

REPORT AND RECOMMENDATION OF HEARING OFFICER

Public Hearing: Department of Health
Subject Matter: Public Hearing on Proposed Wholesale Drug Importation Program.
Hearing Date: December 2, 2020
Report Date: December 10, 2020

REPORT OF HEARING OFFICER

A public hearing was held on Wednesday, December 2, 2020 via Cisco Webex and telephone at 9:30 a.m. The hearing was held for the purpose of considering the Department of Health's ("DOH" or "the Department") proposed Wholesale Prescription Drug Importation Program ("Importation Program" or "Program"). Craig T. Erickson presided as Hearing Officer. The DOH was represented by Shelley Strong, Assistant General Counsel.

There were 34 other participants in the hearing. They are identified below in the sections of this Report related to the DOH's introductory remarks and the summary of public comments.

The proceeding was recorded via Cisco Webex and an electronic audio device monitored by Ms. Strong. Both recordings are in the possession of the DOH, Office of General Counsel.

The Hearing Officer opened the proceeding by introducing himself and Shelley Strong. The Hearing Officer then explained that the purpose of this public hearing was to give the public an opportunity to comment on the proposed Wholesale Prescription Drug Importation Program.

The Hearing Officer further stated that, pursuant to Notice, this matter was being heard on the 2nd day of December 2020 via Cisco Webex online, and via telephone. He also stated that pursuant to notice, the public has been given the opportunity to comment on the proposed rule via Cisco Webex and telephonically, and through the submission of written comments. The opportunity was also given to the public to submit written comments via email messages, through the close of business on December 2, 2020.

The Hearing Officer also stated that this proceeding was being held in accordance with NMSA 1978, § 26-4-4 of the Wholesale Prescription Drug Importation Act.

The Hearing Officer also explained that after his opening remarks, the Department would provide a brief introduction to the proposed Program, introduce the Department's Exhibits, and move for admission of the Department's Exhibits into the record. The public would then be provided the opportunity to make public comment.

There were two representatives of the DOH who offered introductory remarks about the Importation Program: Aryan Showers and Courtney Lovato. Their remarks are summarized below.

Introductory Remarks by Aryan Showers

Aryan Showers is the Policy Director of the DOH Office of Policy and Accountability. She began by thanking representatives of the Department and participants in the public hearing for their contributions to this process. She stated that this Program is a “work-in-progress” and a labor of love.

Ms. Showers stated that this process began with the passage of Senate Bill 1 in the 2020 session. She stated that this bill was passed unanimously by both chambers of the legislature. It was intended to provide states with a pathway to provide safe and more affordable medications from one of the world’s countries that have low priced drugs. SB1 did not specify that the drugs could only come from Canada. It allowed for drugs coming from other countries, to provide some flexibility with federal laws that might evolve in the future. The intention here is to reduce consumer costs and to reduce state costs.

Ms. Showers stated that additional features of SB1 include the following:

- Certain types of drugs are excluded from SB1—those that are controlled substances. Federal law excludes other categories of drugs.
- Great focus was given to high-cost medications, and medications that are a particular need for people in New Mexico, and which would provide for the most cost savings and the highest impacts in managing chronic diseases in New Mexico.
- SB1 also requires that the Program meet U.S. Food and Drug Administration (“FDA”) requirements for safety and efficacy. They must comply with federal law on tracking and tracing. They are required to perform regular audits on the Program’s compliance.
- The Program will benefit individuals with private insurance, state employees, and institutional purchases [?] [inaudible on recording] for the uninsured.
- DOH was directed to form a committee involving the Office of the Superintendent of Insurance, HSD, General Services Department, and the Board of Pharmacy. They have been working together with many of these actors. They have been meeting with outside stakeholders as well to get input from various industries that they know would be affected by the Program. They have tried to take into consider the interests of all the stakeholders so that they can have a robust Program that everyone is in agreement with.

Ms. Showers stated that once they submit the Program to the federal government, the implementation process would follow an approval. Six months following approval from the U.S. Department of Health and Human Services (“HHS”), they would begin implementation.

Ms. Showers stated that a Wholesale Prescription Drug Importation Program fund was also created. DOH is required to submit an annual report to the Governor and to the Legislature about the operation and impact of the Program.

The timetable that they continue to look at is that the public hearing and receipt of comments from the public, they intend to submit the plan to HHS, and within six months of approval, they will implement the plan.

Introductory Remarks of Courtney Lovato

Courtney Lovato is the Director of the New Mexico Board of Pharmacy. Ms. Lovato appeared telephonically. Ms. Lovato explained the process by which they developed their drug list. She stated that obtained data from twelve insurance plans in New Mexico. They utilized that data to formulate the list. They had to manage and format the data so that it would be consistent. They then took the data from the insurance plans and compared it to the Canadian unit cost. Based upon that comparison, they excluded product that would cost more to import by adding in 45% for transaction costs. They also excluded other products in accordance with federal regulations, including controlled substances, biologic products, infused products, intravenously injected medications, medications that are inhaled during surgery, other injected drugs, and medications that were subject to a risk evaluation and mitigation strategy.

After they removed the excluded products, they kept all the medications that were listed as the top potential cost savings for New Mexicans. As a consequence of evaluating information about the supply chain, she noted that currently many medications are listed as having been manufactured outside of the United States and brought into the U.S. She stated that this will be a very similar process, where they have a global drug manufacturer who will send the medication to a Canadian supplier, and will then be imported into the U.S. The medications will then be distributed by a New Mexican wholesaler and be sent to pharmacies, clinics, etc., and be available to New Mexican residents.

Part of the process in the importation plan will be ensuring the safety of the medications. She said that there will be testing of all of the imported products prior to distribution in New Mexico. The imports will be re-labeled to FDA specifications, including for National Drug Code and billing information for payment purposes.

Ms. Lovato also stated, in addition, that the State has developed a thorough compliance plan, as required by federal regulation. It details everything from registration of participants to potential manufacturer recalls. As part of that compliance plan, New Mexico will ensure that the importations of products are for products that will only be used in New Mexico for safety assurance. There will be no U.S. manufacturer rebates on the imported product.

Ms. Lovato stated that steps they will be taking also include the following. They will be listing the prices of the medications that will be publicly available on the DOH website including price information. Price will be based on the supply chain and the imported cost of the medication. The imported price will be the basis for claim payments. The imported price will also be the basis of the imported cost share or out-of-pocket if the individual is uninsured. Only Canadian drugs that show a net savings will be imported through the Program.

Finally, Ms. Lovato turned to Aryan Showers to discuss the states of the final rule process that was started in September.

Ms. Shower's Comments on the Final Rule

Ms. Showers stated that comments and concerns were received by the Department on the proposed rule. Some of those comments and concerns were reflected in the final rule, some were not. They are still working on the final rule.

THE EXHIBIT BINDER

After the introductory remarks of two Department representatives, Ms. Strong identified and moved for the admission of the exhibits that the DOH was introducing at hearing, which include the following:

- DOH Exhibit No. 1: Proposed Program: Wholesale Prescription Drug Importation Program Application
- DOH Exhibit No. 2: FDA/Canadian Labeling [electronic copy only, in the possession of the DOH OGC]
- DOH Exhibit No. 3: Amended Notice of Public Hearing
- DOH Exhibit No. 4: Affidavit of Publication in the Albuquerque Journal [Amended Notice of Hearing]
- DOH Exhibit No. 5: Affidavit of Publication in the New Mexico Register [Amended Notice of Hearing]
- DOH Exhibit No. 6: Notice of Public Hearing
- DOH Exhibit No. 7: Affidavit of Publication in the Albuquerque Journal [Notice of Hearing]
- DOH Exhibit No. 8: Affidavit of Publication in the New Mexico Register [Notice of Hearing]
- DOH Exhibit No. 9: Letter Appointing Hearing Officer
- DOH Exhibit No. 10: Written Comments

The foregoing exhibits, upon motion by Ms. Strong, were admitted into and made part of the record for this Public Hearing.

WRITTEN COMMENTS

The written comments from the public are contained in DOH Exhibit No. 10. A summary of those comments follows.

Written Comments of the National Association of Chain Drug Stores

The National Association of Chain Drug Stores (NACDS) submitted a written comment in opposition to the proposed Wholesale Prescription Drug Importation Program. *See* DOH Exhibit No. 10, the written statement of NACDS at 1. The NACDS acknowledges that, although the Food and Drug Administration (FDA) has adopted regulations that would allow the commercial importation of pharmaceuticals from Canada, they believe commercial importation programs cannot successfully be implemented.

The NACDS argues that any importation Program would violate federal laws against drug importation, undermine federally mandated security protections of the drug supply chain, and increase the use of counterfeit drugs. It also asserts that both FDA Commissioners and the Canadian government have raised serious concerns about danger to public safety posed by allowing commercial importation.

The NACDS argues that the Importation Program would weaken the Drug Supply Chain Security Act (DSCSA), which is designed to prevent counterfeit drugs from entering the U.S. supply chain because it is impossible to enforce the DSCSA over foreign facilities, manufacturers, wholesalers, and dispensers. The NACDS also asserts that the Importation Program would create loopholes within the DSCSA regulatory framework and easily allow counterfeit drugs to reach New Mexico.

The NACDS also argues that the FDA, for the last 15 years, has repeatedly sounded the alarm as to the risk of patient safety posed by importation programs. It asserts that five former FDA commissioners have made statements in opposition to drug importation, raising concerns about foreign counterfeit drugs. It also asserts that the Canadian government shares these concerns, and the New Mexico Importation Program ignores the serious safety concerns raised by these entities.

The NACDS states that with counterfeit drugs, people will get sick and potential die. It asserts that the World Health Organization has stated that 10% of drugs worldwide are counterfeit, so the risk of illness and death is very real.

The NACDS also asserts that there are questions regarding whether international sources of pharmaceuticals are adequate and consistently reliable, as well as safe. It asserts that the Importation Program could provide only a sporadic supply of international drug products and imported drugs from Canada could pose safety concerns because they often have different shapes, sizes, colors, and trade names. They can also be made from different active ingredients and in different doses. The NACDS assert that each of these factors could cause confusion in patients and health professionals, putting patients at risk.

The NACDS asserts that in contracting with entities in a foreign country, New Mexico would have no authority or ability to ensure that a given entity is a legitimate business and not dealing in counterfeit drugs, and patients would have no legal recourse if harm occurs.

The NACDS further assert that it is particularly troubling that the proposal for state and health plans to inform enrollees about which pharmacies were not dispensing imported medication so patients could avoid these pharmacies. It argues that the state of New Mexico has not proven that it can import drugs safely while delivering significant savings, and until it can do so, it should not threaten pharmacies that continue to put patient safety first.

Finally, the NACDS must address pharmacy-specific concern in the Importation Program. In particular, it argues that the proposed requirement for pharmacies to report adverse events within 15 or 90 days, depending on the type of event, is not workable. In addition, the NACDS asserts that pharmacies would be reluctant to participate because they could not be assured of adequate reimbursement.

Written Comment of Incyte

Incyte Corporation, a biopharmaceutical company that manufactures and markets Jakafi® (ruxolitinib tablets) in the U.S., submitted a written comment. Incyte states that New Mexico's Proposed Section 804 Importation Plan (SIP) lists a Canadian drug, Jakavi® (ruxolitinib tablets) for importation. Incyte states that there are key differences between the FDA-approved NDA for Jakafi and the Canadian-approved application for Jakavi, which means that the two drugs are not "eligible prescription drugs" under the FDA's Final Rule, published in the Federal Register on October 1, 2020 for the importation of "eligible prescription drugs" from Canada. Consequently, Incyte requests that those drugs should be removed from New Mexico's Proposed SIP before it is submitted to the FDA.

Incyte asserts that the critical question in determining whether Jakavi is an "eligible prescription drug" for important pursuant to the FDA's Final Rule at 62126-27 (21 C.F.R. § 251.2) is whether it meets the conditions of the FDA-approved NDA for Jakafi (other than labeling). Incyte states that this standard is not met here.

In particular, Incyte states that Jakafi and Jakavi are manufactured by different entities, have different approved indications, are sold in different dosage strengths, and have different physical appearances. For the specific details of these differences between the two drugs, see Incyte's December 1, 2020 letter to Aryan Showers at the NM Department of Health at 2 to 3. Incyte argues that as a consequence of the foregoing differences between the two drugs, Jakavi cannot meet the condition in the Jakafi NDA "relating to the drug substance, drug product, production process, quality controls, equipment, and facilities" in 21 C.F.R. § 251.2, and is not an "eligible prescription drug." Accordingly, Incyte argues that the NM Proposed SIP should be corrected now, before it is submitted to the FDA, by excluding Jakafi and Jakavi from its list of "eligible prescription drugs." See DOH Exhibit No. 10, Incyte's December 1, 2020 letter to the DOH at 4.

Written Comment of The Partnership for Safe Medicines

The Partnership for Safe Medicines (PSM) is a non-profit group that works to protect patients from counterfeit and substandard medicines. It submitted a written comment to the Department on December 1, 2020. PSM states that it is concerned that the Importation Program as proposed in New Mexico could expose New Mexico patients to unreliable and counterfeit medicine and will not show significant savings.

PSM argues specifically that the proposed Importation Program breaks the track-and-trace system in the DSCSA, which was passed to protect patients from fake medicines that had made their way into the U.S. drug supply. It asserts that when the DSCSA is fully enacted, every package of prescription medicine sold in the U.S. will have a secure electronic listing every entity involved in the distribution of the product from the manufacturer to the patient. PSM asserts that this process will help to ensure against counterfeit drugs. However, Canada does not have a compatible system and, as a consequence, any importation Program would result in waiving the track-and-trace system. This, PSM asserts, would open a path for black market drug sellers to substitute counterfeit and unsafe drugs in the U.S. supply chain.

PSM also asserts that the proposed plan relies on Canadian licensing to validate the legitimacy of foreign sellers, but licensed Canadian drug sellers have sold counterfeit drugs in America in the past. Further, it argues that Canadian authorities have explicitly stated that they cannot take responsibility for the safety of drugs Canadians may sell to U.S. patients. In addition, it asserts that Health Canada has said that it will not allow bulk exports of medication that might cause shortages in Canada, where there are already “enormous drug shortages.” *See* DOH Exhibit No. 10, PSM written comment at 2.

PSM states that the draft Importation Program would not result in a significant reduction in the cost of prescription drugs to New Mexican consumers. It asserts that the draft plan includes no assessment of whether it would result in a significant reduction of cost. It further asserts that experts from the London School of Economics have studied this issue in Europe and found that savings are usually consumed by middlemen in the supply chain.

PSM further claims that past state-administered drug importation Programs were not safe and did not save money. It claims that in 2004 inspectors in Minnesota’s Canadian pharmacies had safety violations that would shut down any pharmacy in Minnesota and engaged in other threats to public health. *See* DOH Exhibit No. 10, PSM written comment at 2. Similar claims were made with respect to Programs in four other states. *Id.*

PSM next argues that drug importation will not help any Medicaid/CHIP participants because the rebates they receive already lower the price of drugs more than importation would. PSM also argues that the costs of importation Programs are prohibitively expensive, particularly the cost of testing pharmaceuticals. *Id.* at 3.

PSM asserts that the draft Importation Program risks New Mexicans’ well-being. In particular, it argues that New Mexico’s Board of Pharmacy and Department of Health have no ability to regulate foreign sellers, and the state attorneys general cannot compel foreign sellers to

appear in court. Consequently, PSM asserts that if a Canadian seller provided fake drugs to a New Mexico wholesaler, there would be little recourse against the Canadian seller. PSM also argues that the “rule” relies on stepped up review by overwhelmed state regulators.

PSM further claims that costly implementation requirements and disparity between U.S. and Canadian markets make drug importation unworkable. It argues that prosecuting overseas drug sellers for counterfeit drug crimes is very expensive, time consuming and challenging, and that it does not guarantee justice for victims. PSM cites a couple of examples of this at DOH Exhibit No. 10, PSM written comment at 4. It also claims that the draft plan would exacerbate risk posed by transshipments and counterfeits from or through Canada, citing former FBI Director Louis Freeh. *Id.* at 5. In addition, PSM claims that the draft plan could lead to drug shortages in Canada, harming Canadian public health. It asserts that Canada already has significant drug shortages, with more than 1,500 medicines in shortage today. It asserts that one in four Canadians has experienced or known someone who has experienced drug shortage, and that U.S. demand would overwhelm Canadian production. PSM asserts that Canadian distributors, the Canadian government, and Canadian patients oppose exportation of drugs to the U.S.

PSM argues that New Mexico should not move forward with this plan, and instead encourages the Department to consider other proven solutions to bring patients financial relief at the pharmacy counter. In particular, PSM argues that New Mexico should regulate middlemen with predatory pricing practices such as pharmacy benefit managers. PSM asserts that middlemen are making enormous profits by marking up medicine prices, citing studies in West Virginia and Ohio. *See* DOH Exhibit No. 10, PSM’s written statement at 6.

PSM also recommends fostering new pricing models by implementing flat-fee agreements, citing the “Netflix” model used in Australia and Washington state. *Id.* at 6-7.

Written Comment of Healthcare Distribution Alliance

Healthcare Distribution Alliance (“HDA”) also submitted a written comment. HDA is a national trade association representing primary pharmaceutical wholesale distributors. It serves over 1500 pharmacy customers in New Mexico. In its response, HDA states that it specifically seeks clarity and a better understanding of the role of vendors in the Importation Program.

HDA states that it was engaged throughout the legislative process, outlining the complex issues associated with SB1, and it remains concerned that the Wholesale Prescription Drug Importation Act will negatively impact the pharmaceutical supply chain and jeopardize patient safety.

HDA also argues, as did NACDS, that Canadian practices do not have a tracing system like the tracing system established in the U.S. through the DSCSA, increasing the risk of illegitimate or counterfeit medications entering the U.S. and putting patient safety at risk. It argues that the FDA is in the process of finalizing its second phase of regulatory guidance, and it would be counterproductive to introduce foreign pharmaceuticals now, which would need repackaging, relabeling, and serialization, as well as screening for counterfeiting, before the current supply chain is able to conform and comply with new DSCSA standards.

HDA states that its members are an essential part of the closed distribution system for pharmaceutical medications, working daily with supply chain partners, law enforcement, and government regulators to help ensure that prescription medications are delivered safely to licensed pharmacies. It asserts that when comparing the current structure and standards of the U.S. pharmaceutical supply chain with international standards, it does not see how meeting such requirements is possible and verifying and tracking foreign products in the U.S. pharmaceutical supply chain to ensure patient safety and prevent diversion by the strict standards established by federal law will not be possible.

Finally, it asserts that the DOH must understand the risks associated with an importation Program, specifically, that it is asking potential vendors contracted under the Program to assume with the inherent uncertainty that exists.

Written Comment of Pharmaceutical Research and Manufacturers of America

Pharmaceutical Research and Manufacturers of America (“PhRMA”) submitted a written comment. PhRMA states that it represents the country’s leading innovative biopharmaceutical research companies.

PhRMA states that New Mexico’s draft SIP application does not demonstrate that importation will pose no additional risk to public health and safety. In particular, it asserts that this policy will have a devastating impact on patient safety by (1) increasing the risk that patients will be harmed by unapproved, misbranded, and adulterated drugs entering the market; (2) undermining the U.S. regulatory system; (3) increasing consumer confusion about imported drugs; and (4) leaving consumers vulnerable to unscrupulous actors. PhRMA also asserts that the draft SIP application fails to show that importation will significantly reduce the cost of prescription drugs for New Mexico consumers, and that it ignores significant costs that could eliminate any savings. It urges that New Mexico abandon the Program based on the foregoing factors.

PhRMA argues that the proposed importation plan will expose patients to the risks associate with imports of unapproved, misbranded, and adulterated drugs. It argues that there is no way to ensure that imported drugs will meet the requirements of the Federal Food, Drug and Cosmetic Act (“FDCA”) or the FDA’s regulations which are designed to ensure the safety and overall quality of drugs purchased in the U.S. It asserts that improper storage, testing, or processing can cause consumers to receive medicines that can cause serious injury or death, particularly in vulnerable populations such as children and the elderly. *See* DOH Exhibit No. 10, PhRMA’s written comment at 2.

PhRMA acknowledges the Program’s compliance plan and the creation of a registry for drug importation participants to reduce concerns about adulterated drugs but asserts that registration alone is insufficient to ensure that entities test and hold prescription drugs in compliance with current good practices and otherwise meet their obligations. *Id.*

Like other entities who submitted written comments, PhRMA argues that New Mexico’s proposed Importation Program would increase the potential for adulterated drugs to enter the U.S.,

at the very earliest stages in the supply chain, because Canada lacks a track-and-trace system, and it is impossible to know with certainty that drugs were not tampered with before entering the U.S. Further, although testing helps, it asserts that no testing scheme is foolproof, and New Mexico's provisions on statutory testing leave critical questions unanswered.

In particular, PhRMA states that the draft plan outlines that all products imported through the Importation Program will be held at a "licenses facility" within "the Customs and Border Protection port of entry or foreign trade zone" and "shall not be released for distribution until Statutory testing has been conducted, and all FDA approvals are obtained, and the product has been re-labeled in accordance with FD&C Act requirements." However, PhRMA argues, it is unclear how long prescription medicines could be held awaiting testing results, and re-labeling prior to distribution. *Id.* at 3. Further, PhRMA argues, the proposed Importation Program does not describe a plan to assure that imported drugs are appropriately stored, handled, and re-labeled/packaged while at the Customs and Border Protection port of entry or foreign trade zone. *Id.* "Even more concerning," it does not identify testing levels necessary to ensure confidence and reliability, according to PhRMA. *Id.*

PhRMA states that New Mexico's proposed Importation Program proposes using the New Mexico Board of Pharmacy (NMBOP) to conduct on-site inspections of resident Program participants to ensure compliance with state and federal regulations, and for non-resident Program participants, the NMBOP will review reports from the FDA, local licensing bodies, or NMBOP-recognized third parties. PhRMA asserts that, in order to provide meaningful oversight of non-resident Program participants, both NMBOP and the FDA must inspect them. PhRMA asserts that FDA approval is the gold standard when it comes to safety of the medicine supply and relying on reports by any party, but the FDA coupled with the NMBOP significantly jeopardizes public safety. PhRMA argues that the FDA's refusal to commit to conducting pre-importation inspections, coupled with no NMBOP inspection, poses additional risk.

PhRMA states that it is particularly concerned about vesting state licensing bodies related to adverse event reporting and recalls. *See* DOH Exhibit No. 10, PhRMA's written comment at 3. It asserts that this process requires several complex steps requiring medical and scientific expertise as to whether the event is serious and unexpected, and caused by the drug. It asserts that the draft application does not address whether the state has the relevant expertise to meet these requirements. *Id.*

PhRMA's next argument is that New Mexico's proposed Importation Program will introduce consumer confusion and adverse event reporting failures. *Id.* It asserts that the FDA admits that product labeling for imported drugs could lead to confusion between products with the same name. PhRMA argues that it is likely that consumers will not understand the distinction between drugs imported under Section 804 and FDA-approved drugs with the same name. It further argues that if a patient taking an imported drug has an adverse event, the patient and/or health professionals who are involved may not know which entity to contact, increasing gaps or delays in reported adverse events. In addition, it argues that New Mexico appears to spread the responsibility for handling the adverse event across all participants in the supply chain, leading to additional risks because no one party has full visibility or accountability.

PhRMA argues that New Mexico’s proposed Program would allow unscrupulous actors to take advantage of the confusion around imported drugs. *Id.* at 4. It asserts that the FDA notes that criminals frequently “use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients.” *Id.* PhRMA cites as an example the practice of unscrupulous actors using their names like “CanaRx” to imply that patients are receiving medicines approved in Canada when they are likely from other countries and may be counterfeit. *Id.* PhRMA asserts that the proposed Program does not explain how the state will address entities which falsely promote themselves as Program participants.

PhRMA asserts that New Mexico’s draft SIP application fails to show how the state will significantly reduce costs for New Mexico consumers, and estimates ignore significant costs associated with establishing and administering an importation Program. *Id.* at 4-5. It asserts that New Mexico’s draft SIP largely focuses on estimated cost-savings for health plans, but only offers the “roughest back-of-the” envelope math to support its claim that consumers will see significant savings. *Id.* at 5.

In addition, PhRMA argues that New Mexico’s plan fails to account for significant costs. In particular, PhRMA makes the following argument. New Mexico estimates an additional 45% markup to account for “transaction costs.” *Id.* at 5. The includes an allowance of profit for commercial entities within the supply chain (20%), repackaging/relabeling (15%), and record-keeping and recall management (5%). PhRMA asserts that the plan does not consider the following additional costs:

- Start-up and ongoing costs for ensuring compliance with existing federal laws and registering, licensing, and auditing Program participants.
- Significant law enforcement costs which can put a strain on law enforcement agencies.
- Public and stakeholder education costs.
- Costs imposed on supply chain entities including new capital, operating, and maintenance costs associated with drug importation paperwork requirements, costs associated with inspecting imported prescription drugs, costs associated with reliably recording and sharing adverse events, costed related with recall and disposal of recalled drugs, development of systems and reporting infrastructure, and new capital expenditures toward an importer’s re-labeling and repackaging requirements.

Id. at 5.

ORAL COMMENTS

Prior to receiving public comments, the Hearing Officer explained that his role in this matter is to provide a written report to the Cabinet Secretary in which he summarizes the oral comments and written comments submitted by members of the public in this public hearing process. He also indicated that this proceeding is different from a rulemaking hearing, for example,

in that the Hearing Officer has not been asked to make a recommendation to the Cabinet Secretary with respect to the comments made by the public.

The following oral public comments were offered at hearing by participants to the hearing:

Public Comment of Russ Toal

Mr. Toal is the Superintendent for the Department of Insurance. He thanked the Department for their efforts in this matter and stated his support for the proposed Program.

Public Comment of Christina Adams

Ms. Adams is the Chief Pharmacy Officer for the Canadian Society of Hospital Pharmacists (“CSHP”). They are a non-profit organization that represents pharmacy professionals in hospitals to improve patient care and safe and effective medication use. She is also a practicing pharmacist. She raised concerns about New Mexico’s Importation Program. She stated that she is concerned because her nation of 38 million people does not have the pharmaceutical supply for the U.S.’s 329 million citizens for the proposed Drug Importation Program. She also raised a concern that even importation by the 2.9 million people of New Mexico could have a significant negative effect on the drug supply in Canada, which was experiencing record shortages before the pandemic, and “shocking shortages” since the pandemic began. She stated that if New Mexico imports Canadian drugs on any scale, price differences between the two countries are likely to disappear.

Ms. Adams stated that as an organization of pharmacists, CSHP is sympathetic to the challenges that New Mexico patients face in accessing affordable medicines. However, importation is such a poor solution that they have joined the Alliance for Safe On-Line Canada to advocate for a ban on medicine exports for U.S. Programs like New Mexico’s Program.

She stated that importation will exacerbate drug shortages that already harm Canadian patients. She said that Canadian already manages 2,000 drug shortages at any given time. In a recent survey, one in four Canadian patients reported being directly affected by drug shortages. In hospital settings, these drug shortages directly and negatively affect patient outcomes. Instead of doing clinical work with patients, pharmacists spend too much time sourcing scarce drugs finding appropriate substitutes and communicating with other health care professionals about these shortages.

Ms. Adams stated that wholesale drug importations will hurt Canadians and will not help New Mexicans with drug prices. They hope New Mexicans can pursue other avenues to make medicines more affordable for its citizens.

Public Comment of Leah Lindahl

Ms. Lindahl is with the Healthcare Distribution Alliance. This trade association represents 35 national pharmaceutical wholesale distributors. HDA submitted formal written comments. *See*

DOH Exhibit No. 10. She noted conflicts between the Program and existing federal law and other issues which are addressed in the written submission.

Public Comment of Colin Baillo

Mr. Baillo stated that he wanted to thank DOH staff for all the great work they have done to pull this proposal together. He noted the “really dire issue” faced by New Mexico consumers with access to prescription medications and he applauds the efforts of the DOH.

Public Comment of David Roddy

Mr. Roddy indicated that he is the Policy Director with the New Mexico Primary Care Association. He also wanted to thank DOH and recognized the many challenges that will be faced with this Program, indicating his hope that everyone could work together and provide some great benefits to the consumers in New Mexico.

Public Comment of Jackie Cooper

Ms. Cooper is a volunteer with AARP and thanked the DOH for all of its work on the Program.

Public Comment of Dr. Jamie Majdi

Dr. Majdi is a primary care doctor in Albuquerque and thanked the group for all the work that is being done to help consumers.

Public Comment of Jeanne Hamrick

Ms. Hamrick is a volunteer with AARP. She stated she is also a person with very high drug prices that would possibly be affected with this Program. She thanked everyone for their hard work.

Public Comment of Katelin Lucariello

Ms. Lucariello is the Director of State Policy for PhRMA. She offered her thanks for allowing her to join the discussion on the day of hearing. She stated that she had submitted a written comment on behalf of PhRMA in opposition to the proposed Importation Program. *See* DOH Exhibit No. 10. She indicated that they have continued concerns about how the Program would ensure patient health and safety, as well as how the Program would lower costs. She noted that they had detailed those issues in their written comments.

Public Comment of Pam Politis

Ms. Politis appeared as a representative of Incyte Corporation. She indicated that they had also submitted a written comment. *See* DOH Exhibit No. 10. She indicated her appreciation for the opportunity to comment. She stated that Incyte is a biopharmaceutical manufacturer. She

indicated that one of their drugs was listed in the application, and their comments are focused on the technical aspects of why it is an ineligible product under the FDA Final Rule. *Id.*

Public Comment of Shabbir Safdar

Mr. Safdar is the Executive Director of PSM. PSM is non-profit, working to protect patients from counterfeit medicines for almost two decades. They are concerned that New Mexico's plan to import prescription drug medicines could expose patients to unreliable and counterfeit medicines and will not show significant savings. He noted that they had submitted written comments as well. *See* DOH Exhibit No. 10.

He noted that the proposed is a "non-starter" for Canadian advocates and stated that Canada has indicated new restrictions in November on exporting drugs for states like New Mexico, effectively preventing any Program from being implemented. He also stated that there is no other "magical country" that will be more tolerable with shortages than Canada, and there is no federal law allowing importation from any country besides Canada.

Mr. Safdar stated that PSM's full analysis is on their website and has, as he noted earlier, been submitted as a written comment in this proceeding. He stated that this plan will not help the most needy people in New Mexico; the Medicaid plan already makes medicine cheaper for one in three New Mexico residents.

He also raised a concern that the plan allows for pharmacies who do not participate to be "named and shamed" which is a disappointing way to treat businesses and front-line workers during the pandemic. He stated it will also expose pharmacists to non-compliance with their wholesale contractors' purchasing agreements. It does not explain how it will figure the cost of testing, which is significant, suggesting that testing will be shortcut. He further asserted that it creates a conflict of interest in the reporting of adverse events, in which the state risks having a plan shut down by the FDA may find incentives to not report adverse events. It provides no liability shield for pharmacists when imported medicines turn out to be counterfeit. He also stated it puts an impossible job on the Board of Pharmacy, expecting them to somehow license and regulate foreign national companies that they have no legal control over.

Finally, Mr. Safdar argued, the plan breaks track-and-trace. He has heard advocates say that the plan has been written to comply with federal track-and-trace requirements, but asserts that what they do not say, is that federal requirements have been deepened to allow this Program to work. Today, he noted, you can track any medicine back to the manufacturer floor from the pharmacy shelf; that will not be true of these imported Canadian medications.

Public Comment of Dr. Thomas Massaro

Dr. Massaro is the Chief Medical Officer for the DOH. He stated that his comments are in the written report. He stated that believes that if they are able to do something like this Program, it could help numerous New Mexicans who may not have Medicaid, and who are subject to relatively outrageous drug prices.

The other participants in the rulemaking hearing did not make public comments. Those participants include the following: Aaron Young, an individual with a phone number ending in #05, an individual with a phone number ending in #08, an individual with the initials "BC," Ellen Pinnes, Gaspar Laca, Jacqueline Smith (with Presbyterian Healthcare), Jane Horvath, Jane Wishner, Lugina Mendez-Harper, Marisa Schlafir, Matthew Rubin, Nai Walter, Natasha Ning (Sp?), Nisha Quasba, Nikki Lovett (Curry County Health Council), Regina Stivers (PCNA), Sahar Hassanin, Sarah Orrange (America's Health Insurance Plans), Scott Brown, Tracie Collins (DOH Cabinet Secretary), and Valentino Livingston.

The Hearing Officer closed the hearing by stating that he would be drafting a report to the Cabinet Secretary that summarizes the information submitted through the written and oral comments that were provided to the Department and thanked the people who participated in the hearing for their input.



Craig T. Erickson

12/10/20

Date