



December 1, 2020

New Mexico Department of Health
Attn: *Aryan Showers, Director*
Office of Policy and Accountability
Runnels Building 1190 South S. Francis Drive
Santa Fe, New Mexico 87505

Sent via email to Aryan.showers@state.nm.us

Re: Pharmaceutical Research and Manufacturers of America (PhRMA) Comments on New Mexico’s Draft State Importation Plan (SIP) Application

Dear Ms. Showers:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on New Mexico’s Draft Section 804 State Importation Program (SIP) application. PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the past two decades, PhRMA member companies have invested nearly \$1 trillion in the search for and development of new treatments and cures, including an estimated \$83 billion in 2019 alone.

Prescription medicines have revolutionized the treatment of numerous serious health care conditions, saving lives, improving quality of life, and reducing the need for hospitalization. The United States is by far the global leader in the development of new medicines. American patients benefit from earlier and wider access to new medicines compared to patients in other countries, where governments restrict access.¹

PhRMA shares a commitment to address patient affordability within the health care system and reduce costs in the State of New Mexico. However, importation is not the solution.

New Mexico’s draft SIP application does not demonstrate that importation will pose no additional risk to public health and safety. To the contrary, this hurried policy could have a devastating impact on patient safety by (1) increasing the risks 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. Moreover, New Mexico’s draft SIP application fails to show that importation will significantly reduce the cost of prescription drugs for New Mexico consumers. Indeed, it ignores significant costs that could eliminate any savings. Considering the significance of these issues, PhRMA urges New Mexico to abandon

¹ Zhang Y, Hana CH, Hernandez I. Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. *Journal of Managed Care Specialty Pharmacy*. 2017;23(2):247-254.

implementation of an importation program.

New Mexico’s proposed importation program would pose additional risks to the public’s health and safety.

Section 804(l)(1) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) requires the U.S. Secretary of Health and Human Services to certify that importation will “pose no additional risk to the public’s health and safety.” We are generally concerned that New Mexico’s proposal provides little detail about how the state will ensure importation does not increase public health and safety risks. Our most significant concerns with the proposal are described below.

New Mexico’s proposed importation scheme would expose patients to the risks associated with imports of unapproved, misbranded, and adulterated drugs.

Importation would expose patients to the risks associated with imports of unapproved, misbranded, and adulterated drugs. The FDCA and FDA’s regulations ensure the safety and overall quality of drug products consumers purchase in the United States. Drugs marketed in the U.S. must be approved, not misbranded, and not adulterated, in addition to meeting other requirements outlined in the FDCA. The FDCA and FDA’s regulations give American consumers confidence that the drugs they use are safe and effective and are not expired, subpotent, contaminated, counterfeit, or otherwise unsafe for patient use. FDA’s regulations for section 804 importation do not inspire that same level of confidence. As HHS indicated in the HHS Task Force Report, “there is no way to ensure that [drugs imported under section 804] have been appropriately stored, processed, and packaged.”² Improper storage, testing, or processing can cause consumers to receive unsafe medicines that can cause serious injuries and even death, particularly if any of these drugs would be used to treat vulnerable populations such as children and the elderly.

New Mexico’s compliance plan is insufficient to assure the safety of the drug supply. In an apparent attempt to reduce concerns about adulterated drugs, the draft application states that the NMDIP will create a registry for drug importation participants which will “ensure that the storage, handling, and distribution practices of supply chain participants, including transportation providers, meet certain requirements (including those requirements in 21 CFR Part 205) and do not affect the quality or impinge on the security of the eligible prescription drugs.” Yet, registration alone is insufficient to ensure that entities test and hold prescription drugs in compliance with current good manufacturing practices (“cGMP”) and otherwise meet their obligations.

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 — before they enter the U.S. Canada lacks a track-and-trace system, and it is impossible to know with certainty that drugs were not tampered before arrival in the U.S. Although testing helps, “no testing scheme is foolproof,”³ and New Mexico’s provisions on statutory testing leave critical questions unanswered. For example, the draft application outlines that all products imported through New Mexico’s importation program will be held at a “licensed facility” within “the Customs and Border Protection (CBP) port of entry or foreign trade zone” and “shall not be released

² HHS, Task Force on Drug Importation, Report on Drug Importation (Dec. 2004) at 29.

³ Id. at 30.

for distribution until Statutory testing has been conducted, all FDA approvals are obtained, and the product has been re-labeled in accordance with FD&C Act requirements.” It is unclear how long prescription medicines could be held at the CBP or FTZ awaiting testing results, and re-labeling prior to distribution. The application also does not describe a plan to assure that imported drugs are appropriately stored, handled, and re-labeled/repackaged while at the CBP or FTZ prior to being distributed in the state. Even more concerning is the fact that the draft application does not identify testing levels necessary to ensure confidence and reliability. Statutory testing is expensive and may be neglected if the state does not articulate specific standards that must be met.

New Mexico’s proposed importation program would undermine regulatory protections provided by FDA.

According to the draft application, the New Mexico Board of Pharmacy (NMBOP) will conduct on-site inspections of resident program participants to ensure compliance with state and federal regulations. For non-resident program participants, NMBOP will review reports from FDA, local licensing bodies, or NMBOP-recognized third parties. However, to provide meaningful oversight of program non-resident participants, NMBOP and FDA must inspect them. FDA approval is the gold-standard when it comes to regulating the safety of our medicine supply. Relying on reports conducted by any party except FDA, to the extent such reports exist, coupled with not conducting a NMBOP inspection, significantly jeopardize public safety. FDA’s refusal to commit to conduct pre-importation inspections of participants, coupled with the NMBOP’s plan to not inspect non-resident program participants, undeniably means that importation will pose additional risk. Furthermore, it is unclear if the data collected by local licensing bodies or third parties could differentiate whether the collected information relates to drugs distributed under an importation plan.

PhRMA is particularly concerned about vesting state licensing bodies with responsibilities related to adverse event reporting and recalls. Adverse event reporting requires a number of complex steps in which entities take in adverse event information and make assessments that require medical and scientific expertise as to whether the event is serious and unexpected and is, in fact, caused by the drug.⁴ Among other requirements, effectuating a recall requires the ability to quickly and effectively ensure that distribution of the drug stops, any potentially affected entities are notified, and that appropriate communications are issued to the public.⁵ The draft application does not address whether the state has the relevant expertise to adequately meet these requirements.

New Mexico’s proposed importation program would introduce consumer confusion and adverse event reporting failures.

FDA admits that product labeling for imported drugs could lead to potential confusion between products with the same name.⁶ Under the federal final rule, a drug imported under section 804 will be labeled with FDA-approved labeling, the name of the imported drug’s manufacturer, the name of the imported drug’s Importer, and a statement that the imported drug was distributed under a SIP. It is likely that consumers will not understand the distinction between drugs imported under section 804 and FDA-approved drugs

⁴ See 21 C.F.R. § 318.80(b)(2)(B).

⁵ See generally 21 C.F.R. § 7.42.

⁶ Importation of Prescription Drugs, 84 Fed. Reg. 70796, 70819 (Dec. 23, 2019).

with the same name. If a patient taking an imported drug experiences an adverse event, a patient, caregiver, or healthcare professional may not know which entity to contact, which increases the risk of delays or gaps in adverse event reporting. Adding to this complexity, New Mexico appears to spread responsibility for handling adverse events across all participants in the supply chain. This could lead to additional risks because no one party has full visibility or accountability.

New Mexico’s proposed importation scheme would allow unscrupulous actors to take advantage of the consumer confusion around imported drugs.

The same unscrupulous entities that use advanced technologies to deceive American consumers into personally importing counterfeit goods are likely to try to take advantage of commercial importation by capitalizing on consumer confusion about New Mexico’s importation plan. As FDA notes, criminals frequently “use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients.”⁷ Consumers may believe they are buying safe and effective medications online, but often they are being deceived and put at risk by individuals who put financial gain above patient safety.

FDA is already struggling to educate consumers about the risks associated with online pharmacies and buying prescription drugs from countries outside the U.S. As FDA notes, unscrupulous actors, like CanaRx, “use their names to imply that patients are receiving medicines approved in Canada, when it’s likely that patients are receiving medicines from other countries, and which may be sub-potent, super-potent or counterfeit.”⁸ These companies use sleek advertising to “give false credence to their operation.”⁹ Whereas now, at least some consumers may understand there is no FDA-authorized importation program in New Mexico, opening up a closed distribution system to commercial importation of drugs from Canada would make consumers more susceptible to unknowingly importing illicit, counterfeit drugs from outside the U.S.

Unsuspecting individuals who do not know the intricate details of the importation scheme may buy from unauthorized entities, believing that these entities are part of New Mexico’s authorized SIP program. New Mexico’s compliance plan does not address how the state will address individuals or entities that falsely promote themselves as program participants. Although New Mexico does plan to create an educational webpage with “specifically tailored for consumers,” this guardrail is inadequate because it does not address the potential for unscrupulous actors to deceive consumers.

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.

Both section 804(l)(1) of the FDCA and New Mexico’s Senate Bill 1, the Wholesale Prescription Drug Importation Act, require importation to result in a “significant” reduction in the costs of covered

⁷ Id. at 70800.

⁸ FDA Press Release: FDA Warns CanaRx for Selling Unapproved, Misbranded, and Unsafe Imported Drugs to Unsuspecting Americans (Feb. 28, 2019).

⁹ Id.

prescription drugs for consumers. However, New Mexico’s draft SIP does not provide clear estimates of cost-savings for consumers. Instead, New Mexico’s proposal largely focuses on estimated cost-savings for *health plans*, and offers only the roughest back-of-the envelope math to support its claim that importation would reduce the cost of covered products for *consumers*.

Moreover, New Mexico’s draft SIP application fails to account for significant costs. New Mexico estimates there will be an additional 45% markup to account for “transaction costs” associated with the program. This markup includes an allowance of profit for commercial entities within the supply chain (20%), repackaging/re-labeling (15%), testing (5%), and record-keeping and recall management (5%).¹⁰ The draft application does not consider additional costs associated with establishing and administering an importation program, which will significantly limit cost savings or eliminate any savings entirely.

- *Start-up and Ongoing Costs:* The draft application lays out plans for the NM Drug Importation Program (NMDIP) to take on several new responsibilities, including ensuring compliance with existing federal laws and registering, licensing, and auditing program participants. However, the draft application does not describe any associated costs or address how these activities will be funded.
- *Law Enforcement Costs:* The state would rely on the “good faith” efforts of dispensing providers and pharmacists to ensure the medicine is not taken out of state without considering law enforcement’s role in protecting the safety of the U.S. drug supply chain. As former FBI director Louis J. Freeh emphasized in a 2017 article, “the sheer strain that legalized drug importation would have on law enforcement agencies cannot go unappreciated... [W]e’ve also been faced with resource and budget challenges that force us to do more with less. Rolling the dice on a drug importation law would undoubtedly take resources away from other important law enforcement efforts.”¹¹
- *Public and Stakeholder Education Costs:* The draft application describes a “three-pronged education outreach program,” including a multi-modal outreach and marketing campaign, a helpline, and a dedicated webpage. The NMDIP would also offer quarterly training for all program participants that “will be tailored to their specific role so that they may understand their compliance-related obligations.” New Mexico’s cost-savings estimates do not account for the costs of either of the above programs.
- *Costs Imposed on Supply Chain Entities:* The draft application would impose a number of obligations on the Importer, Foreign Seller, and other entities involved in the SIP, which are not accounted for in the above markup estimate. Such expenses include new capital, operating, and maintenance costs associated with the drug importation paperwork requirements; costs

¹⁰ These same estimates were used in other states. See National Academy for State Health Policy (NASHP), Vermont’s Canadian Wholesale Importation Program for Prescription Drugs, Concept Paper (Oct. 2019), <https://www.nashp.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf>; Colorado Department of Health Policy and Financing (HCPF), Section 804 Importation Program, Colorado Drug Importation Program-Draft Application (Mar. 2020), <https://www.colorado.gov/pacific/sites/default/files/Colorado%20Draft%20SIP%20-%20Version%203-9-2020.pdf>.

¹¹ Louis J. Freeh, “Cost of Drug Importation Could Unfairly Shift to Law Enforcement,” *Philadelphia Inquirer* (May 5, 2017).

associated inspecting imported prescription drugs; costs associated with reliably recording and sharing adverse events; costs related with recall and disposal of recalled drugs; development of IT systems and reporting infrastructure; and new capital expenditures toward an Importer’s re-labeling and repackaging requirements. Entities may also have freight, broker, storage, and other charges associated with transporting drugs through interstate commerce.¹² These expenses could ultimately be passed down to the consumer.

Other features of the draft SIP application substantially limit any potential cost-savings for consumers. For example, the draft application acknowledges that the list of drugs used to determine these savings will undergo two additional rounds of analysis before finalizing, which could significantly affect cost-savings. Additionally, because Medicaid already obtains medicines at a low cost, and because Medicaid rebates are not available for imported drugs, these medicines will not be used in New Mexico’s Medicaid program. Medicaid beneficiaries, who represent over one third of New Mexico residents,¹³ will not see a benefit from importation. Moreover, the plan does not prevent middlemen, such as health plans and pharmacy benefit managers, from marking up prices to the detriment of patients.¹⁴

Conclusion

In closing, PhRMA shares a commitment to ensure patient safety and to address patient affordability within the health care system and in the State of New Mexico. However, we do not believe the implementation of a drug importation program will produce the desired results for the reasons stated above. We encourage New Mexico to abandon its proposal.

Sincerely,

_____/s/_____
Katelin Lucariello
Director, State Policy, PhRMA

¹² See FDA, Preliminary Regulatory Impact Analysis, Docket No. FDA-2019-N-5711 (2019), at 13.

¹³ See Kaiser Family Foundation, Medicaid in New Mexico (Oct. 2019), <http://files.kff.org/attachment/fact-sheet-medicaid-state-NM>.

¹⁴ See The Partnership for Safe Medicines, An Analysis of New Mexico’s Draft Canadian Drug Importation Plan (Nov. 12, 2020), <https://www.safemedicines.org/2020/11/an-analysis-of-new-mexicos-draft-canadian-drug-importation-plan.html>.