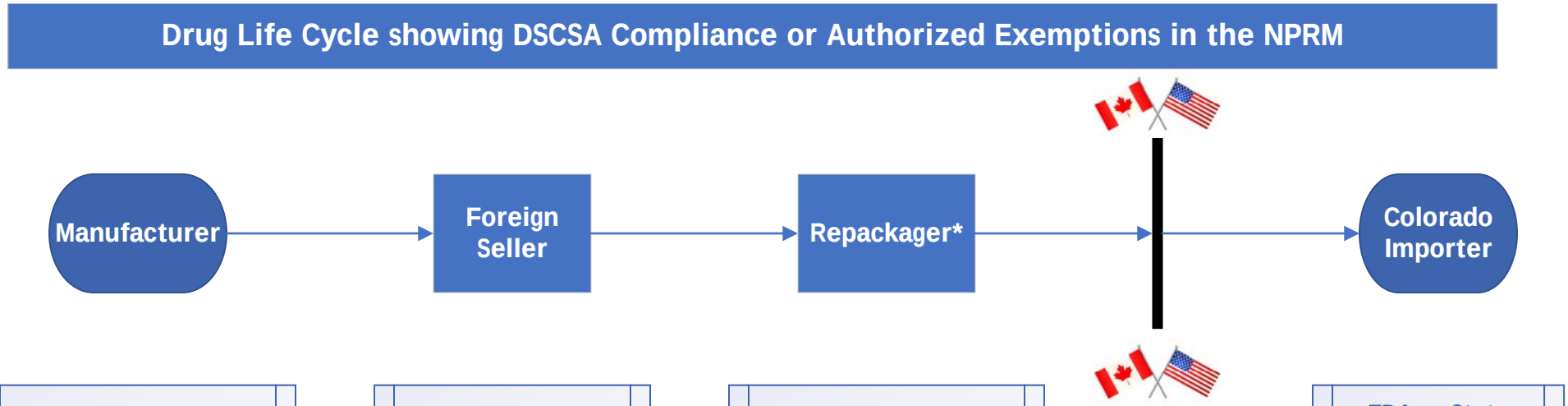

Colorado Drug Importation Proposed Path with Canadian Repackager/Relabeler
FDA approved manufacturer(s) (Ireland, Italy, etc.)
Same manufacturers who make U.S. drugs today
Foreign Seller (Canadian Supplier)
Equivalent of a Canadian Wholesaler
Importer is responsible for ensuring the drug is tested and relabeled.
Statutory Testing (either samples are taken in Canada prior to relabeling, or the testing of the relabeled drug is conducted during importation.)
Repackager relabels the product in accordance with FDA requirements, on behalf of the Colorado Importer
Repackager
Colorado Importer (takes ownership of drug)
F.D.A.'s import review under FDCA section 801
Testing
Qualified Lab in US with ISO 17025 Classification & satisfactory FDA inspection history
Test results sent to the F.D.A. for approval
Wholesaler
Colorado Pharmacy (hospital, chain, independent, mail order)
Colorado Importer is likely a wholesaler but 804 & NPRM also permit a pharmacy to be the importer (allowing drugs to go directly to consumers)
Colorado Consumer

Figure 4::


Drug Life Cycle showing DSCSA Compliance or Authorized Exemptions in the NPRM
Manufacturer
Foreign Seller
Repackager*
Colorado Importer
FDA Registered
1. Manufactures Drug in accordance with the requirements of the FDA approval and the FDCA (excluding U.S. labeling requirements)
2. Provides comprehensive documentation to the foreign seller about the sale of the specific drug from the manufacturer to the foreign seller, which third parties can use to verify the sale
Licensed through Canadian federal and provincial laws
1. New registration with the FDA
2. Assigns and affixes unique SSI
3. Provides comparable T3 data as described by DSCSA sections 581(25-27) (with SSI instead of DSCSA product identifier)
FDA Registered
Authorized Trading Partner
Relabels with FDA required/US labeling standards on behalf of the Colorado Importer (or Foreign Seller if Final Rule will allow)
• Places DSCSA-required product identifier (PI) if not completed by the manufacturer
• Places NDC unique to imported drug
FDA or State Registered
Authorized Trading Partner
1. Maintains records linking SSI and PI for the drug
2. Responsible for testing for authenticity and degradation as required by FDCA 804 and NPRM (a requirement that applies only to drugs imported under a SIP)
* If the Final Rule does not permit drugs to be relabeled in Canada, the steps described would happen in the U.S.