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Food and Drug Administration
Department of Health and Human Services
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Rockville, MD 20852

CITIZEN PETITION

Covington & Burling LLP, on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), Ballard Spahr LLP, on behalf of the Partnership for Safe Medicines (“PSM”), and Sidley Austin LLP, on behalf of the Council for Affordable Health Coverage (“CAHC”), respectfully submit this citizen petition pursuant to 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs take the actions set forth below with respect to the New Mexico Department of Health’s Section 804 Drug Importation Program Application (hereinafter the “Application”).

Actions Requested

Through this petition, PhRMA, PSM, and CAHC respectfully request that the U.S. Food and Drug Administration (“FDA”) refrain from authorizing the Application and disclose the identities of the Foreign Seller, Importer, and FDA-registered repackager or relabeler (if different from the Importer), as well as the final list of drugs to be imported, for public comment.

Statement of Grounds

I. Executive Summary

In a letter dated September 23, 2020, the Secretary of the Department of Health and Human Services (“HHS”) purported to certify to Congress that implementation of the commercial importation provisions of section 804 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) will not pose any additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the American consumer (the “Certification”). The next day, HHS and FDA (together, the “Agencies”) publicly released a final rule (the “Final Rule”) permitting the commercial importation of certain prescription drugs from Canada without the manufacturer’s authorization. The Final Rule provides for commercial importation through Section 804 Importation Programs (“SIPs”), which will be authorized by FDA and managed by states or tribes.

On November 23, 2020, PhRMA, PSM, and CAHC filed suit challenging the Certification and the Final Rule. The complaint alleges that the Certification is invalid for multiple reasons. For instance, section 804 does not permit a conditional certification that assumes states or tribes will submit SIPs in the future that will meet the safety and cost criteria, and contrary to

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section 804, the Final Rule would allow SIPs to be approved based on potential cost savings that do not reflect a significant reduction in the cost of covered products to the American consumer. The complaint further alleges that the Final Rule is unlawful because, for example, the SIP scheme exposes patients to risks associated with imports of unapproved, misbranded, and adulterated drugs.

In compliance with the December 15, 2020 submission deadline provided under New Mexico law, New Mexico submitted its Application to FDA for review. FDA is not authorized to approve the Application because the Certification is invalid and the Final Rule is unlawful for the reasons described in the litigation. As for the Application itself, New Mexico submitted a proposal so short on detail that FDA cannot assess whether the safety or cost criteria can be met. New Mexico has not identified a Foreign Seller, Importer, or FDA-registered repackager or relabeler, and it provides only the first iteration of the list of drugs to be imported. The Application is so deficient on its face that we urge FDA to refuse to file it for review, much like it would for a new drug application that is deficient on its face in a way that precludes a complete review.

Even if the Application can be evaluated, it cannot be authorized because it fails to satisfy either of the primary criteria for authorization. With respect to safety, the Application fails to provide adequate assurance that imported drugs will be transported, stored, repackaged, and relabeled appropriately and lacks robust supply chain security measures that are necessary to protect patients from counterfeits and other substandard medicines. Furthermore, the pharmacovigilance, recall, and return provisions are inadequate to respond to adverse events, products that need to be removed from distribution, and noncompliance. The Application also omits any discussion of whether the SIP participants have the requisite funding and capacity to ensure that imported drugs would be safe.

Moreover, the Application does not demonstrate that the SIP will result in the significant reduction to the cost of covered products for consumers required by federal law. The Application instead utilizes only the roughest back-of-the-envelope math (based largely on spending by health plans, not individual consumers) to arrive at multiple disparate cost savings estimates, all of which have substantial limitations. Moreover, the State's estimates ignore significant costs associated with establishing and administering an importation program.

The Application also suffers from additional flaws and deficiencies that will harm manufacturers. The Application does not provide sufficient evidence that manufacturer trade secrets and confidential commercial information ("CCI") will be protected. Additionally, the lack of information on proposed labeling jeopardizes the manufacturer's reputational interests.

Finally, we request that FDA publicly disclose the names of the Foreign Seller, Importer, and FDA-registered repackager or relabeler, as well as the final list of drugs to be imported, as soon as this information is identified, as doing so is important for promoting transparency, due process, and international coordination.

II. Legal and Regulatory Background

A. Commercial Importation under the FDCA

To ensure the safety of the U.S. drug supply, the FDCA prohibits entities other than a drug's manufacturer (or entities authorized by that manufacturer) from importing into the U.S. a drug that was originally manufactured and labeled for another country, with narrow

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exceptions.¹ One such exception is section 804 of the FDCA. Section 804 provides two pathways for HHS to authorize the importation of certain prescription drugs by wholesalers or pharmacists (“commercial importation”) or by individuals for personal use (“personal importation”). However, Congress conditioned the implementation of section 804 on an initial certification by the Secretary. Section 804(l) provides that the section shall become effective only if implementation 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.²

Section 804(b) of the FDCA, the provision that concerns commercial importation and is cited as the source of statutory authority for New Mexico’s proposed importation program, directs the Secretary to promulgate regulations “permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.”³ The FDCA imposes a number of conditions and limitations on commercial importation in sections 804(c) through (h). Regulations must include safeguards to ensure that imported product complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of the FDCA, as well as other “appropriate” safeguards determined by the Secretary.⁴ Additionally, section 804 imposes a number of conditions and limitations on commercial importation, including labeling conditions, reporting and recordkeeping responsibilities, and laboratory testing requirements for authenticity and degradation.⁵

Section 804 does not exempt imported prescription drugs from the premarket approval, misbranding, or adulteration provisions of the FDCA. Section 801 of the FDCA explicitly directs that any drugs “being imported or offered for import into the United States” that appear to be unapproved, misbranded, or adulterated “shall be refused admission” to this country.⁶ This provision is mandatory, and FDA has “no discretion to make an exception” by allowing the importation of drugs that appear to violate this prohibition.⁷

B. The Certification and Final Rule

Until now, every HHS Secretary has declined to authorize importation of prescription drugs under section 804 due to safety risks and the inability to show the required cost savings. A 2004 HHS Task Force Report (“Task Force Report”) made numerous factual findings about the problems of importation, including that it would increase the risk that counterfeit drugs

¹ FDCA § 801(d).

² *Id.* § 804(l)(1).

³ *Id.* § 804(b).

⁴ *Id.* § 804(c). Sections 501 and 502 of the FDCA define, respectively, adulterated and misbranded drugs. Section 505 prohibits the introduction into interstate commerce of unapproved drugs.

⁵ *Id.* § 804(d)–(h).

⁶ *Id.* § 801(a)(3).

⁷ *Cook v. FDA*, 733 F.3d 1, 8–9, 12 (D.C. Cir. 2013).

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would enter the drug supply chain and have little impact on drug prices.⁸ The Task Force was chaired by the Surgeon General and included representatives from HHS (including then-General Counsel Alex Azar and then-Administrator of the Centers for Medicare & Medicaid Services Mark B. McClellan), FDA, and other agencies. As recently as May 2018, former HHS Secretary Azar derided importation as a “gimmick” that would have “no meaningful effect” on drug prices and could not “be safely achieved.”⁹

On December 18, 2019, FDA and HHS issued a notice of proposed rulemaking (the “NPRM”) soliciting comments on a proposal to authorize commercial—but not personal—importation of certain prescription drugs from Canada under section 804.¹⁰ In a letter dated September 23, 2020, the Secretary wrote to Congress purporting to certify that implementation of the commercial importation provisions in subsections (b) through (h) of section 804 “poses no additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the American consumer.”¹¹ Immediately after the Secretary signed the letter to Congress, FDA and HHS publicly posted the Final Rule allowing for the commercial importation of certain drugs from Canada.¹²

The Final Rule authorizes the importation into the U.S. of certain drugs that are approved for sale in Canada. Such drugs could be imported from Canada under SIPs, which would be sponsored by states or tribes. The SIPs must identify Canadian wholesalers (“Foreign Sellers”), which would buy drugs from manufacturers and resell them to U.S. wholesalers or pharmacists (“Importers”), which in turn would arrange for the drugs to be imported and tested for authenticity and degradation (among other things). The Final Rule contains a nonseverability provision stating that if any provision therein is invalidated, the entire rule will cease to be effective. In addition to the entire rule becoming invalid, the Certification also would become “null and void.”¹³

A potential SIP Sponsor must submit an application (a “SIP proposal”) that identifies the SIP Sponsor and any co-sponsors, the eligible prescription drugs to be imported, the Foreign Seller in Canada that will purchase the eligible prescription drug directly from the manufacturer,

⁸ HHS Task Force on Drug Importation, Report on Prescription Drug Importation x–xi (Dec. 2004) (“Task Force Report”), <http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf>.

⁹ Alex M. Azar II, Remarks on Drug Pricing Blueprint (May 14, 2018), <https://web.archive.org/web/20201221180159/https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

¹⁰ The NPRM was published in the Federal Register on December 23, 2019. See Importation of Prescription Drugs, 84 Fed. Reg. 70,796 (Dec. 23, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-12-23/pdf/2019-27474.pdf>.

¹¹ Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020) (the “Certification”), <https://www.safemedicines.org/2020/09/hhs-secretary-sent-congress-the-certification-to-allow-canadian-drug-importation.html>.

¹² The Final Rule was published in the Federal Register on October 1, 2020. See Final Rule, Importation of Prescription Drugs, 85 Fed. Reg. 62,094 (Oct. 1, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf>.

¹³ 85 Fed. Reg. at 62,111.

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the Importer in the U.S. that will buy the drug directly from the Foreign Seller, the FDA-registered repackager or relabeler (if different from the Importer), and the laboratory in the U.S. which will conduct the testing required under section 804 (if the Importer will be responsible for conducting the statutorily-required testing).¹⁴ A SIP proposal must also explain how the SIP Sponsor will ensure, among other things, that:

- imported drugs meet applicable testing requirements;
- the supply chain is secure;
- the labeling requirements of the FDCA and the Final Rule are met;
- the post-importation pharmacovigilance and other FDCA requirements are met; and
- the SIP will result in a significant reduction in the cost to the American consumer.¹⁵

FDA must decline to authorize a SIP proposal for failure to meet the Final Rule's requirements.¹⁶ Furthermore, even if a SIP Proposal does meet the relevant requirements, FDA may nonetheless decide not to authorize a SIP proposal for a wide array of reasons, including because of potential safety concerns, uncertainty that a SIP proposal would adequately ensure the protection of public health, or the relative likelihood that a SIP proposal would not result in significant cost savings to the American consumer.¹⁷

Neither the Certification nor the Final Rule analyzed the safety or cost savings implications of section 804 implementation. Instead, the Secretary determined that implementation of section 804 as contemplated by the Final Rule would satisfy the requisite safety and savings standards because FDA and HHS would approve only those SIPs that demonstrated the ability to achieve those standards.

C. Ongoing Litigation

On November 23, 2020, PhRMA, PSM, and CAHC filed a complaint in the U.S. District Court for the District of Columbia challenging the Certification and the Final Rule.¹⁸ Among other allegations concerning the Certification, the complaint alleges that the Certification fails to satisfy section 804(D)(1) of the FDCA because that provision does not permit the Secretary to make a certification that is conditioned on future events or information, i.e., information

¹⁴ 21 C.F.R. § 251.3(d)–(e). The Final Rule provides for the possibility of a phased review process to evaluate a SIP proposal that does not identify a Foreign Seller but otherwise meets the relevant requirements, provided the Foreign Seller is identified within six months of the initial submission date. *Id.* § 251.4.

¹⁵ *Id.* § 251.3(d)–(e).

¹⁶ *Id.* § 251.4(a).

¹⁷ *Id.*

¹⁸ Compl., PhRMA v. U.S. Dep't of Health & Human Servs., No. 1:20-cv-03402 (D.D.C. Nov. 23, 2020).

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contained in future SIP proposals.¹⁹ The complaint also alleges that section 804(D)(1) requires the Secretary to certify that implementation of section 804 would reduce the *cost of covered products to American consumers* (whereas the Final Rule indicates that HHS and FDA may approve SIPs that demonstrate cost savings in ways not contemplated by the statute).²⁰ Additionally, the complaint challenges the Final Rule as unlawful on multiple grounds, including because it threatens patient safety.²¹ Based on these claims, among others, the plaintiffs seek an order holding unlawful, setting aside, and declaring invalid both the Certification and the Final Rule, as well as enjoining FDA and HHS from implementing section 804 and the Final Rule.

D. New Mexico's Application

On March 4, 2020, the New Mexico Legislature enacted legislation requiring the New Mexico Department of Health (“NMDOH”) to design a “wholesale prescription drug importation program” to allow for the importation of prescription drugs from Canada.²² The Wholesale Prescription Drug Importation Act (the “Act”) required the program design to, among other things, “contract with one or more state drug wholesalers to seek federal certification and approval” to import Canadian drugs.²³ The Act directed NMDOH to submit a formal request to the Secretary for certification of the State’s program on or before December 15, 2020,²⁴ and to begin implementing and operating the program within six months of receiving approval.²⁵

On October 27, 2020, NMDOH released its draft SIP application for public comment.²⁶ Comments from PhRMA, PSM, the Healthcare Distribution Alliance (“HDA”), and the National Association of Chain Drug Stores (“NACDS”) raised significant patient safety concerns associated with the proposed importation scheme, including concerns that importation would expose patients to adulterated, counterfeit, or otherwise substandard foreign product and that it would undermine federally mandated security protections of the drug supply chain.²⁷ PhRMA and PSM also emphasized that New Mexico’s importation plan did not demonstrate savings to

¹⁹ *Id.* ¶ 103.

²⁰ *Id.* ¶ 106.

²¹ *Id.* ¶¶ 125, 135; *see also id.* ¶¶ 61–71.

²² Wholesale Prescription Drug Importation Act, 2020 N.M. Laws ch. 45, *codified at* N.M. Stat. § 26-4-1 *et seq.*

²³ *Id.* § 26-4-4.

²⁴ *Id.* § 26-4-6.

²⁵ *Id.* § 26-4-7.

²⁶ NMDOH, Section 804 Drug Importation Application (Oct. 27, 2020), <https://www.nmhealth.org/publication/view/policy/6418/>.

²⁷ Comment from PhRMA (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6487/>; Comment from PSM (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6479/>; Comment from HDA (Nov. 30, 2020), <https://www.nmhealth.org/publication/view/general/6480/>; Comment from NACDS (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6477/>.

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the American consumer. NMDOH held a public hearing on December 2, 2020.²⁸ PSM's executive director testified about the problems with New Mexico's draft plan at the public hearing, and PSM's analysis of New Mexico's Draft Canadian Drug Importation Plan is posted on its website.²⁹

To meet the December 15 submission deadline required by state law, New Mexico had only two weeks to review public comments to the draft proposal. Although NMDOH made one update to the list of drugs to be imported, it made *no changes* to the body of the Application in response to written and oral comments received. In its apparent haste to file before the statutory deadline, New Mexico left in statements from the draft application stating that the document was being "published for public input and comment" in advance of submission to HHS.³⁰

According to the Application, the SIP is sponsored by the State of New Mexico through NMDOH and the New Mexico Board of Pharmacy ("NMBOP").³¹ If the SIP is approved, NMDOH plans to create and staff a Drug Importation Program Division ("NMDIP"), which will be dedicated solely to implementation of the approved SIP, maintenance of the drug importation program, and ensuring compliance with the requirements of section 804 of the FDCA, the Final Rule, the Drug Supply Chain and Security Act ("DSCSA"), other applicable provisions of the FDCA and its implementing regulations, and any applicable state regulations.³² NMDIP will work closely with NMBOP, which oversees the licensing of manufacturers, pharmacies, wholesale distributors, and limited drug clinics within New Mexico.³³

²⁸ See Video of Hearing on Wholesale Prescription Drug Importation Act (uploaded Dec. 4, 2020), <https://www.youtube.com/watch?v=IgalPR5GM34>; Report of Hearing Officer (Dec. 10, 2020), <https://www.nmhealth.org/publication/view/report/6519/>.

²⁹ New Mexico Public Hearing on Canadian Drug Importation (Dec. 3, 2020), <https://www.safemedicines.org/2020/12/new-mexico-public-hearing-on-canadian-drug-importation.html>; PSM, 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>.

³⁰ NMDOH, Section 804 Drug Importation Application ("Application") at 2 (Dec. 2020) (on file and received through records request under the New Mexico Inspection of Public Records Act); see also *id.* at 4 ("This Section 804 Importation Program (SIP) is being uploaded to the Department of Health Website on October 27th to provide an adequate period for public comment and a hearing on December 2nd before finalizing and submitting the SIP to the USDHHS on or before December 15, 2020.").

³¹ *Id.* at 14.

³² *Id.*

³³ *Id.*

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III. FDA cannot authorize the Application for the reasons set forth in the litigation.

FDA cannot authorize the Application because it was submitted pursuant to an invalid Certification and unlawful Final Rule. No SIPs can be authorized until the Secretary makes a valid Certification and FDA and HHS promulgate a valid rule pursuant to section 804.

A. Secretary Azar’s purported certification is invalid because it violates the FDCA and the Administrative Procedure Act (“APA”).

The Certification is contrary to section 804(l)(1) in several respects. For example, the Certification is conditioned on assumptions that states will submit SIPs in the future that will meet the safety and cost criteria. Yet, the statute requires the Secretary to certify “that the implementation of [section 804] *will*” produce significant savings for American consumers at no additional risk to public health and safety³⁴—leaving no room for the Secretary to defer this determination until sometime into the future. Additionally, Secretary Azar did not certify “implementation of this section,” as required by statute,³⁵ but instead certified only commercial importation under subsections (b) through (h). The Certification also implements section 804 through discrete SIPs sponsored by individual states or tribes, even though the statute requires the Secretary to certify that implementation will pose “no additional risk to the *public’s* health and safety” and will “result in a significant reduction in the cost of covered products to *the American consumer*.”³⁶ Furthermore, section 804(l)(1) requires the Secretary to certify that implementation of section 804 will lead to a “significant reduction *in the cost of covered products* to the American consumer,”³⁷ but the Final Rule permits SIPs to be approved on the basis of “cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program.”³⁸

The Certification also does not satisfy the APA’s requirement of reasoned decision-making. The Secretary inadequately considered both the potential health risks and the consumer savings associated with importation. He also entirely failed to consider, or failed to adequately consider, important aspects of the problem before him and failed to acknowledge or adequately explain HHS and FDA’s departure from long-held prior positions and factual findings related to importation. Furthermore, the Secretary’s stated rationale for certification is internally inconsistent and fails to support his decision to authorize commercial importation under the Final Rule.

Finally, the Certification was procedurally improper. HHS lacked authority to promulgate the NPRM before the Certification was issued. By failing to disclose facts or analyses supporting the Certification during the notice-and-comment process, the Secretary also deprived parties of the opportunity to comment meaningfully on the Certification.

³⁴ FDCA § 804(l)(1) (emphasis added).

³⁵ *Id.*

³⁶ *Id.* (emphasis added).

³⁷ *Id.* (emphasis added).

³⁸ 85 Fed. Reg. at 62,101.

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B. The Final Rule violates the APA, the FDCA, and the U.S. Constitution.

The Final Rule conflicts with the FDCA in key respects. Drugs imported under the Final Rule would necessarily be unapproved new drugs and misbranded drugs, neither of which can legally be imported into the U.S. Under the FDA's rigorous approval process, FDA scrutinizes everything about the drug, including its composition, the method of its manufacture, its packaging, and its labeling.³⁹ Drugs imported under the Application, however, would differ from drugs approved in the respective applications, for example, because the parties responsible for relabeling and repackaging a drug imported under a SIP and the relabeling and repackaging processes would not be identified in the New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") of the comparable FDA-approved drug. For similar reasons, drugs imported under the Final Rule would also be misbranded, because attaching FDA-approved labeling to an imported drug under the Final Rule would be both false and misleading.⁴⁰ The labeling mandated by regulation would mislead consumers that the drugs have been approved by FDA (which they have not), are identical to FDA-approved drugs (which they are not), and have the assurances associated with FDA-approved drugs (which they do not).

Additionally, the Final Rule is unlawful because FDA lacks the authority to (1) require a manufacturer to attest that a drug meets the conditions in an approved NDA or ANDA but for the fact that the drug bears Canadian labeling, or to notify FDA and explain with specificity why it cannot provide that attestation; (2) disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same; and (3) require manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and the FDA-approved drug to Importers for free.

The Final Rule is also arbitrary and capricious. Nowhere does the Final Rule explain why HHS is deviating from its longstanding policy that "Canadian versions" of FDA-approved drugs are unapproved and misbranded drugs that are not eligible for importation, and its prior repeated determinations that section 804 importation would not significantly reduce consumer drug costs. Additionally, the Final Rule fails to adequately consider how commercial importation under SIPs will necessarily increase the likelihood that U.S. patients will receive adulterated drugs and otherwise compromise U.S. public health and safety.⁴¹ That is because the Final Rule, among other things, shifts relabeling and repackaging from FDA-inspected facilities that are identified in an application to other facilities that FDA has not necessarily inspected and refuses to commit to inspect prior to SIP authorization; loosens restrictions on the drug supply chain by exempting supply chain members from DSCSA requirements; and increases the number of entities that are in the supply chain and which test product. The Final Rule asserts that States will be able to protect public health and safety because FDA will approve a SIP proposal only upon a demonstration that public health and safety will be protected—but that is a tautology, not the reasoned explanation required by law. Moreover, the Final Rule is arbitrary and capricious insofar as it fails to offer a reasoned explanation for why manufacturers cannot charge Importers reasonable, market-based prices for the costs of conducting the statutory testing or provision of trade secrets and CCI, analytical reference standards, and FDA-approved drugs.

³⁹ See FDCA § 505(b)(1).

⁴⁰ See *id.* § 502(a) (stating that a drug is misbranded if its labeling is false or misleading).

⁴¹ See *id.* § 501(a)(2)(B) (stating that a drug is adulterated if it is not manufactured and held in conformance with FDA's current and good manufacturing practice requirements).

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Furthermore, the Final Rule compromises manufacturers' constitutional speech rights. As promulgated, the Final Rule compels manufacturers to allow Importers to use, at no cost, the manufacturers' FDA-approved labeling, which includes the manufacturers' speech. This compelled use of manufacturers' labels, which often include the manufacturer's name and other trademarks, would imply that the manufacturers vouch for the quality of the imported drugs and the accuracy of their labeling and are associated with the Importer and the SIP, notwithstanding the statement that drugs were being imported without manufacturers' authorization. The compelled attestation, use-of-labeling, and testing provisions also amount to a compelled subsidy of Importers, and a knowing failure to comply with the testing provisions is a crime punishable by up to 10 years' imprisonment.⁴² Furthermore, in addition to forcing manufacturers to associate themselves with imported drugs, the Final Rule deprives them of the opportunity to add to the labels any disclaimers or other language to indicate, for instance, that they do not stand behind such products. In addition, because the Final Rule does not establish a process for solving disputes over attestations, manufacturers may feel compelled to make attestations with which they disagree, in violation of the First Amendment.

Finally, the Final Rule raises serious questions under the Fifth Amendment Takings Clause. The Fifth Amendment to the U.S. Constitution prohibits the Government from taking property without providing just compensation. The Final Rule would work an uncompensated taking by expropriating manufacturers' intellectual property in their drug labeling, testing protocols (or testing services), and in the similarity (or lack thereof) of U.S. and Canadian drugs, and giving it to Importers without providing any compensation.

IV. FDA should refuse to file the Application because it is incomplete.

Under the Final Rule, a SIP proposal serves as the critical mechanism for FDA to determine whether an importation program meets statutory and regulatory standards. Accordingly, the Final Rule requires the SIP Sponsor to submit a detailed "importation plan" that includes the key building blocks of the proposed program, including the SIP participants and the eligible prescription drugs to be imported. The Application New Mexico submitted is incomplete on its face. New Mexico fails to identify a Foreign Seller, Importer, or FDA-registered repackager or relabeler. Additionally, the Application provides only a tentative list of drugs to be imported, which will undergo two additional rounds of analysis before it is finalized.

FDA cannot assess whether the safety or cost criteria can plausibly be met without knowing the identity of pivotal supply chain participants or the drugs to be imported. Petitioners therefore urge FDA to refuse to file the Application for review, much like it would refuse to file an NDA or Biologics License Application ("BLA") that is deficient on its face in a way that precludes a complete review.⁴³

⁴² *Id.* § 303(b)(6).

⁴³ 21 C.F.R. §§ 314.101(d) (NDA or supplemental NDA), 601.2 (BLA or supplemental BLA); *see also* Draft Guidance for Industry, Refuse to File: NDA and BLA Submissions to CDER (Dec. 2017), <https://www.fda.gov/media/109758/download>.

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A. New Mexico misreads the Final Rule and provides FDA with almost no visibility into the supply chain.

The Final Rule emphasizes the importance of a short supply chain limited to just three entities—one manufacturer, one Foreign Seller, and one Importer—and the central role that each plays in a state’s ability to distribute drugs that meet the safety and cost criteria. Each SIP proposal must include the name and address of each of the above entities.⁴⁴ Each SIP proposal must also identify an FDA-registered repackager or relabeler that will relabel the imported drugs with the required U.S. labeling, if the Importer will not conduct the relabeling itself.⁴⁵ Not only must the SIP Sponsor supply the name and address of the above entities, it must also submit information sufficient for FDA to determine that such entities are capable of fulfilling their responsibilities throughout the supply chain.⁴⁶

During the notice-and-comment period, New Mexico and other commenters asked that FDA conditionally approve SIPs that are unable to designate the above SIP participants at the time of submission.⁴⁷ In response, FDA revised the Final Rule to allow SIP proposals to be submitted without naming the Foreign Seller. As the preamble explains, FDA will conduct a “phased review” where the Foreign Seller is not identified in the initial SIP, provided a Foreign Seller is identified within six months.⁴⁸ But FDA explicitly insisted that SIP Sponsors identify Importers and FDA-registered repackagers or relabelers in the initial submission of the SIP proposal. “[T]he required information regarding importers, relabelers, and repackagers still must be included in the initial submission,” even if a Foreign Seller is not identified until a later date.⁴⁹

The Application misreads the Final Rule, stating that “FDA has agreed to conditionally approve SIPs that are unable to designate a foreign seller, importer, and repackager at the time of SIP submission.”⁵⁰ New Mexico goes on to request a conditional approval without the designation of an Importer and repackager or relabeler—despite the fact that FDA explicitly refused to allow for such approvals under the Final Rule. The end result is that the only insight

⁴⁴ 21 C.F.R. § 251.3(d)(4)–(9), (e)(1).

⁴⁵ *Id.* § 251.3(d)(10).

⁴⁶ *Id.* §§ 251.3(e)(2)–(3) (requiring the submission of an attestation and information statement containing a complete disclosure of any past criminal convictions or violations against the Foreign Seller or Importer, as well as a list of all disciplinary actions for the previous seven years); 251.3(e)(4) (requiring the submission of the Health Canada inspectional history for the Foreign Seller and the state and federal inspectional history for the Importer); 251.3(d)(10) (requiring submission of adequate evidence of registration and of satisfactory resolution of any objectionable conditions or practices identified during the most recent FDA inspection at the repackager or relabeler).

⁴⁷ Application at 5; NMDOH, Written Comments in Response to Proposed Rulemaking 2–3 (Mar. 9, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1251> (reproduced in Appendix B in the Application).

⁴⁸ 85 Fed. Reg. at 62,099; *see also* 21 C.F.R. § 251.4.

⁴⁹ 21 C.F.R. § 251.4.

⁵⁰ Application at 5.

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FDA has into the supply chain is the manufacturer of the finished drug product—and, as explained below, even this limited information is subject to change.⁵¹

Evaluating the proposed importation scheme without knowing the identity of the Importer or the FDA-registered repackager or relabeler is impermissible according to the Final Rule. Doing so is also fundamentally unworkable, particularly where a Foreign Seller is also not provided. FDA must evaluate, among other things, whether the Importer is licensed by New Mexico as a pharmacist or wholesale distributor, has been the subject of disciplinary actions, and has demonstrated the capability of meeting current good manufacturing practice (“CGMP”), supply chain security, and pharmacovigilance requirements. And, if the Importer will not conduct relabeling on its own, FDA must evaluate whether the repackager or relabeler is properly registered and capable of relabeling the imported drugs with the required U.S. labeling, including the carton and container labeling, Prescribing Information, and any patient labeling, such as Medication Guides, Instructions for Use, and patient package inserts.

Failure to identify a Foreign Seller within 6 months of the initial submission is grounds to deny a SIP proposal.⁵² In addition, FDA cannot approve the Application unless and until a Foreign Seller is identified that meets statutory and regulatory requirements.⁵³ If and when New Mexico names the Foreign Seller, FDA must evaluate, among other things, whether the Foreign Seller is licensed to wholesale drugs by Health Canada and registered with FDA as a Foreign Seller, has been the subject of disciplinary actions, and has demonstrated the capability of meeting CGMP requirements and supply chain security requirements, including serialization, maintaining traceability records, and monitoring for counterfeit drugs. Closely inspecting the Foreign Seller is also essential to evaluating the risks posed by transshipments and counterfeits and the jurisdictional and enforcement challenges posed by the Foreign Seller being an ex-U.S. entity. In addition, the Foreign Seller’s sales arrangements with the Importer must be examined to meaningfully assess whether importation will result in cost savings to the American consumer.

B. The Application provides only a tentative list of drugs to be imported.

The Final Rule also requires a SIP Sponsor to submit a list of drugs to be imported under the SIP for FDA’s review.⁵⁴ Yet, the Application provides only a tentative list of eligible

⁵¹ See Part IV.B, *infra*.

⁵² 21 C.F.R. § 251.4 (“[T]he SIP Proposal will be denied if a Foreign Seller is not identified within 6 months of the initial submission date of the SIP Proposal.”).

⁵³ 85 Fed. Reg. at 62,099 (“A Foreign Seller will still need to be identified and registered with FDA, and FDA will still review information about the Foreign Seller, before FDA will authorize a SIP.”).

⁵⁴ See 21 C.F.R. § 251.3(d)(3)–(4) (stating that a SIP proposal must include the name and DIN of each eligible prescription drug that the SIP Sponsor seeks to include in the SIP, as well as the name and address of the applicant that holds the approved NDA or ANDA and the approved NDA or ANDA number). Additionally, the SIP Sponsor must list the name and address of the manufacturer of the finished dosage form of the eligible prescription drug and the name and address of the manufacturer of the active ingredient or ingredients, if known or reasonably known. 21 C.F.R. § 251.3(d)(5)–(6). The Application fails to provide this information and offers no explanation for why such information is not known or reasonably known. The Application

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prescription drugs, which the State admits will undergo significant revision prior to commencement of the program.

Appendix C of the Application provides a list of forty drugs with “potential cost savings,”⁵⁵ and Section V of the Application provides that these represent the “top-spend drugs from each of the licensed payers in the state.”⁵⁶ However, the Application goes on to provide that this list represents only the first round of analysis. After the SIP is approved, NMDOH will develop a common list of drugs for which payers anticipate savings after accounting for supply chain costs. In a third round of analysis, participating health plans, NMBOP, hospitals, and other interested stakeholders will review the list to assess whether operational considerations weigh against importation of any drug proposed for importation. Only after this third round will a final list of drugs be presented to FDA.⁵⁷

New Mexico’s approach directly contradicts the text of the Final Rule, which requires a SIP proposal to provide FDA with a list of each eligible prescription drug that the SIP Sponsor actually seeks to import. It also stymies FDA’s ability to adequately assess the safety and cost implications of the proposed SIP program. In the Final Rule, FDA clarifies that it will determine whether a product can be imported safely in the context of a specific SIP proposal on a product-by-product basis.⁵⁸ However, New Mexico’s list of products is so tentative—dependent, as it is, on future analyses—that the State cannot explain how it “it will address any concerns arising from the manufacture, storage, and transport of each eligible prescription drug,” and FDA cannot adequately determine whether such products can be imported safely.⁵⁹

Petitioners also note that New Mexico was “unable to locate” the Canadian proprietary name, Canadian generic name, DIN, company, strength, dosage form, number of active ingredients, and Canadian ingredients for a drug it added to the list following public comment.⁶⁰ This oversight further indicates that the State has not conducted the requisite due diligence on the drugs it seeks to import.

also fails to provide adequate evidence that each HPFB-approved drug’s FDA-approved counterpart is currently commercially marketed in the United States. *Id.* § 251.3(e)(6).

⁵⁵ Application at Appendix C.

⁵⁶ *Id.* at 6. To identify these drugs, NMDOH requested a list of the 40 top-spend drugs, and then identified drugs common to all payers.

⁵⁷ Application at 7.

⁵⁸ 85 Fed. Reg. at 62,097. Drugs to be evaluated on a product-by-product basis include sterile drugs, drugs requiring special storage conditions, and drugs intended to be used solely with a specific, separately distributed delivery system.

⁵⁹ *Id.*

⁶⁰ Application at Appendix D, tbl.2, at 6.

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V. **The Application’s compliance plan does not demonstrate that importation will pose no additional risk to public health and safety.**

Section 804(*I*)(1) of the FDCA requires the Secretary to certify that importation will “pose no additional risk to the public’s health and safety.”⁶¹ The preamble to the Final Rule emphasizes that commercial importation can be implemented consistently with the section 804(*I*)(1) certification criteria because “[t]he final rule includes requirements relating to the types of drugs eligible for importation, the distribution channels and methods used for product traceability, and the testing of eligible prescription drugs for authenticity and degradation” and because “[t]he SIP Sponsor must demonstrate, among other things, how it will ensure that the supply chain in the SIP is secure.”⁶² The Application fails to satisfy these safeguards, thereby posing significant safety risks that require FDA to reject the Application.

The stakes are too high to afford the State leeway here. Petitioners emphasize that many of the safety issues flagged below were raised to NMDOH by stakeholders during the public comment period. However, New Mexico hastily submitted the Application without addressing *any* of the comments from PhRMA, PSM, HDA, and NACDS.⁶³

A. **The Application fails to provide assurance that imported drugs will be transported, stored, repackaged, and relabeled in compliance with CGMP requirements.**

A drug is adulterated if it is not manufactured and held in conformance with FDA’s current good manufacturing practice (“CGMP”) requirements.⁶⁴ The Application contains *no mention* of CGMP requirements at all and otherwise fails to provide adequate assurance that imported drugs will be transported, stored, repackaged, and relabeled in a CGMP-compliant manner.

As described in the litigation and above, commercial importation necessarily increases the risk that the imported drugs will not conform with CGMP requirements. Although FDA typically inspects packagers and labelers identified in NDAs before they are permitted to engage in packaging and labeling, FDA is refusing to commit to inspect repackagers and relabelers identified in SIP proposals before they are permitted to engage in repackaging and relabeling.⁶⁵ In addition, commercial importation increases the number of entities that are in the supply chain, including a Canadian wholesaler and a U.S. repackager. Moreover, for NDA products, FDA’s inspection oversight of packaging and labeling facilities goes well beyond general facility, personnel, and procedural controls. It also includes evidence that the facility is capable of packaging and labeling the specific product submitted in the NDA. Therefore, the mere use of FDA-registered facilities for repackaging and relabeling activities without disclosure of such a facility in the NDA and the safeguard of a potential inspection to assure product-specific capability would undermine important regulatory protections.

⁶¹ FDCA § 804(*I*)(1).

⁶² 85 Fed. Reg. at 62,106.

⁶³ N.M. Stat. § 12-8-4.

⁶⁴ FDCA § 501(a)(2)(B).

⁶⁵ 85 Fed. Reg. at 62,101.

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The NMBOP inspection provisions in the Application do not alleviate the above concerns. According to the Application, NMBOP will conduct on-site inspections of resident program participants to ensure compliance with state and federal regulations; for non-resident program participants (including, by definition, the Foreign Seller), NMBOP will review reports from FDA, local licensing bodies, or NMBOP-recognized third parties.⁶⁶ New Mexico provides no indication of how often NMBOP will conduct inspections, what will trigger an inspection, and how an inspection will proceed. Moreover, New Mexico does not indicate when it plans to implement these provisions. Not only has New Mexico failed to describe how it will carry out inspections under its Application, the State also does not address how it will conduct inspections during the COVID-19 pandemic. FDA has paused most on-site inspections for the duration of the public health emergency.⁶⁷

The lack of any inspections of non-resident program participants is even more troubling. It is not clear whether New Mexico refuses to inspect non-resident participants because of jurisdictional limitations or resource constraints. Yet, to provide meaningful oversight of program non-resident participants, NMBOP and FDA must inspect them. Relying on reports conducted by any party except FDA, to the extent such reports exist, coupled with FDA's refusal to commit to conduct pre-importation inspections of participants and 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 be disaggregated to differentiate between SIP drugs and drugs under the control of the manufacturer. And FDA might not be able to share establishment inspection reports without significant redactions, which would limit NMBOP's ability to rely on FDA inspections to inform the State's oversight over non-resident program participants.

To the extent that New Mexico attempts to otherwise articulate policies and procedures to ensure CGMP compliance, the State falls far short of regulatory requirements. The Application, for instance, states that “[t]he importer must screen eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product.”⁶⁸ Yet, the Application fails to include how exactly the Importer will meet this requirement and how the State will ensure compliance, as required under the Final Rule.⁶⁹ The Application similarly offers a conclusory statement that “[r]elabeling shall be done by parties who, and in a manner that meets all state and federal

⁶⁶ Application at 15, 19–21.

⁶⁷ See Guidance for Industry, Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency: Questions and Answers 3 (Aug. 2020), <https://www.fda.gov/media/141312/download> (“FDA is using its COVID-19 Advisory Rating system to determine what categories of regulatory activity can take place in a given geographic region and, based on this determination, FDA is either continuing, on a case-by-case basis, to conduct only ‘mission-critical’ inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval and surveillance inspections.”) (internal citations omitted).

⁶⁸ Application at 23.

⁶⁹ See 21 C.F.R. § 251.3(e)(11)(iii) (requiring the SIP proposal to describe the procedures the SIP Sponsor will use to ensure that the “Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product”).

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requirements.”⁷⁰ Such unsupported statements do not adequately establish that each drug is what it purports to be.

Several drugs on the tentative list of drugs to be imported raise significant adulteration concerns. Seven drugs on the initial list of eligible prescription drugs are HIV/AIDS drugs, which must be stored at a temperature that does not exceed 30 degrees Centigrade. The Application provides no guidelines for ensuring that each supply chain participant complies with the storage instructions included in each drug’s labeling. Adverse consequences resulting from improper storage, testing, or processing would be material to consumers, particularly among vulnerable populations such as patients with HIV/AIDS. Exposure to substandard or counterfeit HIV/AIDS medications could also lead to antiviral resistance, which could “halt the progress made combatting the HIV epidemic.”⁷¹

Other categories of drugs proposed for importation could also pose heightened safety concerns because they require specialized storage conditions, including temperature, handling, and packaging requirements. For example, the eight cancer drugs listed must be stored at room temperature, and improper storage may reduce efficacy and increase side effects.⁷² Temperature requirements for diabetes drugs vary from drug to drug—some must be kept at room temperature, while others must be kept refrigerated—and may include product-specific instructions with implications for patient safety. For instance, one drug must be stored in the refrigerator but not directly adjacent to the refrigerator cooling element and cannot be used if it is inadvertently frozen. Labeling for other drugs, such as those used to treat cancer, multiple sclerosis, and asthma/chronic obstructive pulmonary disease, include storage instructions about protection from heat, moisture, and light, and/or require the drugs to be stored in the original container. Improper storage and transportation of imported drugs impacts patient safety by reducing potency or rendering them otherwise unsafe.⁷³

B. The Application does not adequately address testing, supply chain security, and post-importation requirements.

Precautions in section 804 and the Final Rule related to testing, supply chain security, and post-importation pharmacovigilance are essential to ensuring that drugs imported under section 804 will not pose an additional risk to patient safety. The Application does not sufficiently address these considerations.

⁷⁰ Application at 24.

⁷¹ Gilead Sciences, Inc., Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 4–6 (Mar. 7, 2020), <https://beta.regulations.gov/comment/FDA-2019-N-5711-1223>.

⁷² ND Vlieland et al., *Actual Versus Recommended Storage Temperatures of Oral Anticancer Medicines at Patients’ Homes*, 25 J. Oncol. Pharm. Practice 382 (2017), <https://journals.sagepub.com/doi/10.1177/1078155217741767>.

⁷³ Genentech, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 2 (Mar. 9, 2020), <https://beta.regulations.gov/comment/FDA-2019-N-5711-1207>.

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1. Statutory Testing

Although “no testing scheme is foolproof,”⁷⁴ testing helps ensure that imported product will pose no additional risk to the public’s health and safety. Accordingly, section 804 of the FDCA and the Final Rule mandate that the Importer or the manufacturer test imported drugs for authenticity, degradation, and compliance with established specifications and standards of the FDA-approved drug (“Statutory Testing”).⁷⁵ The Final Rule further requires that a SIP proposal include a summary of how the SIP Sponsor will ensure that “[t]he imported eligible prescription drugs meet the Statutory Testing requirements.”⁷⁶

New Mexico’s provisions on Statutory Testing leave critical questions unanswered. The Application states that all products imported through New Mexico’s importation program will be held within the Customs and Border Protection (“CBP”) port of entry or foreign trade zone approved by FDA pending FDA review and approval of the testing results.⁷⁷ However, the Application does not address how the sample will be collected, transported, and tested. This information is necessary to evaluate the safety of drugs imported under the State’s plan.

Moreover, the Application states that Statutory Testing “shall be conducted by a qualifying laboratory approved by the FDA,”⁷⁸ but does not provide the name of the qualifying laboratory as required under the Final Rule.⁷⁹

2. Supply chain security

A SIP proposal must include the procedures a SIP Sponsor will use and the steps it will take to ensure that “(i) storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of part 205 of this chapter [providing guidelines for state licensing of wholesale prescription drug distributors] and do not affect the quality or impinge on the security of the eligible prescription drugs; and (ii) [the] supply chain is secure.”⁸⁰ The Final Rule assigns SIP Sponsors responsibility for administering SIPs, even

⁷⁴ HHS Task Force Report at 30.

⁷⁵ FDCA § 804(e), (d)(1)(J)–(L); 21 C.F.R. § 251.16(a). “Statutory Testing” is defined to mean “the testing of an eligible prescription drug as required by section 804(d)(1)(J) and (L) and section 804(e) of the [FDCA], including for authenticity, for degradation, and to ensure that the prescription drug is in compliance with established specifications and standards.” 21 C.F.R. § 251.2.

⁷⁶ 21 C.F.R. § 251.3(d)(11)(i).

⁷⁷ Application at 24.

⁷⁸ *Id.*

⁷⁹ 21 C.F.R. § 251.3(e)(7) (“The SIP Sponsor’s importation plan must also identify the qualifying laboratory that will conduct the Statutory Testing for the Importer, if the Importer is responsible for conducting the Statutory Testing, and it must establish that the laboratory is qualified in accordance with § 251.15 to conduct the tests.”).

⁸⁰ 21 C.F.R. § 251.3(e)(11)(i)–(ii); *see also id.* § 251.3(d)(11)(ii) (stating that the overview of the SIP proposal must include a summary of how the SIP Sponsor will ensure that the supply chain is secure).

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though states play no role in implementing the DSCSA and therefore lack experience overseeing the supply chain.⁸¹ The Application, meanwhile, provides little concrete information on how New Mexico plans to ensure that drugs are stored, handled, and distributed appropriately and that the supply chain is not threatened.

The Application states that registration with the NMDIP, combined with the NMBOP facility licensure requirement and state regulations that require compliance with the DSCSA and oversight of the importation program, will “help to 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.”⁸² Although New Mexico acknowledges that the Foreign Seller will not be licensed with the NMBOP, the Application provides that the Foreign Seller shall “agree . . . to comply” with NMDIP requirements, including “[complying with] applicable DSCSA requirements, having systems in place to determine whether a drug to [be] imported to the U.S. Importer is a suspect product or illegitimate product, and applying the [section 804 serial identifier] SSI and responding promptly to SSI inquiries.”⁸³

However, the uncertainty regarding FDA’s ability (much less New Mexico’s ability) to enforce compliance by entities located outside the U.S. will pose additional risk to public health and safety. As Innovative Medicines Canada noted in its comment to the NPRM, certain companies involved in commercial importation may not have a nexus to the U.S. and may therefore “fall outside FDA’s regulatory ambit,” thereby impeding FDA’s ability to ensure compliance and to fully investigate and redress violations.⁸⁴ The Application does not explain how the SIP program will address FDA’s limited reach overseas, much less how New Mexico can exercise jurisdiction over entities with no connection to the State. Nor does it address the practical limitations of pursuing enforcement against foreign entities. By failing to address loopholes within the DSCSA framework, New Mexico’s plan would increase the risk of illegitimate or counterfeit medications entering the U.S. and place patient safety in jeopardy.

With respect to the Importer, the Application simply reiterates the requirements of the Final Rule, which imposes significant obligations on Importers that are not required of wholesale distributors and pharmacists outside of commercial importation. Yet, beyond stating that the Importer “shall agree to comply” with applicable requirements, New Mexico does not establish that the as-yet-unidentified Importer has the relevant expertise and capacity.

New Mexico’s proposed oversight mechanisms, meanwhile, demonstrate that the State has not fully thought through its responsibilities. The Application provides that NMDIP will conduct audits of all registered program participants to ensure, for instance, that “the storage, handling, and distribution practices . . . meet certain requirements.”⁸⁵ Yet, New Mexico does not have the experience and know-how to assess compliance with many of these federal supply

⁸¹ See generally FDCA § 581 *et seq.*

⁸² Application at 17.

⁸³ *Id.* at 17–18.

⁸⁴ Innovative Medicines Canada (“IMC”), Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 6 (Mar. 6, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1145>.

⁸⁵ Application at 21.

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chain requirements, and it does not explain how it will procure the experience and knowledge to perform its responsibilities. The Application further states that audits will evaluate whether “the supply chain is secure,” but New Mexico provides no meaningful information about what this evaluation will involve.⁸⁶ The same flaws identified above with respect to CGMP inspections apply equally here, as well. Most notably, NMBOP will not be inspecting non-resident facilities, creating a gap in the State’s control over the drug supply chain.

The Application’s provisions on managing suspect and illegitimate products raise additional concerns. The procedures described conflict with certain statutory requirements. For example, the DSCSA includes detailed requirements regarding how supply chain entities identify suspect and illegitimate products, conduct investigations, and, if necessary, take further action. New Mexico’s procedures, however, do not clearly distinguish between these steps, which could cause confusion for Foreign Sellers new to the DSCSA. Moreover, the Application suggests that New Mexico has not considered the full range of issues that could give rise to a product being suspect or illegitimate. The Application states that “[i]f a product is determined to be unfit for distribution, it shall remain quarantined until further direction is received by the FDA.”⁸⁷ This provision is unduly narrow compared to what the DSCSA requires. *One* of the issues that could lead a trading partner to determine that a product is suspect or illegitimate is if it seems unfit for distribution. Yet, the statutory definitions also address products that are or appear to be counterfeit, diverted, or stolen, intentionally adulterated, or the subject of a fraudulent transaction.⁸⁸

The Application’s statement that “[p]roduct that has been cleared for destruction shall be processed as an unsaleable return to a FDA registered reverse distributor based in the U.S.” leaves critical questions unanswered.⁸⁹ The term “cleared for destruction” does not appear in the DSCSA, and it is unclear how it intersects with DSCSA requirements. Moreover, the Application does not address what the reverse distributor is supposed to do with product that is cleared for destruction and how New Mexico will verify that such product does not re-enter the supply chain. Finally, the State appears to rely on FDA to provide direction on disposing of unsafe product, even though the State is supposed to be implementing the commercial importation program and ensuring the safety of imported product.⁹⁰

The Application’s deficiencies are all the more concerning in light of the fact that New Mexico already faces a crisis of counterfeit pharmaceuticals masquerading as legitimate medicine.⁹¹ As noted in four comments to the draft application, Canada lacks a track-and-trace

⁸⁶ *Id.*

⁸⁷ *Id.* at 26.

⁸⁸ FDCA § 581(8), (21).

⁸⁹ Application at 26.

⁹⁰ *Id.* (“If a product is determined to be unfit for distribution, it shall remain quarantined until further direction is received by the FDA.”). Similarly, New Mexico states that “[i]f a supply chain participant receives a request for verification from FDA for a product, the supply chain participant shall follow the steps listed above.” *Id.* This suggests that New Mexico does not plan to send its own verification requests and would rely on the FDA.

⁹¹ PSM, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 3 (Feb. 11, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-0055>.

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system, and it is impossible to know with certainty that drugs were not tampered with before arrival in the U.S.⁹² State residents have died from taking counterfeit, fentanyl-laced pills.⁹³ Moreover, 10 different medical practices in New Mexico have been implicated in black market supply chains associated with counterfeit cancer treatments and other therapies.⁹⁴

3. Post importation requirements

The Final Rule requires a SIP Sponsor to demonstrate that post-importation pharmacovigilance and other requirements of the FDCA and the Final Rule are met.⁹⁵ Additionally, the Final Rule requires that a SIP proposal include the SIP's recall plan, including an explanation of how the SIP Sponsor will obtain recall or withdrawal information and how it will ensure such information is shared among the SIP Sponsor, Foreign Seller, Importer, manufacturer, and FDA.⁹⁶ In language added following public comment, the Final Rule also requires the SIP proposal to include the SIP's return plan, including an explanation of how the SIP Sponsor will ensure that non-saleable returned product is properly dispositioned in the U.S. and how the SIP Sponsor will prevent the non-saleable returned drugs from being exported from the U.S.⁹⁷

Pharmacovigilance involves 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. Manufacturers have complex pharmacovigilance systems and processes in place to detect, assess, and understand any adverse effects and drug-related problems, but there is no indication that New Mexico has similar systems and processes in place. Moreover, the State might find incentives to not report adverse events, if the consequence could be termination of the SIP program.⁹⁸

New Mexico seems to be asking FDA to approve its SIP on the basis of licensure requirements for each entity to “develop a plan for handling any complaints or reported adverse

⁹² Comment from PhRMA (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6487/>; Comment from PSM (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6479/>; Comment from HDA (Nov. 30, 2020), <https://www.nmhealth.org/publication/view/general/6480/>; Comment from NACDS (Dec. 1, 2020), <https://www.nmhealth.org/publication/view/general/6477/>.

⁹³ PSM, The Deadly Counterfeit Drug Trade Thrives in New Mexico (Sept. 2019), <http://www.safemedicines.org/wp-content/uploads/2019/09/NM-2020-DesignUpdate-infosheet-SECURE.pdf>.

⁹⁴ *Id.*

⁹⁵ 21 C.F.R. § 251.3(d)(11)(iv).

⁹⁶ *Id.* § 251.3(e)(13).

⁹⁷ *Id.* § 251.3(e)(14).

⁹⁸ PSM, 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>.

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events in accordance with the NMDIP and federal laws and regulations.”⁹⁹ Without seeing the plans themselves, however, FDA cannot evaluate whether these plans are adequate. To highlight just one potential deficiency, it is unclear whether any of these entities employs medical professionals who can make determinations regarding causation. Importers and wholesalers also have no experience with or infrastructure for reporting adverse events to FDA or following up on adverse event reports to receive more information. Moreover, as discussed above, NMBOP has no oversight over the Foreign Seller, and therefore its assurance that the Foreign Seller will develop an appropriate plan deserves little weight.

Moreover, the Application’s recall and return plans are insufficient to ensure that dangerous products will be taken out of distribution. New Mexico states that “[t]he high level of tracing required by the DSCSA will ensure that all recalled products shall be quickly identified and removed at all levels of the supply chain.”¹⁰⁰ However, as discussed above, the proposed importation plan creates numerous loopholes in the DSCSA regulatory regime that undermine such an assumption. Furthermore, although the Application outlines the responsibilities of the supply chain participants in the event of the recall, it does not address how any one entity will make the critical determination of whether a recall is warranted. Traditionally, the decision to institute a recalls falls under the purview of the manufacturer and FDA, but the Final Rule requires the SIP Sponsor to assume the role of effectuating a recall if mandated or requested by FDA, or initiated by the SIP Sponsor itself, the Foreign Seller, the Importer, or the manufacturer.¹⁰¹ New Mexico acknowledges that it bears “ultimate responsibility” for drug recalls but does not demonstrate that it is equipped to make a recall determination.¹⁰²

The return plan is also flawed. The Application provides that saleable and non-saleable goods will be subject to the as-yet-unidentified Importer’s return policy and procedures.¹⁰³ Without seeing the relevant policy and procedures, however, FDA cannot identify whether they are sufficient to ensure that statutory and regulatory requirements are met.

C. The Application does not demonstrate that the SIP entities have the financial resources and capacity necessary to ensure that drugs imported under the SIP would be safe.

The Final Rule assigns SIP Sponsors responsibility for administering SIPs. But states lack the know-how to ensure that drug supply chain participants are compliant with CGMP and good distribution practices; do not have the systems in place to inspect drug supply chain participants; play no role in implementing the DSCSA; lack expertise with pharmacovigilance;¹⁰⁴ and do not traditionally effectuate product recalls and returns. States seeking to pursue commercial importation will need to dedicate appropriate resources to fulfill these

⁹⁹ Application at 18–20 (providing for similar requirements for the Foreign Seller, Importer, and relabeler, as well as for the “drug warehouse, pharmacy, and limited drug clinic”).

¹⁰⁰ *Id.* at 26.

¹⁰¹ *Id.* § 251.18(e).

¹⁰² Application at 26.

¹⁰³ *Id.* at 28.

¹⁰⁴ PhRMA, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 22 (Mar. 9, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1236>.

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responsibilities. However, the Application provides no explanation of how the importation program will be funded. State regulators already are strapped for resources, and failure to budget adequate funds could impede the State's efforts to secure the safety of the drug supply.¹⁰⁵

The new responsibilities assumed by the Foreign Seller and Importer—including serialization, meeting CGMP and supply chain security requirements, and carrying out pharmacovigilance responsibilities—also are resource and expertise-intensive.¹⁰⁶ Assigning such tasks to an underfunded and capacity-constrained entity would inevitably increase safety risks (as well as require substantial investments, the recoupment of which would greatly reduce, if not eliminate, any purported cost savings from importation).

VI. The Application fails to demonstrate how the SIP will result in a significant reduction in the cost to the American consumers as required by the statute and the Final Rule.

As discussed above in Section III, section 804 requires a demonstration that importation will lead to a “significant reduction in the *cost of covered product to the American consumer.*”¹⁰⁷ The Final Rule purports to allow for consumer cost savings to be demonstrated in other ways, such as by increasing the number of people covered by a state government program or increasing the availability of drugs covered by the program.¹⁰⁸ Even if that were permitted by the statute (and it is not), the Application provides scant indication that the proposed SIP program will lead to any—let alone significant—reduction in cost to consumers. The Application offers only the roughest back-of-the-envelope math (based largely on spending by health plans, not individual consumers) to support its claims that importation would reduce the cost of covered products to New Mexico consumers. Moreover, the Application ignores substantial start-up and administrative costs which will limit the State's cost savings or eliminate any savings entirely.

¹⁰⁵ Nat'l Ass'n of Boards of Pharmacy, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 4 (Mar. 4, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1082> (“This Proposal comes at a time when boards of pharmacy around the country are feeling pressure to do more with less. It is vital that the very expertise the Proposal contemplates utilizing within the state government is sufficiently resourced to handle the incredibly important safety obligations this Proposal would place on Sponsors.”); Partnership for Safe Medicines, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 3–4 (Feb. 11, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-0055> (“Law enforcement and regulators are already struggling to inspect large volumes of pharmaceuticals coming over the U.S. border, including deadly fentanyl and other drugs masquerading as legitimate medicine. These resource-strapped regulators will not have the ability to oversee an importation program under the proposed rule and would not be able to protect the public health. Moreover, a state importation program would stretch resources even more, exacerbating risks already posed by counterfeit medicines.”).

¹⁰⁶ PhRMA, Comment Letter on NPRM, at 22–23.

¹⁰⁷ FDCA § 804(l)(1)(B).

¹⁰⁸ 85 Fed. Reg. at 62,101; *see also* 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

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A. **Contrary to the statute and the Final Rule, the Application focuses on purported savings to health plans.**

Both the FDCA and the Final Rule require a demonstration of “significant” cost savings to consumers.¹⁰⁹ Indeed, FDA states in the preamble to the Final Rule that a SIP proposal should “clearly articulate the mechanism by which the proposal will reduce costs to consumers” and “provide relevant information given that context.”¹¹⁰ By contrast, New Mexico seeks approval primarily based on health plan estimates. These estimates will undergo two additional rounds of analysis before being finalized, which could significantly affect cost savings.

New Mexico’s savings estimates provided in the Application are based largely on utilization and cost data from “12 of the larger commercial insurance firms” in the State.¹¹¹ Based on its analysis of this data, the State found that these plans “are spending greater than \$64 Million dollars/year above what these same drugs cost on the international market.”¹¹² However, as discussed above in Section IV.B, New Mexico explicitly acknowledges that further analyses are necessary. Following federal approval, the State plans to have each payer compare the estimated per unit import cost with its own net unit cost of each drug, so as to develop a common list of drugs for which payers anticipate savings after accounting for supply chain costs. In a third round of analysis, stakeholders will address whether all of the drugs on this list are suitable to dispensers, whether any listed drugs will lose U.S. patent rights in the coming years, and whether there are concerns regarding the continuity of supply for the drugs on the list. As New Mexico winnows the list of drugs over time, the potential savings will decline, as well. The \$64 million figure also does not account for the rate at which plans will substitute U.S.-approved prescription drugs with imported product.

New Mexico’s final estimates of savings to health plans fall far short of the “sufficiently detailed” explanation required under the Final Rule. The Application simply states:

The estimated, aggregate amount of savings on drug spend in dollars and as a percentage of health plan drug spend will be provided to USDHHS [following the third round], but early estimates project a savings of \$40 million if plans replaced all prescriptions with those from the drug importation program. Even with a 15% substitution, savings for the uninsured would amount to \$6 million. This estimate seems reasonable given planned program outreach, marketing, and education.¹¹³

New Mexico does not explain how it arrived at the \$40 million figure or why a 15% substitution rate is “reasonable.”

¹⁰⁹ FDCA § 804(l)(1)(B); 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

¹¹⁰ 85 Fed. Reg. at 62,101.

¹¹¹ Application at 9–10.

¹¹² *Id.* at 11; *see also id.* at Appendix C, tbl.1.

¹¹³ *Id.* at 7.

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B. The Application offers only the roughest back-of-the envelope math to support its claims that importation would reduce the cost of covered products to New Mexico consumers.

The estimated savings to consumers are even more attenuated. New Mexico cobbles together several data sources, which it crudely uses to arrive at disparate cost savings estimates, none of which is supported by detailed analysis.

First, New Mexico attempts to analyze consumer savings by using the claims data from insurance plans discussed above. With minimal explanation, and no discussion of the “insurance formularies, [Pharmacy Benefit Managers] PBMs, [and] rebate structures” that it acknowledges will impact the actual cost for consumers, the Application concludes that \$9.8 million (or \$6.0 million if HIV drugs are excluded) “is a realistic number,” since it assumes that only 15% of the \$64 million in potential savings would be realized by consumers.¹¹⁴ However, payers and PBMs are not obligated to reduce premiums or copayments in response to importation, and thus there is no guarantee that consumers will see any savings at all. Moreover, adjustments to copayments typically are done on a plan-wide basis, not a drug-by-drug basis, making it difficult for payers and PBMs to reduce copayments for imported products only. Furthermore, as PSM stated in its analysis of the draft importation plan, New Mexico’s Application does not prevent middlemen, such as health plans and PBMs, from *inflating* prices to the detriment of patients.¹¹⁵

Next, the Application attempts to approximate savings to New Mexico consumers using all payer data from Colorado. The Application concludes that “[g]iven the uncertainties in these calculations and adjusting for population (5.8 million in CO and 2.1 million in NM), size of the economy (\$353B vs. \$94B), penetration of commercial insurance (60% vs. 28%), and Medicaid (20% vs. 42%), a \$4.0 Million savings in NM is reasonable.”¹¹⁶ However, the Application offers no insight into how it weighed the above factors in its analysis. New Mexico also cites analyses from Vermont, but offers no explanation as to how the demographics of that state compare to those in New Mexico.

Third, New Mexico uses a recent paper in the *Journal of the American Medical Association*¹¹⁷ to estimate out of pocket costs for the uninsured to purchase drugs for 13 major conditions. For example, the paper states that pharmaceutical costs associated with diabetes equaled \$52 billion in 2016; NMDOH adjusts this figure to account for New Mexico’s population as a percentage of the national population and to reflect the percentage of New Mexicans who are uninsured, arriving at a “rough estimate” of \$41 million in out of pocket costs.¹¹⁸ It is not clear how these out-of-pocket costs relate to potential cost savings under the proposed

¹¹⁴ *Id.* at 11.

¹¹⁵ See PSM, 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>.

¹¹⁶ Application at 11.

¹¹⁷ Joseph L. Dieleman et al., *US Healthcare Spending by Payer and Health Condition, 1996-2016*, 323 JAMA 863 (2020), <https://jamanetwork.com/journals/jama/fullarticle/2762309>.

¹¹⁸ Application at 11–12.

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importation scheme. Indeed, many of the drugs used to treat the listed conditions, such as insulin, are not eligible for importation under the Final Rule.

Finally, the Application compares the cost of seven diabetic drugs purchased at Walmart with the “probable cost” of the same drugs purchased through importation, arriving at a potential savings of \$513,000 for uninsured New Mexicans.¹¹⁹ New Mexico itself acknowledges that “[t]here is considerable uncertainty in this approximation,” most notably the fact that the U.S. cost estimates are based on data from the commercial and Medicaid populations, and not the uninsured population.¹²⁰

Notably, the Application does not address the fact that Medicaid beneficiaries, who represent over one third of New Mexico residents,¹²¹ will not see a benefit from importation. 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.¹²²

C. The Application ignores significant costs associated with establishing and administering an importation program.

New Mexico’s Application fails to account for significant importation costs. New Mexico estimates that there will be an additional 45% markup to account for “transaction costs” associated with the program. This markup purportedly accounts for an allowance of profit for commercial entities within the supply chain (20%), as well as costs associated with repackaging/re-labeling (15%), testing (5%), and record-keeping and recall management (5%).¹²³ The 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 Application lays out plans for NMDIP to take on several new responsibilities, including ensuring compliance with existing federal laws

¹¹⁹ Application at 12.

¹²⁰ *Id.* at 13.

¹²¹ See Kaiser Family Foundation, Medicaid in New Mexico (Oct. 2019), <http://files.kff.org/attachment/fact-sheet-medicaid-state-NM>.

¹²² PSM, 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>.

¹²³ These same estimates were used in other states. See Nat’l Acad. for State Health Policy (“NASHP”), Concept Paper, Vermont’s Canadian Wholesale Importation Program for Prescription Drugs 5 (Oct. 2019), <https://www.nashp.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf>; Colo. Dep’t of Health Policy and Financing (“HCPF”), Section 804 Importation Program, Colorado Drug Importation Program-Draft Application 4 (Mar. 2020), <https://www.colorado.gov/pacific/sites/default/files/Colorado%20Draft%20SIP%20%20-%20Version%203-9-2020.pdf>.

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and registering, licensing, and auditing program participants. However, the 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 that medicine is not taken out of state,¹²⁴ 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.”¹²⁵
- *Public and Stakeholder Education Costs:* The Application describes a “three-pronged education outreach program,” including a multi-modal outreach and marketing campaign, a helpline, and a dedicated webpage.¹²⁶ 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.”¹²⁷ 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 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 costs associated with inspecting imported prescription drugs; reliably recording and sharing adverse events; recalls and disposal of recalled drugs; development of IT systems and reporting infrastructure; and new capital expenditures to support an Importer’s re-labeling and repackaging obligations. Entities may also have freight, broker, storage, and other charges associated with transporting drugs through interstate commerce. These expenses could ultimately be passed down to the consumer.

VII. The Application suffers from additional flaws that will harm manufacturers.

The Application suffers from additional legal flaws. New Mexico’s Application does not address the protection of trade secrets and confidential commercial information (“CCI”), leaving manufacturers vulnerable to significant reputational damage if such information is released to the public. Additionally, the failure of the proposed labeling to adequately distinguish between SIP drugs and drugs under the control of the manufacturer raises additional risk of reputational harm.

¹²⁴ Application at 23.

¹²⁵ Louis J. Freeh, *Cost of Drug Importation Could Unfairly Shift to Law Enforcement*, Philadelphia Inquirer (May 5, 2017), <https://www.inquirer.com/philly/health/addiction/cost-of-drug-importation-could-unfairly-shift-to-law-enforcement-20170504.html>.

¹²⁶ Application at 22.

¹²⁷ *Id.* at 23.

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A. The Application lacks any protection of trade secrets and CCI.

The Final Rule requires manufacturers either to conduct Statutory Testing themselves or to divulge highly confidential trade secrets and CCI to Importers to facilitate the authentication of drugs and their labeling.¹²⁸ In apparent recognition of manufacturers' significant intellectual property rights in their drugs and trade secrets, the Final Rule requires a SIP proposal to explain how the SIP Sponsor will ensure that trade secrets and CCI "are kept in strict confidence and used only for the purposes of testing or otherwise complying with" the FDCA and the Final Rule.¹²⁹

The Application does not address how this valuable and highly confidential information will be protected. Manufacturers invest in security systems with multiple layers of protections to ensure that trade secrets and CCI are kept confidential, yet no such systems are identified in the Application. Even with their sophisticated security systems, pharmaceutical companies are targeted by cybercriminals, and Importers and laboratories are even easier targets, as many have not invested in sophisticated security systems. Manufacturers would suffer significant economic effects if such information became public.

B. Failure to adequately incorporate SIP-specific language in the labeling will lead to reputational harm for manufacturers.

The Final Rule requires that a SIP proposal include "a copy of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling . . . with all differences annotated and explained."¹³⁰ The Application includes copies of the FDA-approved labeling, but does not provide a copy of the proposed labeling or a side-by-side comparison.

Drug labeling must distinguish between a SIP drug, distributed by an Importer, and a drug under the control of the manufacturer. Improper repackaging and relabeling can adversely impact the manufacturer's reputation and goodwill in the market by associating its brand with products that it cannot vouch for or control. For example, failure to incorporate or poor incorporation of SIP-specific language in the labeling can lead consumers to believe that the imported drug was sponsored or approved by the manufacturer, even though it was not. Additionally, adverse events inappropriately linked to the manufacturer through unclear labeling will cause negative financial and reputational repercussions, which could extend to the manufacturer's other products.

VIII. FDA should disclose the identity of the Foreign Seller, Importer, and FDA-Registered Repackager or Relabeler, as well as the final list of to-be-imported eligible prescription drugs, for public comment.

Petitioners request that FDA disclose the names of SIP participants and, in particular, the names of the Foreign Seller, Importer, and FDA-registered repackager or relabeler added to

¹²⁸ 21 C.F.R. § 251.16(b).

¹²⁹ *Id.* § 251.3(e)(16).

¹³⁰ *Id.* § 251.3 (e)(8). A SIP proposal must also include a copy of the HPFB-approved labeling.

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New Mexico's Application as soon as the State provides the relevant information to FDA. FDA should also disclose the final list of drugs to be imported.

A. The public interest weighs heavily in favor of disclosure.

The public interest undoubtedly weighs in favor of disclosure because, as argued above, the SIP must meet the statutory criteria for safety and cost savings to the American consumer. The identities of the Foreign Seller, Importer, and FDA-registered repackager or relabeler, as well as the final list of drugs to be imported under the SIP, are critical to assessing whether those criteria can plausibly be met. Furthermore, disclosure is critical for promoting transparency and due process, particularly in the context of a novel and untested program. It is impossible for a petitioner to fully comment on a SIP proposal that includes no information on the entities actually responsible for purchasing drugs from the manufacturer, importing drugs across the border, testing drugs for authenticity and degradation, and relabeling the drugs. Likewise, safety and cost considerations will vary depending upon the drugs to be imported.¹³¹

Disclosure is also important for promoting international coordination. Under a recently released interim order, the Canadian government may take action with respect to the Foreign Seller if its plans to export specific drugs would cause or exacerbate a drug shortage in Canada.¹³² Public identification of the Foreign Seller, Importer, and FDA-registered repackager or relabeler, as well as identification of the drugs to be imported, would allow relevant federal and state regulatory bodies to coordinate with their Canadian counterparts to ensure smooth operation of the commercial importation program.

B. The requested information is not confidential information that must be protected from disclosure.

The identities of the Foreign Seller, Importer, and FDA-registered repackager or relabeler do not qualify as confidential business information that FDA must protect from disclosure. Commercial or financial information is considered confidential within the meaning of the Freedom of Information Act ("FOIA") under Exemption 4 where it is both customarily and actually treated as private by its owner and is provided to the government under an assurance of privacy.¹³³ Nothing in the Final Rule, New Mexico's importation statute, or the

¹³¹ See 85 Fed. Reg. at 62,097 ("FDA will determine whether the product can be imported safely in the context of a specific SIP Proposal on a product-by-product basis, including, for example, sterile drugs; drugs requiring special storage conditions such as temperature controls; or drugs intended to be used solely with a specific, separately distributed delivery system (such as may be the case for drug constituent parts of cross-labeled combination products, see 21 CFR 3.2(e)(3), (4)).").

¹³² Specifically, the Interim Order prohibits Canadian "establishment licence" holders from distributing drugs "for consumption or use outside Canada unless the [licence holder] has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug." Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply) § 2 (Nov. 27, 2020), <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html>.

¹³³ *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2,356, 2,366 (2019).

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Application indicates that the Importer or FDA-registered repackager or relabeler would be treated as private.

FDA asserts in the preamble to the Final Rule that it “do[es] not intend to publicly disclose information from the SIP Proposal or authorization that is confidential business information where such disclosure is restricted by law, *potentially* including information about Foreign Sellers or the eligible prescription drugs that might be imported.”¹³⁴ However, it is far from clear whether states would treat the identity of the Foreign Seller as confidential. As the preamble to the Final Rule recognizes, information concerning the SIP supply chain may become public through state open records laws.¹³⁵ State open records laws may require public dissemination of the identity of the Foreign Seller if, for example, a state does not consider the identity of the Foreign Seller to be confidential business information, the information is voluntarily provided to a state agency without a promise of confidentiality, the information is submitted to the agency as required by law or conditioned on receipt of a governmental contract or other benefit, or the public’s interest in disclosure weighs in favor of disclosure. New Mexico law provides that “[e]very person has a right to inspect public records,” with narrow exceptions, none of which apply here.¹³⁶ FDA has the burden of demonstrating that FOIA Exemption 4 properly applies to the identity of the Foreign Seller,¹³⁷ and so may not decline to disclose the identity of the Foreign Seller unless it has received information from a state sufficient to demonstrate that the relevant state’s law would provide for confidential treatment and all other requirements of Exemption 4 are met.

Additionally, the identity of the Foreign Seller will have to be disclosed to the manufacturer, which has no obligation to keep the Foreign Seller’s identity confidential. The regulations state that “the manufacturer must provide to the Importer, within 30 calendar days of receiving the Importer’s request, a copy of all transaction documents that were provided from the manufacturer to the Foreign Seller.”¹³⁸ Obviously, a manufacturer cannot provide copies of these documents without knowing the identity of the Foreign Seller. Moreover, nothing in the regulations requires manufacturers to keep the identity of the Foreign Seller confidential. Thus, FDA cannot claim that the identity of a Foreign Seller is provided with an express or implied assurance of confidentiality.

The final list of drugs to be imported also is unlikely to be considered private. Indeed, New Mexico plans to publish a list of all drugs imported from Canada along with their corresponding prices on a webpage dedicated to educating stakeholders about the drug importation program.¹³⁹

¹³⁴ 85 Fed. Reg. at 62,100 (emphasis added).

¹³⁵ *Id.*

¹³⁶ N.M. Stat. 14-2-1.

¹³⁷ *Citizens for Responsibility & Ethics in Wash. v. U.S. Dep’t of Justice*, 746 F.3d 1,082, 1,088 (D.C. Cir. 2014).

¹³⁸ 21 C.F.R. § 251.14(b).

¹³⁹ Application at 22.

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IX. Conclusion

For the reasons explained above, FDA should refrain from authorizing the Application. The Application was submitted pursuant to an invalid Certification and an unlawful Final Rule, and cannot be approved for the reasons described in the litigation. New Mexico's Application falls significantly short of regulatory requirements and does not provide enough information for FDA to conduct a thorough review. In addition, the information that is provided fails to satisfy either of the primary criteria for authorization. New Mexico does not adequately demonstrate that importation will pose no additional risk to public health and safety, and it fails to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for consumers. Other deficiencies in the Final Rule raise issues of reputational harm for manufacturers. Finally, the failure to submit the identities of the Foreign Seller, Importer, and FDA-registered repackager or relabeler (if different from the Importer), as well as the finalized list of drugs to be imported, for public comment interferes with the public's ability to provide a thorough assessment of the proposed importation scheme and should be rectified by FDA making this information publicly available.

X. Environmental Impact

Petitioners claim a categorical exclusion under 21 C.F.R. § 25.30.

XI. Economic Impact

Petitioners will submit economic information upon request of the Commissioner.

XII. Certification

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to petitioners which are unfavorable to the petition.

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Respectfully submitted,

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