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Submitted via Regulations.gov May 3, 2023

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
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 Colorado Department of Health Care Policy & Financing's Section 804 Drug Importation Program Proposal (hereinafter the "Proposal").

Actions Requested

Through this petition, PhRMA, PSM, and CAHC respectfully request that the U.S. Food and Drug Administration ("FDA") (a) refrain from authorizing the Proposal and (b) disclose the final list of drugs to be imported and any amendments to the Proposal for public comment.

Statement of Grounds

I. Executive Summary

In a letter dated September 23, 2020, then-Secretary of the Department of Health and Human Services ("HHS") Alex M. Azar II 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"). Immediately thereafter, 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 Indian Tribes.[1]

[1] Hereinafter, the term "State" is used to refer to any state or territory of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or any Indian tribe that sponsors a SIP.

On November 23, 2020, PhRMA, PSM, and CAHC filed suit challenging the Certification and the Final Rule. The complaint, which was amended on July 2, 2021, alleged that the Certification was invalid for multiple reasons. For instance, section 804 does not permit a conditional certification that assumes States will submit SIPs in the future that will meet the safety and cost criteria, and contrary to section 804, the Final Rule allows 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 alleged 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. The Government moved to dismiss the first amended complaint for lack of subject matter jurisdiction and, alternatively, for failure to state a claim upon which relief can be granted. On February 6, 2023, the Court dismissed the case solely on standing grounds, reasoning that because a SIP has not been authorized and may never be authorized, the harms asserted in the amended complaint do not rise to the necessary level to support injury-in-fact. The Court did not reach the merits of plaintiffs' claims.

On December 5, 2022, the Colorado Department of Health Care Policy & Financing (the "Department") submitted its Proposal to FDA for review. FDA is not authorized to approve the Proposal because the Certification was invalid and the Final Rule is unlawful for the reasons described in the litigation. As for the Proposal itself, it provides so little clarity on the eligible prescription drugs to be imported that FDA cannot assess whether the safety or cost criteria can be met. Petitioners urge FDA to reject the Proposal without further review because it provides only an "aspirational" drug list and therefore is incomplete.

Additionally, the Proposal cannot be authorized because it fails to satisfy either of the primary criteria for authorization. With respect to safety, the Proposal lacks robust supply chain security protections that are necessary to protect patients from counterfeits and other substandard medicines, and it does not provide information on specific testing that will be performed. Furthermore, the pharmacovigilance provisions and recall and return plan are inadequate to respond to adverse events and products that need to be removed from distribution, and the compliance plan lacks any forward-looking policies or standard operating procedures ("SOPs"). Perhaps most critically, the Proposal hints at use of a potential "mail order pharmacy," while providing *no* explanation of how the Department will address known safety risks associated with these entities.

The Proposal also 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 Proposal utilizes crude back-of-the-envelope math (based on spending by health plans, not individual consumers) and does not explain how the Department will leverage drug price differences to result in cost savings for the American consumer. Moreover, the Proposal ignores significant costs associated with establishing and administering an importation program.

In addition, the Proposal suffers from other flaws and deficiencies that will harm manufacturers. The Proposal does not provide sufficient evidence that manufacturer trade secrets and other confidential information will be protected. The Department also prematurely requests to omit the required labeling statement: "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program." The Department does not support this request with any evidence that the Department has actually obtained authorization from any manufacturer.

In short, the Proposal makes clear that the Department and its partners are not prepared for the onerous requirements required for the safe importation of prescription drugs from Canada. The Proposal highlights that the Department and its partners would not be ready to

conduct the new activities required of them by the Final Rule, including but not limited to relabeling and testing product. Further, the Proposal illustrates that the Department and its partners are ill-equipped for FDA's stringent regulatory requirements, such as pharmacovigilance processes, track and trace requirements, and recall and return procedures, which may have a detrimental impact on the health and safety of Colorado's patients. The Proposal's deficiencies underscore that HHS's and FDA's Certification would be invalid, as the importation of prescription drugs from Canada under Colorado's Proposal would present an unreasonable risk to patients living in the state.

Finally, we request that FDA publicly disclose the final list of drugs to be imported, the proposed labeling, and side-by-sides with the FDA-approved labeling, as soon as this information is identified. Disclosure 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 broadly prohibits reimportation of a drug that is manufactured in the United States and exported unless the drug is imported by the drug's manufacturer.[2] Section 801(d)(1)(B) prohibits importation of a drug for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.[3] One exception to both Section 801(d)(1) prohibitions is Section 804 of the FDCA. Section 804 provides 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 of HHS (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.[4]

Section 804(b) of the FDCA, the provision that concerns commercial importation and is cited as the source of statutory authority for Colorado's proposed importation program, directs the Secretary to promulgate regulations "permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[5] 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

[2] FDCA § 801(d)(1)(A).

[3] *Id.* § 801(d)(1)(B).

[4] *Id.* § 804(*l*)(1).

[5] *Id.* § 804(b).

"appropriate" safeguards determined by the Secretary.[6] 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.[7]

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.[8] 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.[9]

B. The Certification and Final Rule

Before September 2020, every Secretary had 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 risks of importation, including that it would increase the risk that counterfeit drugs would enter the drug supply chain and have little impact on drug prices.[10] The Task Force was chaired by the Surgeon General and included representatives from HHS (including then-General Counsel Alex M. Azar II and then-Administrator of the Centers for Medicare & Medicaid Services Mark B. McClellan), FDA, and other agencies. As recently as May 2018, then-Secretary Azar derided importation as a "gimmick" that would have "no meaningful effect" on drug prices and could not "be safely achieved."[11]

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.[12] In a letter dated September 23, 2020, on the eve of the 2020 Presidential election, then-Secretary Azar wrote to Congress purporting to certify that implementation of the commercial importation provisions in

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[6] *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.

[7] *Id.* § 804(d)–(h).

[8] *Id.* § 801(a)(3).

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

[10] 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.

[11] 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.

[12] 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.

subsections (b) through (h) of section 804 pursuant to the Final Rule "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."[13] Immediately after the former Secretary signed the letter to Congress, FDA and HHS publicly posted the Final Rule allowing for the commercial importation of certain drugs from Canada.[14]

The Final Rule authorizes the importation into the United States of certain drugs that are approved for sale in Canada under SIPs sponsored by States. Each SIP must identify Canadian wholesalers ("foreign sellers"), which will buy drugs from manufacturers and resell them to U.S. wholesalers or pharmacists ("importers"), which in turn will 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 will become "null and void."[15]

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, the importer in the United States that will buy the drug directly from the foreign seller, the FDA-registered repackager or relabeler (if different from the importer) (the "relabeler"), and the qualified laboratory in the United States which will conduct the testing required under section 804 (if the importer will be responsible for conducting the statutorily-required testing) (the "qualified laboratory").[16] 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;

[13] 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.

[14] 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.

[15] 85 Fed. Reg. at 62,111.

[16] 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.

- 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.[17]

FDA must decline to authorize a SIP proposal if it fails to meet the Final Rule's requirements.[18] 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.[19]

Neither the Certification nor the Final Rule analyzed the safety or cost savings implications of section 804 implementation. Instead, then-Secretary Azar 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. Litigation

On November 23, 2020, PhRMA, PSM, and CAHC filed a complaint in the U.S. District Court for the District of Columbia against HHS, FDA, then-Secretary Azar, and then-Commissioner of Food and Drugs Stephen M. Hahn.[20] PhRMA subsequently amended its complaint as of right, on July 2, 2021.[21] Secretary Xavier Becerra and Acting Commissioner Janet Woodcock were substituted for their predecessors in office under Rule 25(d) of the Federal Rules of Civil Procedure.[22]

Among other allegations concerning the Certification, the amended complaint alleged that the Certification failed to satisfy section 804(*l*)(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 contained in future SIP proposals.[23] The complaint also alleged that section 804(*l*)(1) required 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).[24] Additionally, the complaint challenged the Final Rule as unlawful on multiple

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[17] *Id.* § 251.3(d)–(e).

[18] *Id.* § 251.4(a).

[19] *Id.*

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

[21] First Amended Compl., *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. July 2, 2021).

[22] *Id.*

[23] *Id.* ¶ 133.

[24] *Id.* ¶ 136.

grounds, including because it threatens patient safety.[25] Based on these claims, among others, the plaintiffs sought 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.

On August 27, 2021, the Government moved to dismiss the first amended complaint for lack of subject matter jurisdiction and, alternatively, for failure to state a claim upon which relief can be granted.[26]

On February 6, 2023, the Court dismissed the case solely on standing grounds, observing that "Plaintiffs cannot say that the [C]ertification or the [F]inal [R]ule 'will certainly cause' them any future harm because there is at least a possibility that no SIP will even win approval.".[27]

D. Colorado's Proposal

In 2019, the Colorado General Assembly passed Senate Bill 19-005, requiring the Department to develop a drug importation program and pursue approval for such a program from the federal government.[28] The bill required the Department to submit a request for federal approval of the importation program on or before September 1, 2020, and to begin operating the program not later than six months after receiving such approval.[29]

In March 2020, after FDA published its NPRM, the Department submitted a comment letter outlining its concerns with the framework FDA had proposed.[30] Colorado appended to its comment letter a draft SIP proposal seeking to import 168 drugs.[31]

On January 25, 2021, Colorado released an Invitation to Negotiate, seeking two or more vendors to manage the oversight of its importation program.[32] Along with several other states, on March 29, 2022, Colorado sought guidance from FDA on various questions related to SIP proposals and operational policy issues related to importation, including requirements for

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[25] *Id.* ¶¶ 155, 167; *see also id.* ¶¶ 63–72.

[26] Memorandum in Support of Defendants' Motion to Dismiss the First Amended Complaint for Lack of Subject Matter Jurisdiction and, Alternatively, for Failure to State a Claim Upon Which Relief Can Be Granted, *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. Aug. 27, 2021).

[27] Memorandum Opinion 13–14, *PhRMA v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-03402 (D.D.C. Feb. 6, 2023).

[28] Codified at Colo. Rev. Stat. Ann. § 25.5-2.5-201 *et seq.*

[29] Colo. Rev. Stat. Ann. § 25.5-2.5-205(1).

[30] Colo. Dep't of Health Care Pol'y & Fin., Comment Letter on NPRM, Docket No. FDA-2019-N-5711 (Mar. 9, 2020), https://www.regulations.gov/document/FDA-2019-N-5711-1238.

[31] *Id.* at 15–18.

[32] Colo. Dep't of Health Care Pol'y & Fin., HCPF Invitation to Negotiate Solicitation #RFP UHAA 2021000117, https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20ITN%201-22-2021.pdf.

demonstrating safety and cost savings in SIP proposals and FDA's process for reviewing and approving SIP proposals.[33]

On August 18, 2022, Colorado announced that it had partnered with AdiraMedica, Inc., a Canadian wholesaler located in Mississauga, Ontario as the foreign seller,[34] and with Premier Pharmaceuticals, LLC, a Colorado-registered wholesaler located in Boise, Idaho, as the importer.[35] Colorado also announced that Rocky Mountain Poison and Drug Safety ("RMPDS") will be responsible for all FDA required adverse event reporting as well as responding to consumer inquiries.[36]

Colorado submitted its Proposal on December 5, 2022. According to the Proposal, Colorado's SIP will be sponsored by the Department. The Department will house a Drug Importation Division which "will manage the Canadian importation drug list and oversee the activities of all participants in the supply chain to ensure compliance with operational and safety requirements."[37] The Proposal lists AdiraMedica as the foreign seller, Premier Pharmaceuticals as the importer, and RMPDS as the entity responsible for adverse event reporting and responding to consumer inquiries.[38] It also lists Q Laboratories, located in Cincinnati, Ohio, as the qualified laboratory and Omega Tech Labs as the relabeler.[39]

The Proposal includes a list of 112 unique "high cost, high volume" prescription drugs and dosages, including drugs that treat respiratory illnesses, cancer, type 2 diabetes, HIV, and

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[33] Letter from Colo. Dep't of Health Care Pol'y & Fin., Maine Dep't of Health & Human Servs., New Hampshire Dep't of Health & Human Servs, N.M. Dep't of Health & Vermont Agency of Human Servs to S. Leigh Verbois, Director, Office of Drug Security, Integrity & Response, Office of Compliance, Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin. (Mar. 29, 2002) (hereinafter "Guidance Request"), *included in* Colorado's Drug Importation Program, Appendix I at 124–29 (hereinafter "Proposal Appendix"), https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20SIP%20Appendix.pdf.

[34] The corporate office of AdiraMedica, Inc.'s, parent company, AdiraMedica, LLC, is located in Clark, New Jersey. AdiraMedica, LLC specializes in supply chain management for global clinical trials.

[35] Colo. Dep't of Health Care Pol'y & Fin., Press Release, *Polis-Primavera Administration Announces Prescription Drug Importation Partners* (Aug. 18, 2022), https://hcpf.colorado.gov/prescription-drug-importation-partners.

[36] *Id.*

[37] Section 804 Importation Program: Colorado's Drug Importation Program at 8 (Dec. 5, 2022) (hereinafter "Proposal"), https://hcpf.colorado.gov/sites/hcpf/files/Colorado%27s%20Drug%20Importation%20Program%202022%20Formal%20SIP.pdf. For purposes of this petition, we use the term "Department" to refer to the Drug Importation Division, as well as the Department more generally.

[38] *Id.* at 7–8.

[39] *Id.*

multiple sclerosis.[40] The Department concedes that "negotiations are ongoing and therefore, the list presented is aspirational and the [Department] will amend this SIP as we finalize manufacturer agreements."[41]

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

FDA cannot authorize the Proposal 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. Although the Court dismissed the litigation on standing grounds, it did not address the merits of plaintiffs' claims.

A. Then-Secretary Azar's purported Certification was invalid.

Then-Secretary Azar's purported Certification was contrary to section 804(*l*)(1) in several respects and therefore was not issued in accordance with law and was in excess of statutory authority, in violation of the Administrative Procedure Act ("APA").[42] For example, the Certification was conditioned on assumptions that States would submit SIPs in the future that would 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 safety[43]—leaving no room for the Secretary to defer this determination until sometime into the future. Additionally, then-Secretary Azar did not certify "implementation of this section," as required by statute,[44] but instead certified only commercial importation under subsections (b) through (h). The Certification also purported to implement section 804 through discrete SIPs sponsored by States, 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*."[45] 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,"[46] but the Final Rule instead 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."[47]

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[40] *Id.* at 13, 15–20. Five additional drugs and dosages are listed in Appendix D but are not listed in the main body of the Proposal.

[41] *Id.* at 13.

[42] 5 U.S.C. § 706(2)(A), (C).

[43] FDCA § 804(*l*)(1) (emphasis added).

[44] *Id.*

[45] *Id.* (emphasis added).

[46] *Id.* (emphasis added).

[47] 85 Fed. Reg. at 62,101.

The Certification also did not satisfy the APA's requirement of reasoned decision-making.[48] Then-Secretary Azar inadequately considered both the potential health risks and the consumer savings associated with importation. He also failed to consider, or failed to adequately consider, important aspects of the problem before him and failed to acknowledge or adequately explain HHS's and FDA's departure from long-held prior positions and factual findings related to importation. Furthermore, the then-Secretary's stated rationale for the Certification was internally inconsistent and failed to support his decision to authorize commercial importation under the Final Rule.

Finally, the process by which the former Secretary issued the Certification was both inconsistent with the limits placed on his authority by Section 804 and with the APA's rulemaking requirements.[49] HHS lacked the authority to begin implementing Section 804 by promulgating the NPRM before issuing a valid certification. By failing to disclose data or analyses regarding the factual basis for the Certification HHS ultimately issued, HHS also deprived parties of the opportunity to comment meaningfully on the Certification.

B. The Final Rule is unlawful.

1. Violations of the FDCA and the APA

The Final Rule conflicts with the FDCA and is in excess of statutory authority in key respects.[50] Section 804 states that imported drugs must comply with the FDCA's premarket approval requirement and must not be misbranded, along with other requirements.[51] Drugs imported under the Final Rule would necessarily be unapproved new drugs and misbranded drugs, neither of which can legally be imported into the United States. 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.[52] Drugs imported under the Proposal, 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.[53] The labeling mandated by regulation would mislead consumers that the drugs have been approved by FDA (which they have not), are identical to

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[48] 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[49] 5 U.S.C. § 706(2)(C)–(D).

[50] *Id.* § 706(2)(C).

[51] *See* 21 U.S.C. § 384(c)(1) (requiring safeguards be put in place to ensure that each prescription drug imported complies with sections 505, 501, and 502 of the FDCA). Section 505, 21 U.S.C. § 355, prohibits the introduction into interstate commerce of unapproved drugs. Sections 501 and 502 of the FDCA, 21 U.S.C. §§ 351 and 352, define, respectively, adulterated and misbranded drugs.

[52] *See* FDCA § 505(b)(1).

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

FDA-approved drugs (which they are not), and have the assurances associated with FDA-approved drugs (which they do not).

Additionally, the Final Rule misapprehends the statutory standard that must be satisfied for importation to be certified under section 804(*l*)(1). As discussed above, for Section 804 to be implemented, the Secretary must certify that importation will result in a significant reduction in the cost of covered products—*i.e.*, prescription drugs—to the American consumer. And the Secretary has certified that this standard is met because the Agencies would approve only those SIP proposals that adequately demonstrated how they would satisfy this criterion. The Final Rule nevertheless authorizes SIP sponsors to satisfy this criteria with an explanation, for example, of savings to state programs that result in those programs covering more drugs or individuals. Such explanation does not demonstrate a significant reduction in the costs of covered products to the American *consumer*.

Moreover, the requirement that manufacturers allow importers to use their trademarks without their consent and without compensation is inconsistent with trademark law, including international trade agreements to which the United States is a party—namely the U.S.-Mexico-Canada Agreement and the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights. Finally, the Final Rule is unlawful because FDA lacks the authority to (1) deem manufacturers to have provided their labeling for use by importers; (2) 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; (3) disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same; and (4) 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.[54] 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 may increase the likelihood that U.S. patients will receive adulterated drugs and otherwise compromise U.S. public health and safety.[55] That is because the Final Rule, among other things, shifts relabeling and repackaging from FDA-inspected facilities that are identified in an FDA-approved marketing 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 requirements under the Drug Supply Chain Security Act (DSCSA); and increases the number of entities that are in the supply chain and that 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

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[54] 5 U.S.C. § 706(2)(A)

[55] *See* FDCA § 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).

trade secrets and confidential information, analytical reference standards, and FDA-approved drugs. Finally, FDA and HHS have failed to adequately explain why the Final Rule's approach to manufacturers' trademarks was reasonable, lawful, and consistent with HHS's prior positions.

In addition, the procedures adopted by the Final Rule for the promulgation of SIPs fail to meet minimum procedural requirements under the FDCA and the APA.[56] Because the Final Rule determines that the statutorily required safety and cost findings will be made in SIP proceedings, and then denies any opportunity for public notice and comment on SIP proposals, the Final Rule deprives regulated parties and the public at large of any opportunity to comment on the factual basis for the Secretary's safety and cost findings. Moreover, the process by which the Final Rule was promulgated violated the requirement, imposed by Section 804(b), that the HHS Secretary consult with the U.S. Trade Representative and Commissioner of Customs and Border Protection before issuing a final rule.

2. Violations of the U.S. Constitution

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, 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. A manufacturer's violation of its obligations under the Final Rule is punishable under the strict-liability misdemeanor provision of the FDCA by up to one year's imprisonment and under the felony provision of the FDCA by up to three years' imprisonment; a knowing failure to comply with the testing provisions is a crime punishable by to up 10 years' imprisonment.[57] 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 U.S. 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, in 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 reject the Proposal without further review because it provides only an "aspirational" drug list and therefore is incomplete.

Under the Final Rule, FDA must review a SIP proposal to determine whether an importation program meets statutory and regulatory standards. Accordingly, the Final Rule

[56] 5 U.S.C. § 706(2)(C)–(D); FDCA § 804(b).

[57] FDCA § 303(a)(1)–(2), (b)(6).

requires the SIP sponsor to submit a detailed "importation plan" that includes the key building blocks of the proposed program, including the eligible prescription drugs to be imported. The Proposal Colorado submitted is incomplete on its face because it provides only an "aspirational" drug list.[58]

The Proposal's executive summary states that Colorado "anticipate[s] our initial list for the early years of the program to be significantly more narrow than the list presented in this SIP . . . due to likely modest participation from manufacturers in the short-term with a focus on small innovator companies and generic manufacturers."[59] However, the section entitled "Final Drug List & Cost Savings" speaks more broadly about amending the SIP "as we finalize manufacturer agreements," potentially leaving open the possibility that the drug list could be expanded.[60] Indeed, the Proposal's conclusion states that "[a]s the FDA reviews the state of Colorado's SIP application," the Department will be actively pursuing negotiations not only with manufacturers represented on the drug list, "but any others that may have an interest in our program."[61] In addition, in the guidance request appended to the Proposal, Colorado, Maine, New Hampshire, New Mexico, and Vermont collectively asked for flexibility to submit pre-import requests that include prescription drugs beyond those included in those States' respective original SIP proposals.[62] The states emphasized that "[m]arket forces in Canada may present opportunities to acquire drugs outside of the original submitted list."[63] Petitioners are not aware whether FDA has submitted a response to the states' request.

Submitting an over- or under-inclusive drug list in a SIP proposal is inconsistent with the text of the Final Rule, which requires a SIP proposal to provide FDA with information about each eligible prescription drug that the SIP sponsor actually seeks to import.[64] FDA cannot properly assess whether the safety or cost criteria can be met without knowing the identity of the drugs to be imported. Leaving open the option for states to add drugs at the pre-import request stage is particularly risky from a safety perspective. During the SIP proposal review process, FDA determines whether a product can be imported safely on a product-by-product basis considering, for example, the inclusion of 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.[65] Without providing a complete list of drugs to be imported, the SIP sponsor cannot explain how "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.[66] Punting this

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[58] Proposal at 3, 10, 13. Elsewhere, the Proposal describes the drug list as "our starting point in future conversations with manufacturers." *Id.* at 10.

[59] *Id.* at 3.

[60] *Id.* at 13.

[61] *Id.* at 50.

[62] Guidance Request at 127.

[63] *Id.*

[64] 21 C.F.R. § 251.3(d)(3)–(4), (e)(1), (e)(5).

[65] 85 Fed. Reg. at 62,097.

[66] *Id.*

determination to the pre-import request stage is not consistent with the text of the Final Rule, nor is it feasible for FDA to make this determination during the 30-day window prior to the scheduled date of arrival or entry of a shipment.

Even if the drug list in the Proposal included all the drugs to be imported, it is still deficient because the Proposal does not include the manufacturer of the finished dosage form or the manufacturer of the active ingredient for each drug listed.[67] Accordingly, the Proposal does not include sufficient information to ensure that the manufacturing facilities of the Health Products and Food Branch of Health Canada ("HPFB")-approved and FDA-approved drugs are the same and, if not, whether the manufacturing location of the HPFB-approved drug is a location listed in the NDA or ANDA, as required under the definition of "eligible prescription drug" in the Final Rule.[68]

The above deficiencies are fatal to approval, and Petitioners urge FDA to reject the Proposal without further review. Colorado can refile with FDA when its application is complete. We also request that FDA communicate to potential SIP sponsors that proposals must include a complete list of drugs to be imported.

V. The Proposal does not demonstrate that importation will pose no additional risk to public health and safety.

Section 804(*l*)(1) of the FDCA requires the Secretary to certify that importation will "pose no additional risk to the public's health and safety."[69] The preamble to the Final Rule emphasizes that commercial importation purportedly can be implemented consistently with the section 804(*l*)(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."[70] The Proposal fails to satisfy relevant statutory and regulatory safeguards designed to protect the public health and safety from the known safety risks associated with importation. Moreover, the Proposal hints at a potential "mail order pharmacy option," without addressing the unique and significant safety issues associated with online pharmacies. Each of these deficiencies requires FDA to reject the Proposal.

A. The Proposal fails to satisfy safety requirements in the FDCA and the Final Rule

The Proposal does not meet the requirements with respect to safety in the FDCA and the Final Rule. The Department's importation plan is insufficient to assure the security of the drug supply chain, and the Department's provisions on statutory testing leave critical questions

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[67] 21 C.F.R. § 251.3 (e)(1).

[68] Letter from U.S. Food & Drug Admin. To Simone Marstiller, Secretary, Florida Agency for Health Care Administration 2, Case Management Report, Exhibit A, *State of Florida et al. v. FDA*, No. 8:22-cv-01981 (M.D. Fla. Nov. 16, 2022) (hereinafter "FDA Letter to Florida Agency for Health Care Administration").

[69] FDCA § 804(*l*)(1).

[70] 85 Fed. Reg. at 62,106.

unanswered. Finally, the pharmacovigilance, recall, return, and compliance provisions are inadequate to respond to adverse events, products that need to be removed from distribution, and noncompliance by supply chain entities.

1. The Proposal does not satisfy requirements related to 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) [s]torage, 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."[71] Such procedures are essential to ensuring that drugs imported under section 804 will not pose an additional risk to patient safety. However, the Proposal provides little concrete information on how the Department plans to ensure that drugs are stored, handled, and distributed appropriately and fails to address significant loopholes within the DSCSA framework as applied to imported product. These deficiencies are all the more concerning in light of the fact that Colorado already faces a crisis of counterfeit pharmaceuticals masquerading as legitimate medicine. Since 2020, law enforcement departments across Colorado have seized large quantities of counterfeit pills containing fentanyl, and 12 different medical practices in Colorado have been implicated in black market supply chains associated with counterfeit cancer treatments and other therapies.[72]

a) Storage, handling, and distribution

Colorado purports to rely on existing federal regulatory frameworks to ensure that product is stored, handled, and transported in a compliant fashion, stating that "FDA's proven oversight and high standards for the drug supply chain help guarantee the safety and quality of the drugs that currently enter the United States from foreign sources."[73] The Proposal also states that supply chain contracts will set forth standards related to facilities, standards, and reporting.[74] Both of these purported safeguards fall short.

The Proposal places considerable weight on the fact that the foreign seller, importer, and relabeler are licensed by or registered with FDA. Yet, registration alone is insufficient to ensure that entities store, handle, and distribute prescription drugs in compliance with current good manufacturing practices ("CGMP") and otherwise meet their federal statutory and regulatory obligations, as required by the Final Rule. To provide meaningful oversight of supply chain participants, FDA must inspect them. For NDA products, FDA's inspection oversight of

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[71] 21 C.F.R. § 251.3(e)(11)(i)–(iii); *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).

[72] PSM, *Fake Medicine is a Real Problem in Colorado* (July 2021), http://www.safemedicines.org/wp-content/uploads/2021/07/CO-2021-update-infosheet-SECURE.pdf.

[73] Proposal at 34; *see also id.* at 9 ("Any drug imported under the importation program and available for purchase in the state of Colorado will fall under the jurisdiction of the FDA.").

[74] *Id.* at 34–36.

packaging and labeling facilities goes well beyond general facility, personnel, and procedural controls. In approving an NDA, FDA also evaluates evidence that the facility is capable of packaging and labeling the specific product. Yet, FDA is refusing to commit to inspect relabelers identified in SIP proposals before they are permitted to engage in repackaging and relabeling of imported drugs.[75] Therefore, the mere use of FDA-registered facilities for repackaging and relabeling activities without disclosure of such a facility in the NDA to assure product-specific capability would undermine important regulatory protections. And the risks are particularly acute, since Colorado's relabeler will be handling unapproved drugs.

The contractual provisions discussed in the Proposal do not mitigate the above concerns. While the Proposal states that the Department's contracts with supply chain entities will set forth standards related to supply chain facilities, standards, and reporting,[76] it provides no insight into the enforcement provisions within these contracts. Nor does it address the guardrails and enforcement provisions within Premier Pharmaceuticals' contracts with Omega Tech Labs and Q Laboratories. Perhaps most significantly, the Proposal provides no indication of how the Department—an entity that oversees the state Medicaid program and which has no experience in overseeing pharmaceutical distribution—will acquire the expertise and know-how to assess compliance.

As a result of the deficiencies discussed above, there is no assurance that the storage, handling, and distribution practices of supply chain participants will not affect the quality or security of drugs imported into Colorado. This applies to all drugs proposed for importation, but several drugs on the "aspirational" list raise heightened concerns.

- *Drugs packaged in blister packs.* Multiple listed drugs are packaged in blister packs, but Colorado does not address whether such products can be repackaged and relabeled without affecting the container closure system. According to the Final Rule, if it is not possible to relabel a product without affecting the container closure system, then the product cannot be imported under a SIP, due to the "unnecessary risk of adulteration, degradation, and fraud."[77] Nor does the Proposal address how Omega Tech Labs will affix the conforming labeling to such products (e.g., through over-labeling or through some other means). The Final Rule also does not permit affixing a conforming label to the outside of the container closure system in lieu of relabeling the immediate container of the product.[78]

- *Products with device components.* Multiple listed products include device components (e.g., metered-dose inhalers and injection pens). Accordingly, supply chain participants will need to comply with CGMP and reporting requirements for combination products.[79] The Proposal does not address these requirements, nor

[75] 85 Fed. Reg. at 62,101.

[76] Proposal at 34–36.

[77] 85 Fed. Reg. at 62,105.

[78] FDA Letter to Florida Agency for Health Care Administration at 14.

[79] *See* 21 C.F.R. §§ 4.4 (CGMP requirements), 4.102 (reporting obligations); *see also* U.S. Food & Drug Admin., Final Guidance for Industry and FDA Staff, Current Good Manufacturing Practice

does it explain whether supply chain participants have experience complying with them. Moreover, like blister packs, certain combination products may be more difficult to relabel without compromising the container closure system, as the labeling may be printed on the device itself. However, the Proposal does not discuss how such products will be relabeled with the conforming labeling.

- *Sterile drug products*. Certain products listed are sterile drug products. Such products are subject to additional CGMP requirements to control for contamination.[80] Yet, the Proposal does not address how such drugs will be stored, handled, and distributed compliantly. Moreover, Omega Tech Labs, the proposed relabeler that will be engaging in repackaging and relabeling activities, does not appear to have any experience handling sterile drug products. Omega Tech Labs plans to use the Colorado program as its "entre" into the pharmaceutical manufacturing business.[81] Historically, it has served as a contract manufacturer with expertise "producing, packaging, and labeling personal and hygiene care products"[82] Yet, topical, over-the-counter products are not subject to the same stringent controls as sterile drug products. And the Proposal provides no information on how Omega Laboratories will acquire the necessary expertise to repackage and relabel sterile drug products included in the Proposal.

- *Drugs with other specialized storage conditions*. Other drugs on the list require specialized storage conditions, including temperature, handling, and packaging requirements. For example, certain drugs must be refrigerated, and other drugs include storage instructions about protection from heat, moisture, and light. Improper storage of imported drugs could result in adverse consequences, including reduced potency and, in the case of HIV/AIDS drugs, antiviral resistance, which could "halt the progress made combatting the HIV epidemic."[83] However, the Proposal provides no guidelines for ensuring that each supply chain participant complies with the storage instructions included in each drug's labeling, beyond vague assurances that supply chain partners will utilize "temperature control[s]."[84]

b) Track-and-Trace

Requirements for Combination Products (Jan. 2017), https://www.fda.gov/media/90425/download.

[80] 21 C.F.R. §§ 211.84, 211.113; *see also* U.S. Food & Drug Admin., Final Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (Sept. 2004), https://www.fda.gov/media/71026/download.

[81] Proposal Appendix at C at 85.

[82] *Id*. As recently as October 2022, the Omega Tech Labs website stated that the entity specialized in hair care, facial care, bath and body, toothpaste, and pet products. *Omega Labs* (Oct. 5, 2022), https://web.archive.org/web/20221005061247/http://www.omegatechlabs.com/.

[83] 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.

[84] Proposal at 31, 35.

With respect to track-and-trace, the Proposal again purports to rely on existing federal regulatory frameworks, stating that "the provisions set forth in the [DSCSA], once fully implemented, ensure traceability of all products in the current U.S. supply chain."[85] Yet, products imported under the Final Rule are *exempt* from key provisions of the DSCSA. Canada lacks a track-and-trace system, and it is impossible to know with certainty that drugs were not tampered with before arrival onto U.S. soil. Colorado's proposed importation program therefore would increase the potential for counterfeit and otherwise substandard medicines to enter the United States at the very earliest stages in the supply chain.

Nor are federal frameworks sufficient to ensure the traceability of the drug supply once product arrives in the United States, because AdiraMedica and Premier Pharmaceuticals are required to undertake new obligations under the Final Rule that are not applicable to them under the DSCSA. AdiraMedica specializes in supply chain management for global clinical trials, so it is unclear whether the company has extensive experience in implementing the DSCSA, which does not apply to investigational products.[86] But even if AdiraMedica does have experience implementing the DSCSA, it is doubtful that it is well equipped to ensure that a section 804 serial identifier (SSI) is assigned and affixed to or imprinted on each package and homogeneous case of imported product, as it is required to do under the Final Rule.[87] Under the DSCSA, affixing or imprinting product identifiers is solely the responsibility of the manufacturer or repackager—wholesalers such as AdiraMedica have no familiarity with the technical requirements involved with carrying out this task.[88] Similarly, Premier Pharmaceuticals—also a wholesaler under the DSCSA—does not have experience with the technical requirements under the Final Rule with respect to affixing product identifiers on imported drugs.[89] Nor does the Colorado Board of Pharmacy have experience overseeing compliance with such requirements under the DSCSA.

Furthermore, the DSCSA includes detailed requirements regarding how supply chain entities identify suspect and illegitimate products, conduct investigations, and, if necessary, take further action. The Proposal provides no forward-looking procedures or SOPs relevant to meeting these requirements. Nor does the Proposal address what specific steps the Department would take if it determines that AdiraMedica or Premier Pharmaceuticals is not acting in compliance with the Final Rule or the DSCSA.

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[85] *Id.* at 34.

[86] FDCA § 581(12)–(13) (defining "product" as a "prescription drug" subject to section 503(b)(1) that is in a finished dosage form for administration to a patient without substantial further manufacturing).

[87] 21 C.F.R. § 251.14(c)(4)(ii)–(iii)

[88] FDCA § 582(b)(2). When Congress passed the DSCSA, it gave manufacturers a four-year period to comply with the product identifier requirement. FDA then delayed enforcement of the product identifier requirement by one year. U.S. Food & Drug Admin., Guidance for Industry: Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy (Sept. 2018).

[89] 21 C.F.R. § 251.14(d)(2).

2. The Proposal does not provide sufficient detail on statutory testing.

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").[90] 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."[91]

The Proposal includes a high-level list of the types of analytical testing and examinations that are to be used in determining a drug's characteristics and compliance with specifications and standards,[92] but lacks information related to the specific testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the FDA-approved counterpart.[93] The Proposal also does not address how imported drugs will be transported from the port of entry in Buffalo, New York to Premier Pharmaceuticals' secure distribution facility in Boise, Idaho, to Q Laboratories' facility in Cincinnati, Ohio. Moreover, the Proposal does not provide any assurances with respect to Q Laboratories conducting testing for combination products. Furthermore, Colorado does not appear to have developed a contingency plan if the laboratory is inspected and receives an Official Action Indicated or if the ISO 17025 accreditation expires.[94]

3. The Proposal's pharmacovigilance program is not in compliance with the Final Rule.

The Final Rule requires a SIP sponsor to demonstrate that the post-importation pharmacovigilance requirements of the FDCA and the Final Rule are met.[95] Colorado's delegation of pharmacovigilance responsibilities from the Importer to RMPDS is impermissible, and, furthermore, RMPDS may not have the expertise necessary to assume such a role.

Longstanding FDA regulations impose adverse event reporting requirements on NDA/ANDA applicants, *i.e.*, *manufacturers* of prescription drugs,[96] and the Final Rule requires the *importer* to submit adverse events.[97] Pharmacovigilance involves a number of complex

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[90] 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.

[91] 21 C.F.R. § 251.3(d)(11)(i).

[92] Proposal at 41–44.

[93] FDA Letter to Florida Agency for Health Care Administration at 3.

[94] *Id.* at 3–4.

[95] 21 C.F.R. § 251.3(d)(11)(iv).

[96] 21 C.F.R. §§ 314.80, 314.81, 314.98.

[97] *Id.* §§ 251.3(e)(11)(iv), 251.12(a)(7).

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. In its Proposal, Colorado punts pharmacovigilance responsibilities to RMPDS, stating that "RMPDS, as the program's reporting partner, will support meeting compliance-related obligations by ensuring all aspects of reporting and recordkeeping for adverse events and pharmacovigilance are maintained for the program and that adequate education is provided."[98] Such a delegation is inconsistent with the Final Rule, which explicitly vests responsibilities for pharmacovigilance with the importer, not a third-party entity.

Manufacturers have complex pharmacovigilance systems and processes in place to detect, assess, and understand any adverse effects and drug-related problems. While RMPDS supports multiple pharmaceutical companies,[99] the Proposal does not explain whether RMPDS has the systems, processes, and capacity in place to support a state-run importation program where there is minimal if any manufacturer oversight. The Proposal also does not include any contract terms between Colorado and RMPDS. Such an agreement likely would address questions essential to FDA's evaluation of the SIP, including RMPDS' role as an agent of the State of Colorado and whether RMPDS owes a fiduciary duty to the State. Additionally, the agreement likely would address insurance requirements, allocation of risk, rights and remedies, and the applicability of state ethics and consumer protection laws.

4. The Proposal's recall, return, and compliance plans leave critical questions unanswered.

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.[100] In language added following public comment, the Final Rule also requires the SIP proposal to include the SIP's return plan and compliance plan.[101]

The Proposal's recall and return plans are insufficient to ensure that recalled or withdrawn products will be taken out of distribution. Traditionally, the decision to institute a recall 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.[102] Although the Proposal 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. In addition, the recall plan does not include required procedures for the Department to specify the depth to which the recall will extend (if not specified by FDA) or to conduct

[98] Proposal at 9.

[99] RMPDS, *Pharmaceuticals*, https://www.rmpds.org/pharmaceuticals.html.

[100] 21 C.F.R. § 251.3(e)(13).

[101] *Id.* § 251.3(e)(14)–(15).

[102] *Id.* § 251.18(e).

effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action.[103]

The return plan is also flawed. The Proposal states that the Importer will "inspect the drug for evidence of tampering or damage based on a 15 point inspection process to determine whether the product is re-saleable."[104] However, without seeing specifics about the relevant process, FDA cannot identify whether this process is sufficient to ensure that statutory and regulatory requirements are met. Moreover, the Proposal states that the Importer will conduct retesting "[i]f retesting is deemed necessary," yet provides no information on why it would be necessary to retest previously tested product.[105]

Similarly, the compliance plan does not include any specific, forward-looking policies, procedures, and protocols for FDA to evaluate, including those to be used to address noncompliance or misconduct. Nor does the Proposal address even in general terms how the Department will uncover or address conflicts of interest, or how it will create and maintain effective lines of communication (including a process to protect the anonymity of complainants and to protect whistleblowers).[106]

B. Utilizing a mail order pharmacy poses an unavoidable safety risk.

The Proposal hints at the possibility of a "mail order pharmacy option" as a potential solution to initial hesitancy on behalf of pharmacies to participate in importation.[107] Petitioners strongly maintain that such an option is a nonstarter. FDA is already struggling to educate consumers about the risks associated with online pharmacies that purport to sell medicine imported from Canada.[108] As FDA stated in a press release, unscrupulous actors, like CanaRx, "use their names to imply that patients are receiving medicines approved in Canada, when it's likely that patients are receiving medicines from other countries, and which may be sub-potent,

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[103] *Id.* The Proposal simply states that "[a]fter the recall is implemented [t]he State of Colorado conducts effectiveness checks to verify that all cosignees (at the recall depth specified by the strategy) have received notification about the recall and have taken appropriate action." Proposal at 48.

[104] Proposal at 50.

[105] *Id.*

[106] 21 C.F.R. § 251.3(e)(v)–(vi).

[107] Proposal at 9, 11.

[108] PhRMA, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 21–22 (Mar. 9, 2020), https://www.regulations.gov/document?D=FDA-2019-N-5711-1236.

super-potent or counterfeit."[109] These companies use sleek advertising to "give false credence to their operation."[110]

In the event that Colorado permits online pharmacies to distribute commercially imported product under its SIP, there is a substantial risk that unscrupulous actors will target consumers and advertise that they are part of the SIP program even if they are not. Individuals who do not know the intricate details of FDA's importation scheme may buy from unauthorized entities, believing that these entities are part of an authorized SIP program.

VI. The Proposal 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*."[111] 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.[112] Even if that were permitted by the statute (and it is not), the Proposal provides scant indication that the proposed SIP program will lead to any—let alone significant—reduction in cost to consumers. The Proposal offers only the roughest back-of-the-envelope math (based on spending by health plans, not individual consumers) to support its claims that importation would reduce the cost of covered products to Colorado consumers. Moreover, the Proposal ignores substantial SIP implementation costs which will limit the Department's cost savings or eliminate any savings entirely.

A. The Proposal offers only the roughest back-of-the envelope math to support its claims that importation would reduce the cost of covered products.

Under the Final Rule, the explanation of cost savings in a SIP proposal "must be sufficiently detailed to allow for a meaningful evaluation."[113] Critically, it is not sufficient to simply identify differences in drug prices between the United States and Canada.[114] Instead, a

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[109] FDA Press Release: *FDA Warns CanaRx for Selling Unapproved, Misbranded, and Unsafe Imported Drugs to Unsuspecting Americans* (Feb. 28, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-canarx-selling-unapproved-misbranded-and-unsafe-imported-drugs-unsuspecting-americans#:~:text=CanaRx%20claims%20its%20drugs%20are,instead%2C%20its%20violations%20endanger%20consumers&text=Today%2C%20the%20U.S.%20Food%20and,misbranded%20drugs%20to%20U.S.%20consumers.

[110] *Id.*

[111] FDCA § 804(*l*)(1)(B).

[112] 85 Fed. Reg. at 62,101; *see also* 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

[113] 21 C.F.R. § 251.3(e)(9).

[114] Aaron Kearsley, Senior Economist and Acting Director, Division of Science and Public Health Policy, Office of Science and Data Policy, *Projecting Cost Savings for the American Consumer* (Apr. 31, 2022), https://www.fda.gov/media/158564/download.

SIP proposal must demonstrate that the SIP sponsor will be able to *leverage* these drug price differences to result in cost savings for the American consumer.[115] According to an HHS presentation on how states should comply with the Final Rule (as well as FDA communications to the State of Florida), cost savings should be demonstrated through:

- A projection of total annual expenditures the SIP sponsor anticipates if the SIP proposal is authorized and implemented (the "Plan Scenario"), covering at least the first two years of the SIP and identifying the calendar year, or specific 12-month period covered for each year of the analysis;

- A projection of total annual expenditures the SIP sponsor anticipates if the SIP proposal is *not* authorized and implemented (the "Baseline Scenario"), covering the same time period covered under the Plan Scenario *and* the time period between the most recent year of drug pricing data and the first year of the SIP;[116] and

- Cost savings for each year, expressed as the difference between the baseline costs under the Baseline Scenario and the Plan Scenario.

Expenditure projections should be provided for *each drug* under the Plan Scenario and the Baseline Scenario, and these drug expenditure projections should include both quantity and per-unit price estimates.[117]

Rather than providing a robust Plan Scenario and Baseline Scenario for comparison, the Proposal's section on cost savings relies on crudely estimated price differentials between the United States and Canada for drugs on an "aspirational" list.[118] The "U.S. Price" estimates provided on pages 15 to 22 are based primarily on data from the Colorado All Payer Claims Database ("CO APCD"), with the Department assuming identical utilization rates but a lower cost per claim of 10% for the 37% of Coloradans who are covered by self-funded, employer-sponsored programs not included in the CO APCD.[119] The "Importation Price" estimates are based on the "guaranteed selling price" in the July 2022 Quebec Province's "List of Medication", or, when Quebec data was unavailable, Ontario pricing or wholesale prices supplied by the Proposal's foreign seller.[120] The Proposal does not address which Canadian estimates are based on which data set.

Even if the estimated per-drug price differentials were accurate, they are clearly insufficient as a demonstration of cost savings to the consumer. The U.S. prices reflect health plan expenditures, not the out-of-pocket cost for patients, and the Proposal provides only limited and highly speculative estimates of cost savings to consumers. The Department "hope[s]

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[115] *Id.*

[116] *Id.*; *see also* FDA Letter to Florida Agency for Health Care Administration at 5–8. For example, if the SIP covers 2023 and 2024 and the drug pricing data are from 2020, the Baseline Scenario should cover 2020-2024.

[117] *Id.*

[118] Proposal at 15–20; Proposal Appendix E at 67–70.

[119] Proposal at 13.

[120] *Id.* at 14

that insurers would provide reduced cost sharing or co-pays for imported drugs," but offers no evidence that insurers will actually do so.[121]

The Department's total annual savings projections of $53 to $88 million also are not in keeping with the "sufficiently detailed" explanation required under the Final Rule. The Department provides annual savings for one year only and does not specify the calendar year or specific 12-month period for this projection. And the Proposal provides no information to support the Department's estimate of a 15 to 25% replacement rate, other than a statement that it purports to predict manufacturer and health plan adoption. Significantly, the estimated annual savings assumes that all 112 drugs on the list will be imported, even though the Department concedes that "partnerships with manufacturers will be modest in the early years."[122] Indeed, Colorado's "early research" indicates that the initial adopters may be generic drug manufacturers.[123] If so, this would reduce the total savings projections dramatically.

Colorado's ability to realize *any* cost savings is subject to significant uncertainty. Indeed, "[i]n order for this program to be successful, a lot of things must be in Colorado's favor."[124] As an initial matter, Canada's food and drug regulations prohibit exportation if distribution will cause or exacerbate a shortage of the drug,[125] and between 10-15% of drugs are in shortage at any given time.[126] Moreover, as the Proposal acknowledges, there is significant uncertainty regarding the number of pharmacies that will participate in Colorado's SIP and whether insurers will include imported drugs in their benefit designs. Pharmacies have expressed concerns that participation in the importation program may negatively impact primary wholesale contracts, and the Department has also received "soft resistance from health plans and their owned or affiliated [pharmacy benefit managers]."[127]

The Department attempts to overcome key limitations in its projections by framing its proposed importation program as a "pilot,"[128] but such an approach is inconsistent with both the statute and the Final Rule. As discussed in the litigation, Petitioners maintain that the Final Rule improperly delegates responsibility for demonstrating safety and cost savings to State governments, even though the Final Rule states that the *Secretary* must certify that imported drugs pose no additional risk to public safety and will lead to significant savings for the

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[121] *Id.* at 22.

[122] *Id.* at 21.

[123] *Id.* at 22.

[124] Danielle Bargo, Opinion, Importing Medicines from Canada is No Guarantee of Lower Drug Prices, Colo. Sun (Feb. 3, 2023), https://coloradosun.com/2023/02/03/drug-prices-canada-import-medicines-colorado-opinion/.

[125] C.R.C., c. 870, C.01.014.13.

[126] Matthew S. Schwartz, *Canada Blocks Export Of Medications In Short Supply In Response To Trump Plan*, Nat'l Pub. Radio (Nov. 29, 2020), https://www.npr.org/2020/11/29/939890111/canada-blocks-export-of-medications-in-short-supply-in-response-to-trump-plan.

[127] Proposal at 23.

[128] *Id.* at 21.

American consumer. Colorado should not be permitted to punt the determination of cost savings yet again.

B. The Proposal ignores significant costs associated with establishing and administering an importation program.

FDA has stated that a SIP proposal must address importer price markups, other transportation and logistical costs not captured by the importer price markup, and costs associated with drug samples, testing, and other requirements under section 804 and the Final Rule.[129] The Proposal provides for a blanket 50% markup to each unit price "to cover estimated costs of the supply chain," but provides *no* assumptions, methods, or data to support this figure.

The Proposal does not address the profit margin retained by supply chain entities, nor does it appropriately document the expenses imposed on supply chain entities. Relevant expenses include costs associated with inspecting imported prescription drugs; reliably recording and sharing adverse events; effectuating recalls and disposal of recalled drugs; developing IT systems and reporting infrastructure; and new capital expenditures to support 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.

The Proposal also ignores other costs associated with establishing and administering an importation program that likely will be borne by the Department. The Proposal lays out plans for the Department to take on several new responsibilities, including establishing and regularly updating policies and procedures; maintaining contracts with supply chain partners; inspecting program participants and otherwise holding them accountable to contractual, federal, and state requirements; conducting outreach and negotiations with manufacturers, pharmacists, payers, and other stakeholders; setting up a patient call center; and educating patients.[130] However, the Proposal does not address how any of these activities will be funded.

In addition, the Proposal does not address the burden on law enforcement. 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."[131]

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

The Proposal suffers from additional legal flaws. The Proposal includes only the most cursory protection of trade secrets and other confidential information, leaving manufacturers vulnerable to significant reputational damage if such information is released to the public.

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[129] HHS, *Projecting Cost Savings for the American Consumer* (Apr. 31, 2022), https://www.fda.gov/media/158564/download.

[130] Proposal at 32–33, 50–52

[131] 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.

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.

A. The Proposal lacks robust protection of trade secrets and other confidential information.

The Final Rule requires manufacturers either to conduct statutory testing themselves or to divulge highly confidential trade secrets and other confidential information to importers to facilitate the authentication of drugs and their labeling.[132] 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 commercial or financial information that is privileged or confidential "are kept in strict confidence and used only for the purposes of testing or otherwise complying with" the FDCA and the Final Rule.[133]

The Proposal addresses protection of this valuable and highly confidential information in a single paragraph. The Department simply states that Q laboratories and the manufacturer "will create and agree to a confidentiality agreement" and that Q laboratories "will take steps internally" to utilize secure networks, firewalls, and Virtual Private Networks when needed to access information.[134] This falls far short of the Final Rule's requirement of a written policy for handling trade secrets or commercial or financial information that is privileged or confidential. Moreover, the Proposal is completely silent on the importer's obligations to protect the manufacturer's information.

Manufacturers invest in security systems with multiple layers of protections to ensure that trade secrets and other confidential information are kept confidential, yet no such systems are identified in the Proposal. 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. The Proposal prematurely seeks to omit the required labeling statement and otherwise fails to provide required labeling information.

The Final Rule requires that the labeling of imported product bear conspicuously the following statement: "[This drug was/ These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program."[135] The Department strenuously disagrees with this requirement on the basis that "all eligible drugs will have the express authorization of the manufacturer to be included in Colorado's program" and that therefore this statement "is technically incorrect."[136] But Colorado has not provided any factual basis to suggest that it has received express authorization

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[132] 21 C.F.R. § 251.16(b).

[133] *Id.* § 251.3(e)(16).

[134] Proposal at 44.

[135] 21 C.F.R. § 251.13(b)(4)(iv).

[136] Proposal at 44–45.

from any manufacturer, and the regulations themselves do not require the manufacturer to provide express authorization. Accordingly, Colorado's request is premature.

In addition, the Proposal includes only one relabeling example. It is essential for manufacturers to be able to review the proposed labeling side-by-side with the FDA-approved labeling, with all differences annotated and explained,[137] to ensure that the SIP sponsor is not inappropriately using the manufacturer's trademarks and perhaps even the trade dress reflected in the overall design of prescription drug's packaging (assuming such design is sufficiently distinctive to warrant trade dress protection).

VIII. FDA should disclose the final list of to-be-imported eligible prescription drugs, the proposed labeling, and side-by-sides for public comment.

Petitioners request that FDA disclose the final list of drugs to be imported, as well as the proposed labeling for each drug and side-by-sides with the FDA-approved labeling, as soon as the Department provides the relevant information to FDA. The public interest weighs heavily in favor of disclosure, and the requested information is not confidential.

The public interest undoubtedly weighs in favor of disclosure because, as discussed above, the SIP must meet the statutory criteria for safety and cost savings to the American consumer. Since safety and cost considerations will vary depending upon the drugs to be imported, the final drug list is critical to assessing whether those criteria can plausibly be met.[138] Furthermore, disclosure is critical for promoting transparency and due process, particularly in the context of a novel and untested program. To the extent that Colorado seeks to omit the labeling statement required under the Final Rule, it should be required to provide drug-specific information to support such an omission, and manufacturers and the public at large should have the opportunity to comment.

Disclosure is also important for promoting international coordination. Canada's food and drug regulations were amended to prohibit establishment license holders from distributing a drug for consumption or use outside Canada unless the licensee has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug.[139] Public 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.

Neither the final drug list nor the proposed drug labeling is unlikely to be considered private. Indeed, Colorado plans to include the drug list on the Department's website.[140] The

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[137] 21 C.F.R. § 251.3 (e)(8). A SIP proposal must also include a copy of the HPFB-approved labeling.

[138] *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)).").

[139] C.R.C., c. 870, C.01.014.13.

[140] Proposal at 50.

proposed labeling will become public once importation is initiated, and the existing FDA-approved labeling to be included in the side-by-sides is already publicly available.

IX. Conclusion

For the reasons explained above, FDA should refrain from authorizing the Proposal. The Proposal was submitted pursuant to an invalid Certification and an unlawful Final Rule, and cannot be approved for the reasons described in the litigation. The Proposal also 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. The Department does not adequately demonstrate that importation will pose no additional risk to public health and safety, and its cost estimates are too speculative to allow for meaningful evaluation. Other deficiencies in the Final Rule raise issues of reputational harm for manufacturers. Finally, the failure to submit the finalized list of drugs to be imported and the proposed labeling 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.

Respectfully submitted,

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