

March 9, 2020

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

**Re: Docket No. FDA-2019-N-5711: Importation of Prescription
Drugs; Proposed Rule**

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is pleased to provide comments on the Food and Drug Administration’s (“FDA’s” or “the Agency’s”) proposed rule, “Importation of Prescription Drugs” (the “NPRM” or “proposed rule”). PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures, including an estimated \$79.6 billion in 2018 alone.

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

Importation is not the solution to lowering patient costs. PhRMA supports fundamental policy changes to achieve solutions that will help patients and produce better and more efficient care. Although the current drug distribution and payment system has constrained overall spending on medicines, the underlying mechanics could work better for patients. Providing patients with access to negotiated rebates, addressing affordability challenges in patient deductibles, and giving patients information on out-of-pocket costs and healthcare quality would empower consumers and lower out-of-pocket costs. Accordingly, PhRMA has supported the policies underlying the Office of Inspector General’s proposed modifications to safe harbor protection for rebates involving prescription pharmaceuticals.²

While PhRMA supports reducing patient out-of-pocket costs, implementation of section 804 will not achieve that objective but instead will endanger the public’s health, the integrity of the

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

² Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (Feb. 6, 2019).

American pharmaceutical supply chain, and the gold standard that is FDA-approval. Since its enactment in 2003, section 804 of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “FD&C Act”) has remained not in effect and unimplemented for a simple fact – no Secretary of Health and Human Services (“HHS”) has been able to make the requisite findings to certify that importation as envisioned by section 804 could be implemented in a manner that would pose no additional risk to the public’s health and safety and that would deliver significant cost savings on the imported product to the American consumer. Indeed, though the HHS Secretary intends to make the case to support such a certification now, the NPRM issued by FDA makes just the opposite point: the Secretary can no more certify to either prong now than could any of his predecessors.

HHS must abandon its section 804 implementation proposal and withdraw the NPRM. Implementing section 804 and the NPRM would lead to significant public health, safety, cost, and legal harms. As FDA Commissioner Stephen Hahn recently stated, “[c]onsumers and physicians purchasing medicines cannot be assured the products they are receiving are legitimate, safe, or effective if they are obtained from outside of the FDA-regulated pharmaceutical supply chain.”³ Implementation of section 804 and the NPRM would create an opening in the closed U.S. pharmaceutical supply chain that would increase the opportunities for illegitimate, unsafe, and ineffective medicines to enter the U.S. drug distribution system. American patients would assume the risks of receiving counterfeit and substandard drugs without benefiting from any out-of-pocket cost savings for prescription drugs. The section 804 importation proposal would also undermine the FDCA’s carefully constructed framework to promote medical innovation and reduce incentives to invest in pharmaceutical, research, development, and manufacturing.⁴ The importation scheme is contrary to FDA’s public health mission and violates the FDCA, other federal statutes, and the U.S. Constitution.

We summarize our concerns with the proposed rule below:

- The proposed importation scheme would jeopardize the health and safety of patients and fail to reduce patient costs.
 - *HHS has repeatedly concluded that section 804 importation would pose significant risks to the public’s health. The same conclusions apply today.* HHS has consistently refused to effectuate section 804 because it found that importation would pose significant risks to the public’s health and would not result in significant savings for consumers. HHS’s prior conclusions still apply today, as evidenced by HHS’s failure to adequately explain why its prior conclusions are no longer relevant to the proposed program.
 - *The proposed rule would pose additional risks to the public’s health and safety.* The proposed rule would undermine drug supply chain security, pharmacovigilance, and other protections provided by application holder oversight within FDA’s prescription drug regulatory regime. The proposed rule impermissibly circumvents FDA’s regulatory regime by allowing unapproved and

³ FDA Press Release, FDA Takes Action with Indian Government to Protect Consumers from Illicit Medical Products (Feb. 18, 2020).

⁴ See HHS, Task Force on Drug Importation, Report on Drug Importation (Dec. 2004) (“HHS Task Force Report”) at 82 (finding that “legalizing importation would adversely affect R&D of new drugs, causing future drug consumers to forego the health benefits associated with innovation”).

misbranded drugs to be imported under section 804 and increases the likelihood that adulterated drugs will enter the U.S. market. Further, the importation scheme would introduce consumer confusion and increase the risk of medication errors. HHS has not even demonstrated that any Section 804 Importation Program (“SIP”) entities have the capacity to ensure that drugs imported under the proposed rule are safe.

- *The proposed rule would not result “in a significant reduction in the cost of covered products to the American consumer.”* HHS has not shown that its importation scheme would result in significant cost savings of the covered products for the American consumer. The proposed rule does not provide any cost calculations, and instead, FDA admits that it is unable to determine whether the proposed rule will result in significant cost reductions.
- HHS’s proposed certification and FDA’s proposed rule would exceed their authorities under the FDCA and other federal laws.
 - *HHS’s proposal to certify based on temporary, limited, short term plans is inconsistent with section 804.* HHS’s proposal for certification is unlawful for multiple reasons. First, HHS has impermissibly conditioned certification on anticipated future findings. Congress did not allow section 804 to become effective without HHS making the certification findings because Congress knew that section 804 would open a closed drug distribution system. Section 804 cannot be made effective without the required findings. Second, HHS impermissibly proposes to certify with respect to some sections of section 804 (e.g., commercial importation under subsections (b)-(h)), but not others (e.g., personal importation under subsection (j)) because it admits that section 804(j) will pose additional risk to the public’s health and safety. Third, HHS proposes to certify for only particular consumers under particular plans, but section 804 certification must be broadly applicable and cannot be limited to specific consumers under specific plans. Moreover, HHS has impermissibly subdelegated fact-finding necessary for the required certification to third parties.
 - *FDA lacks authority to adopt provisions of the proposed rule.* In addition to posing section 804 certification concerns, the proposed rule impermissibly requires the manufacturer to participate in importation in ways not sanctioned by the FDCA, FDA regulations, and other federal statutes.⁵ These provisions include proposed 21 C.F.R. § 251.16(i) (authorizing FDA to provide the Importer information contained in a new drug application), 21 C.F.R. § 251.16(b)

⁵ Unless otherwise specified, we use the term “manufacturer” to have the same meaning as in section 581(10) of the FDCA (defining “manufacturer” to mean with respect to a product “(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B)”). We use the term “application holder” to refer to a person who holds an application approved under section 505 of the FDCA.

(requiring manufacturer to supply “testing methodologies and protocols that the manufacturer has developed”), 21 C.F.R. § 251.13(a) (deeming authorization to provide labeling), 21 C.F.R. § 251.4(c)(4)(xii) (requiring manufacturer to provide attestation), and 21 C.F.R. § 251.14 (requiring manufacturer to provide an Importer transaction information).

- The proposed rule raises constitutional concerns and is inconsistent with U.S. treaty obligations.
 - *The proposed rule’s attestation, testing, and labeling requirements violate manufacturers’ First Amendment rights.* The required attestation from the manufacturer to an Importer and the required provision of testing information and the manufacturer labeling amount to compelled speech and compelled subsidies in violation of the First Amendment. These provisions unlawfully require a manufacturer to convey a message it disagrees with: that the imported drug is equivalent in quality and other attributes to the manufacturer’s drug intended for the U.S. market and to subsidize their competitors’ products.
 - *Compelled disclosure of trade secrets and confidential commercial information (“CCI”) for competitor use violates the Takings Clause and requires just compensation.* Disclosure of manufacturer trade secrets and CCI for competitor use would interfere with manufacturers’ reasonable investments based on explicit guarantees in section 301(j) of the FDCA, FDA regulations, and the Federal Trade Secrets Act (“FTSA”). Forced disclosure for competitor use would have a significant negative economic impact on manufacturers and would harm a key right associated with their intellectual property: the right to exclude others from using the property.
 - *Requiring manufacturers to allow Importers to use manufacturer trademarks at no cost violates the Takings Clause and requires just compensation.* Forcing manufacturers to allow competitors to use their trademarks would interfere with the manufacturers’ reasonable investments in their trademarks. Such compulsory licenses are disfavored under trademark law because they allow a competitor to both benefit from, and potentially endanger, the reputation associated with the manufacturer’s trademarks.
 - *The proposed rule’s implementation of section 804 would be inconsistent with the World Trade Organization’s (WTO’s) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).* Disclosing manufacturer trade secrets and CCI would violate article 39 of the TRIPS Agreement. A compulsory license from manufacturers to allow Importers to use their trademarks would violate article 21 of the TRIPS Agreement.
- FDA promulgated the proposed rule without effective statutory authority and failed to adhere to other procedural requirements. The proposed rule was issued without any effective statutory authority because it was issued before certification. Further, the public will not have a meaningful opportunity for notice-and-comment on HHS certification. Additionally, the proposed rule suffers from other procedural deficiencies, including failing to comply with the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, Executive Orders 12866 (requiring explanation for determination that the rule is a “significant regulatory action” and requiring inter-agency review), 13175

(requiring assessment of impact on Native American tribes), 12630 (requiring an assessment of Takings Clause implications), the E-Government Act of 2002, and Executive order 13045 (requiring evaluation of the rule's risks to child health). For these reasons, FDA should withdraw the proposed rule.

- PhRMA provides other comments concerning aspects of the proposed rule that are impermissible or would lead to significant public health risks. Although PhRMA believes that FDA should withdraw the proposed rule because its section 804 implementation proposal would be unsafe, costly, and unlawful, PhRMA responds to certain FDA requests for comment on the proposed rule to further emphasize the safety, cost, and legal ramifications of the proposed importation scheme. We highlight a few of these concerns here:
 - *FDA must clarify and revise some of its definitions.* The holder of a prescription drug application is the only suitable entity to fulfill the role of “manufacturer” under the proposed rule. The definition of “eligible prescription drug” should not include drugs with heightened safety concerns, such as combination products, inhaled drugs, modified-release drugs, sterile drugs, ophthalmic drugs, narrow therapeutic index drugs, drugs with boxed warnings, drugs requiring special storage conditions, and drugs requiring Medication Guides under 21 C.F.R. part 208. Further, “eligible prescription drug” should be limited to sole-source drugs, exclude drugs with remaining patents or exclusivities, exclude drugs manufactured using recombinant technologies, and exclude drugs subject to post-marketing commitments and requirements.
 - *Cost savings must go to consumers.* Consistent with the statute, any cost savings must be calculated based on a patient’s out-of-pocket costs for the covered products. FDA must not calculate cost savings passed to consumers in indirect ways.
 - *Drug labeling must distinguish between a SIP drug, distributed by an Importer, and other drugs under the control of the manufacturer.* Disclosing that a drug was imported under the section 804 program is necessary for consumers to properly attribute the drug to the entity responsible for ensuring its quality and safety. Labeling should not reference any purported cost savings. Manufacturers should have the opportunity to review the proposed label and be able to include disclaimers on labeling.

Because implementation of section 804 and the NPRM would be unsafe, costly, and unlawful, HHS must abandon its pursuit of prescription drug importation. We explain our comments in more detail below.

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I. The Proposed Rule Jeopardizes the Health and Safety of Patients and Fails to Reduce Patient Costs.

FDA’s proposed scheme would endanger patients while failing to reduce costs for American consumers. HHS has repeatedly concluded that section 804 importation would pose significant risks to the public health and would not reduce costs in covered products for the American consumer. These conclusions are still valid today. The proposed rule would undermine the U.S. regulatory system that relies on the application holder to ensure American consumers receive safe and effective drugs, create holes in the closed-system supply chain, and increase consumer confusion about imported drugs. These consequences would increase the risks that patients will be harmed by unapproved, misbranded, adulterated, counterfeit, and unsafe drugs entering the market after implementation of section 804. Moreover, the proposed rule would exempt products imported under section 804 from key provisions of the Drug Supply Chain Security Act (“DSCSA”) and undermine developments in supply chain security in the U.S. The proposed scheme is also unlikely to achieve any savings related to the imported products for U.S. consumers, let alone a significant reduction in cost to consumers, as demonstrated by FDA’s failure to quantify the costs of its proposed rule. In light of these significant issues and for the reasons set forth below, HHS cannot certify that section 804 “will” “pose no additional risk to the public’s health and safety; and result in a significant reduction in the cost of covered products to the American consumer.”⁶

- A. HHS has repeatedly concluded that section 804 importation would pose significant risks to the public’s health, and the same conclusion applies today.

Historically, HHS Secretaries under both Democratic and Republican administrations have found that an importation program would pose significant risk to the public’s health and declined to issue certifications to allow imports of drugs into the U.S. In 2007, for example, former HHS Secretary Michael Leavitt warned, “Allowing the importation of drugs outside the current safety system would pose an immediate and significant risk to the public health in the United States.”⁷ Former FDA Commissioner Scott Gottlieb has stated that safeguarding drug importation is “very, very resource-intensive” and there is “no fool-proof way to do this.”⁸ Until recently, current HHS Secretary Alex Azar recognized section 804 importation as a “gimmick”

⁶ FDCA § 804(l) (emphasis added to “will”).

⁷ Lynne Taylor, U.S. Senate Kills Drug Importation Moves, *PharmaTimes* (May 8, 2007). Former HHS Secretary Donna Shalala, who declined to certify to a predecessor of section 804, recently called a Florida Canadian drug importation bill “silly” and “pure politics.” Press Release, Donna Shalala, Good Luck with that Canadian Drug Import Bill (June 8, 2019).

⁸ Rachel Cohrs, Gottlieb Bashes Drug Importation a Day After Trump Supports It, *InsideHealthPolicy* (May 10, 2019).

that “has been assessed multiple times by the Congressional Budget Office, and CBO has said it would have no meaningful effect.”⁹

These HHS determinations rested, in part, on a comprehensive report on section 804 importation released in 2004. After enactment of section 804, HHS produced a report to examine whether importation would pose additional risk to the public’s health and safety and whether importation would result in a reduction in cost on the covered products to the American consumer, the requirements for certification. The HHS Task Force **could not find** that importation would pose no additional risk. Instead, the HHS Task Force concluded that the “increasing volume of imported drugs makes it difficult to quantify, monitor, control, and ensure safety.”¹⁰ The HHS Task Force considered potential safeguards but concluded that many alternative safeguards would not be equivalent to existing safety standards under the FDCA. As a general matter, for example, product testing “does not necessarily ensure that imported drugs were manufactured, handled, or stored in such a way to maintain their quality, safety, and efficacy.”¹¹ Further, “there is no single technology or machine that could do this test for all products as they enter the country and, even if there was, it would be prohibitively resource intensive and logistically impossible to test all imported products.”¹²

Further, the HHS Task Force **could not find** that importation would result in significant cost savings to the American consumer. This was in part because “[o]verall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.”¹³ In fact, the “public expectation that most imported drugs are less expensive than American drugs is not generally true. Generic drugs account for most prescription drugs used in the U.S. and are usually less expensive in the U.S. than abroad.”¹⁴

Any commercial importation, the HHS Task Force reasoned, would require new legal authorities, and limitations in current legal authorities would inhibit the Secretary’s ability to certify the safety of a drug importation program.¹⁵ For example, FDA identified “partnerships with foreign health authorities to verify transactions” as necessary to ensure the pedigree of an imported product.¹⁶ In addition, commenters suggested that for commercial importation to work, FDA would need the same level of authority for international recalls as it currently has for

⁹ Alex Azar, Remarks on Drug Pricing Blueprint (May 14, 2018).

¹⁰ HHS Task Force Report at 8.

¹¹ *Id.*

¹² *Id.* at 43.

¹³ *Id.* at XIII.

¹⁴ *Id.* at XIII.

¹⁵ *Id.* at 25.

¹⁶ *Id.* at 33.

domestic recalls.¹⁷ Today, there is still no Canadian system in place to ensure the pedigree of a product originally intended for Canada that becomes intended for the U.S. or any new international authorities to address the pedigree of the imported product and international recalls. The conclusions in the HHS Task Force Report are thus still relevant today.¹⁸

B. The proposed rule would pose additional risk to the public's health and safety.

Section 804(l)(1) requires HHS to find that implementation of the section will “pose no additional risk to the public's health and safety.” The proposed rule undermines the drug distribution system in the U.S., which in FDA's words, “provides critical assurances to patients.”¹⁹ The risks associated with the proposed importation scheme prevent HHS from certifying under section 804(l)(1).

1. *The proposed importation program would undermine important regulatory protections provided by application holder oversight that keep consumers safe.*

The FDCA and FDA's implementing regulations for prescription drugs rely on one entity, the application holder, to bear primary responsibility for drugs distributed under its application. The application holder is responsible for ensuring that drugs are manufactured and stored in compliance with current good manufacturing practices (“cGMP”) and for ensuring that drugs are distributed under good distribution practices. Once a drug enters the U.S. market, application holders must comply with FDA's pharmacovigilance regulations and implement risk management strategies to minimize risks related to a drug. The application holders design pharmacovigilance systems and processes to detect, assess, and understand any adverse effects or drug-related problems. If the application holder detects a safety signal, it can propose changes to drug labeling to account for newly discovered risks. Thus, under FDA's regulatory regime, one entity, the application holder, has oversight over the drug and can be held accountable if issues with the drug arise.

Implementation of section 804 under the proposed rule would significantly disrupt FDA's regulatory regime and thereby undermine public health and safety. Under FDA's proposed scheme, the application holder would no longer have visibility into the supply chain for a drug; instead, multiple parties would be responsible for packaging, storing, and distributing products to U.S. patients. More importantly, no one entity could be responsible for ensuring that drugs

¹⁷ *Id.* at 24.

¹⁸ See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983) (holding that an agency must show that its decision was the product of “reasoned decisionmaking” to satisfy the arbitrary and capricious standard of review); *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125–26 (2016) (holding that an agency acts arbitrarily and capriciously when it changes policy without accounting for reliance interests created by the prior policy or inconsistencies between the new policy and factual findings made in connection with the prior policy).

¹⁹ FDA Press Release: FDA Warns CanaRx for Selling Unapproved, Misbranded and Unsafe Imported Drugs to Unsuspecting Americans (Feb. 28, 2019).

are manufactured, stored, and distributed safely to U.S. patients. Because the application holder would not have visibility into the supply chain, the application holder would no longer be in a position to monitor and prevent adulteration or departures from good manufacturing or good distribution practices. Adding another supply chain into the system, as well as a second owner of that supply chain, would lead to additional risks because no one party has full visibility or accountability. For example, if a patient reports an adverse event for an imported drug to an application holder, the holder may not have all the information in its possession necessary to perform an informed assessment about whether the event is related to the drug itself or instead related to how a Foreign Seller or Importer repackaged, stored, or distributed the drug. Second, application holders collecting postmarketing safety data on approved drugs would not be able to determine whether the collected information relates to drugs intended for the U.S. or drugs distributed under an importation plan. Finally, if an application holder changes its labeling post-approval to, for example, add a warning, it would not be in a position to ensure that the drugs distributed by the Importer bear that warning.

2. *The proposed importation scheme would expose patients to the risks associated with imports of unapproved, misbranded, and adulterated drugs.*

The FDCA and FDA's regulations ensure the safety and overall quality of drug products consumers purchase in the United States. Drugs marketed in the U.S. must be approved, not misbranded, and not adulterated, in addition to meeting other requirements outlined in the FDCA. The FDCA and FDA's regulations give American consumers confidence that the drugs they use are safe and effective and are not expired, subpotent, contaminated, counterfeit, or otherwise unsafe for patient use.

Mindful of the FDA regulatory regime, Congress mandated that each prescription drug imported under section 804's commercial importation scheme must comply with sections 505 (premarket approval), 501 (adulteration), and 502 (misbranding).²⁰ Section 801(a), which applies to drugs imported under section 804, requires FDA to refuse admission to unapproved new drugs, misbranded drugs, and adulterated drugs.²¹ For these reasons, the HHS Task Force concluded that it did not have legal authority to allow imports of foreign "versions" of FDA-approved drugs because these drugs would be unapproved and misbranded.²² The proposed rule does not cure these concerns: it would allow unapproved and misbranded drugs to be imported under section 804 and would increase the likelihood that adulterated drugs enter the U.S. market. The proposed rule's failure to comply with the approval, misbranding, and adulteration provisions of the FDCA would expose patients to increased health and safety risks.

²⁰ FDCA § 804(c)(1).

²¹ See *Cook v. FDA*, 733 F.3d 1, 7 (D.C. Cir. 2013) (finding that "the ordinary meaning of 'shall' is 'must'").

²² See HHS Task Force Report at 15.

- a) The proposed rule would permit unapproved drugs, not subject to rigorous FDA review, to be imported into the United States.

FDA's approval scheme is essential to ensuring the safety and efficacy of a prescription drug. Section 505 of the FDCA states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."²³ Under the FDA's rigorous evaluation process, the Agency scrutinizes everything about the drug, from the clinical trials evaluating whether a drug is safe or effective to the conditions under which the drug is manufactured. An application approved under a new drug application ("NDA") (section 505(b)) or an abbreviated new drug application ("ANDA") (section 505(j)) includes all components of a drug, all aspects of its manufacture, and all its packaging and labeling.²⁴

To ensure drugs remain safe and effective after initial approval, FDA oversees and monitors any change an applicant may make to a drug. Any change to an approved new drug application must either be submitted to FDA prior to distribution of the drug product made using the change or be described in an annual report for changes that are expected to have a minimal impact on the drug.²⁵ FDA's guidance on "Changes to an Approved NDA or ANDA" describes some of the conditions of an approved application, including manufacturing sites, manufacturing processes, the container closure system, and labeling.²⁶ FDA approval of a new drug application "includes the approval of the exact text in the proposed label."²⁷

A drug imported under the proposed rule will be unapproved because it will differ from the drug approved in the NDA and ANDA and therefore would not have been subject to FDA review.²⁸ We provide examples of these differences below:

²³ FDCA § 505(a).

²⁴ See *New Drugs for Human Use: Proposed Clarification of Requirements for Application Supplements*, 51 Fed. Reg. 20310, 20311 (June 4, 1986) (indicating that the conditions under which a drug is approved included "detailed information about the composition of the drug, the method of its manufacture, and copies of the labeling for the product").

²⁵ 21 C.F.R. § 314.70.

²⁶ FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* (Apr. 2004) (*Changes to an Approved NDA or ANDA Guidance*).

²⁷ *Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

²⁸ PhRMA notes FDA does not have authority to compel the NDA or ANDA holder for the FDA-approved product to submit a supplement. See *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 226 F.Supp.2d 204 (D.D.C. 2002) (holding that, absent clear Congressional intent, FDA had no authority to issue a rule requiring manufacturers to develop a pediatric formulation for a drug product and submit it for approval). Here, as in *Association of American Physicians & Surgeons*, Congress did not explicitly give FDA authority to modify an approved application by requiring companies to submit a supplement.

- There will be manufacturing information for the imported drug that will not be in the NDA or ANDA for the FDA-approved drug. For example, the relabeler/repackager and the relabeling/repackaging processes by the Foreign Seller and Importer will not be included in the NDA or ANDA. In addition, the identity of the qualified laboratory and the testing will not be included in the NDA or ANDA. The chemistry, manufacturing, and controls section in the NDA and ANDA for FDA-approved drugs controls the entirety of the manufacturing process, from active pharmaceutical ingredient through finished product, and must include these types of manufacturing information.²⁹ Moreover, the addition of manufacturing or processing sites are usually required to be submitted to FDA in an application before these changes can occur.³⁰ Because of differences in how a Foreign Seller and Importer store and relabel/repackage the products, these manufacturing differences would change the methods or controls that provide assurance that the drug substance or product has “the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess.”³¹ These differences will render the drug unapproved.
- Likewise, the labeling for the imported drug will necessarily include differentiating information that does not appear on labeling in an FDA-approved NDA or ANDA. The proposed rule requires certain information to appear on a drug imported under it. The imported drug’s labeling will include “the name and place of business of the Importer,” as well as that of the manufacturer if FDA-approved labeling does not include such information. The labeling could also include a SIP website. The imported drug’s labeling must include the following statement: “This drug was imported from Canada under the [Name of State or Other Government Entity and of Its Co-Sponsors, If Any] Section 804 Importation Program to reduce its cost to the American consumer.”³² Labeling is approved as part of a new drug application, and changes in labeling such as

²⁹ FDCA § 505(b)(1)(D) (requiring the applicant to provide to the Secretary a “full description of the methods used in, and the facilities used for, the manufacturing, processing, and packing”); 21 C.F.R. §§ 314.50(d)(1) (requiring an applicant to provide the name and address of each manufacturer of a drug product), 210.3(12) (defining “manufacture, processing, packing, or holding of a drug product” as “packaging and labeling operations, testing, and quality control of drug products”); *see also* FDA, Guidance for Industry: Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers (Oct. 2019).

³⁰ Changes to an Approved NDA or ANDA Guidance at 9–10.

³¹ *Id.* at 15.

³² Importation of Prescription Drugs, 84 Fed. Reg. 70796, 70819 (Dec. 23, 2019). *See also infra* Section V.R (explaining that FDA’s proposed disclosure statement should not include a discussion of cost because inclusion of a such a statement would not be consistent with FDA regulations and the purpose of labeling, which is to provide safety, effectiveness, and use information).

these must be submitted to FDA as part of an FDA-approved application.³³ PhRMA agrees that certain differentiating information, including disclaimers, should be in the labeling,³⁴ but this labeling must be approved by FDA.

As we note above, section 505(a) of the FDCA prohibits a person from introducing a “new drug” into interstate commerce unless it is subject to an approved application under section 505. Section 804 recognizes the importance of ensuring that all drugs imported “compl[y] with section 505 (including with respect to being safe and effective for the intended use of the prescription drug).” In order for a drug to be lawfully imported under section 804, it must be the subject of an approved application under section 505.

The proposed rule would require manufacturers to “attest” that an imported drug is the same as an FDA-approved drug, but for the labeling. Manufacturer “attestation” cannot substitute for FDA’s rigorous oversight of FDA-approved drugs through the statutorily-required procedures for drug approval under section 505 of the FDCA. FDA does not approve a drug by relying on an “attestation,” nor does FDA consider a drug “approved” or in compliance with section 505, “but for the labeling.” Drug approval and 505 compliance are fundamental FDA concepts that should not (and cannot) be distorted to facilitate section 804 importation. Relying on an “attestation” would increase the risk of patient harm by permitting differences between a drug imported under the proposed rule and an FDA-approved drug. Some of these differences may be undetectable through “attestation” or product testing and could increase the risk of adverse events associated with a drug.

If FDA moves forward with the proposal, FDA should apply its well-established procedures for drug approval under the FDCA and FDA’s implementing regulations to drugs imported under section 804. A person may file an application under 505(b)(1) if it contains full reports of investigations of safety of effectiveness that the applicant owns or has a right of reference to use. Alternatively, a person may file a 505(b)(2) application where there is no right of reference, relying on another application for at least some of the information required for approval. A person may also file an ANDA under section 505(j) for a drug product that is a duplicate of a previously approved drug product.

Any filing under section 505(b)(2) or 505(j) for a drug imported under the proposed rule would be subject to patent certification and exclusivity provisions that govern approvals under those sections.³⁵

³³ Changes to an Approved NDA or ANDA Guidance at 24–26; FDA, Draft Guidance for Industry: Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (Dec. 2019), at 3–6.

³⁴ See *infra* Section V.R (supporting differentiating statements in the labeling).

³⁵ See *infra* Section V.C (recommending that eligible prescription drugs exclude drugs with existing exclusivities and patents). See, e.g., *Barr Labs., Inc., v. Thompson*, 238 F.Supp.2d 236, 239–41 (D.D.C. 2002) (explaining how FDA can tentatively approve, but not finally approve, an ANDA prior to the

- b) The proposed rule would permit misbranded drugs to be imported into the United States.

As FDA has noted, “[a]ccurate and complete information is vital to the safe use of drugs.”³⁶ FDA’s misbranding provisions ensure that manufacturers provide patients and providers with truthful and nonmisleading information about prescription drugs, including information about the drug’s effectiveness, side effects, and when a drug’s use should be avoided.

A drug is misbranded if its labeling is false or misleading in any particular.³⁷ A product’s labeling can be misleading when it “fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article” under the article’s conditions of use.³⁸ FDA has interpreted material facts to be those that would “influence reasonable consumers . . . about a product,”³⁹ such as information that influences a person’s understanding of the properties of a product, whether or not the product is appropriate, and whether a person would be willing to accept the risks associated with use of the product.⁴⁰

Labeling the drugs contemplated to be imported under FDA’s proposed rule with the FDA-approved labeling for the FDA-approved product would be false. Unapproved drugs cannot be labeled as approved, and drugs imported under the proposed scheme would be unapproved. FDA’s reliance on attestation to ensure that drugs would be “approved” is inappropriate because, as we discuss in Section III.B.1, a manufacturer cannot attest that a drug that has left its control meets the conditions in an approved application. Importers distributing FDA-approved labeling for drugs imported under the proposed rule would be distributing false information about the approval status of their drugs.

Even if drugs imported under the proposed rule were approved, the labeling for the imported drug would still be misleading because the labeling could lead a consumer to mistakenly

expiration date of a patent that claims the drug or use that is the subject of an ANDA); *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 762 (D.D.C. 2010) (discussing how the FDCA’s exclusivity provisions protect innovative drugs from competition by generic drugs for the specified terms by preventing submission of applications that refer to them).

³⁶ FDA, CDER: The Consumer Watchdog for Safe and Effective Drugs, <https://www.fda.gov/drugs/drug-information-consumers/cder-consumer-watchdog-safe-and-effective-drugs> (current as of May 4, 2016).

³⁷ FDCA § 502(a) (deeming a drug misbranded if “its labeling is false or misleading in any particular”).

³⁸ FDCA § 201(n).

³⁹ FDA, Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009), at 12.

⁴⁰ *Id.*

attribute the drug to the drug's manufacturer.⁴¹ Although the labeling would indicate that the drug was imported from Canada under the section 804 importation program, this phrase would not cure consumer confusion due to seeing the proprietary name, trade dress, and name of the manufacturer on the product. The use of the same labeling, including manufacturer trademarks, on drugs imported pursuant to the proposed rule would lead consumers to believe that the drug would have the same assurances associated with the prescription drug manufactured, tested, and distributed by the manufacturer. Adverse consequences resulting from improper storage, testing, or processing would be material to consumers, particularly if any of these drugs would be used to treat vulnerable populations such as children and the elderly. A consumer theoretically could find more information about the drug by going to the SIP website, but reasonable consumers would not think that a product labeled with the manufacturer's name and having the manufacturer's trademark might actually not be overseen and distributed by the manufacturer.

- c) The proposed rule increases the potential for adulterated drugs to enter the U.S.

The proposed rule would increase the potential for adulterated drugs to enter the U.S. It shifts manufacturing, such as relabeling and repackaging, from inspected facilities to uninspected facilities, loosens the restrictions on the drug supply chain, increases the number of entities that are in the supply chain and involved in testing product, and impedes the ability for entities to detect potentially adulterated drugs through new and different requirements that apply to drugs imported under the proposed rule. In fact, HHS has acknowledged that "the opportunities for adulteration increase as the distribution chain and number of entities handling the products increase."⁴² Further, FDA admits that "allowing repackaging that breaches the immediate container closure system introduces unnecessary risk of adulteration, degradation, and fraud for drugs subject to a SIP."⁴³ PhRMA agrees that repackaging introduces additional risk, but as we discuss in Section I.B.3, other manufacturing activities, such as relabeling, could also affect the closure system to increase risks of adulteration, degradation, and fraud.

Section 501(a)(2)(B) of the FDCA states that a drug is adulterated unless it is manufactured and held in conformance with cGMP. As HHS indicated in the HHS Task Force Report, "there is no way to assure that [drugs imported under section 804] have been appropriately stored,

⁴¹ As discussed below, the proposed rule defines manufacturer to mean an applicant, a person who owns or operates an establishment that manufactures an eligible prescription drug, or a holder of a drug master file ("DMF") containing information necessary to authenticate an eligible prescription drug. FDA should define the manufacturer to be solely the holder of the NDA or ANDA for the relevant FDA-approved product and clarify what roles and responsibilities contract manufacturers and DMF-holders would have under the proposed rule.

⁴² HHS Task Force Report at 30.

⁴³ 84 Fed. Reg. at 70819.

processed, and packaged.”⁴⁴ Although testing helps, “no testing scheme is foolproof.”⁴⁵ Registration with FDA is insufficient to ensure that Foreign Sellers, Importers, Repackagers, Relabelers, and Testing Laboratories test and hold prescription drugs in compliance with cGMP and otherwise met their obligations under the proposed rule. FDA must inspect these entities before allowing them to participate in any importation program, but even inspection alone would not be enough to ensure compliance with cGMP because manufacturers would no longer have oversight to confirm cGMP compliance contemplated for importation under the proposed rule.

3. *FDA’s proposed importation scheme would introduce consumer confusion and could lead to increased medication errors.*

The disruption of FDA’s regulatory regime and the U.S. pharmaceutical supply chain would introduce significant confusion to consumers. FDA proposes that a drug imported under section 804 be labeled with FDA-approved labeling, including the proprietary name of the FDA-approved product, the name of the drug manufacturer, the name of the Importer, and a statement that the drug was distributed under a SIP. FDA admits that product labeling could lead to potential confusion between products with the same name.⁴⁶ It is likely, for example, that consumers may not understand the distinction between drugs imported under section 804 and other drugs distributed with the same name. If a patient taking a drug experiences an adverse event, a patient, caregiver, or healthcare professional may be confused about whether to contact the SIP sponsor, the Importer, or the manufacturer of the drug. This confusion could lead to delays or gaps in reporting when patients experience adverse events.

The proposed rule does not address other areas of consumer confusion that could lead to medication risk and error. The proposed rule prohibits Importers from fully repackaging an imported drug, arguing that “taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container” would breach the immediate container closure system and introduce additional risk.⁴⁷ PhRMA agrees that repackaging would introduce additional risk; relabeling and repackaging are intertwined and both need to be in compliance with cGMP. Immediate container closure systems, such as blister packs, often have labeling on the closure system that differs between countries (e.g., French wording, different barcodes, etc.). It may not be possible to relabel a product (e.g., a blister pack) without affecting the closure system, such as by changing the thickness of the blister pack. Failure to relabel immediate-container closure systems could lead to consumer confusion or medication errors, but relabeling could breach or otherwise damage the immediate container system.

⁴⁴ HHS Task Force Report at 29.

⁴⁵ *Id.* at 30.

⁴⁶ 84 Fed. Reg. at 70819.

⁴⁷ *Id.* at 70819.

4. *FDA's proposed importation scheme would allow unscrupulous actors to take advantage of the consumer confusion around imported drugs.*

The same unscrupulous entities that use advanced technologies to deceive American consumers into personally importing counterfeit goods are likely to try to take advantage of commercial importation by capitalizing on consumer confusion about FDA's importation program.⁴⁸ As FDA notes:

These criminals frequently use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients (Refs. 19 and 20). Consumers go to these websites believing they are buying safe and effective medications, but often they are being deceived and **put at risk by individuals who put financial gain above patient safety.**

For example, Canada Drugs Ltd. ("Canada Drugs") was an internet-based pharmacy corporation located in Winnipeg, Manitoba, Canada, which purchased drugs from **questionable sources that were outside FDA's closed supply chain** (Refs. 21 and 22).⁴⁹

It is possible that these unscrupulous entities could target consumers and advertise that they are part of a state drug importation scheme so that importation of their drugs from Canada is permissible.

FDA is already struggling to educate consumers about the risks associated with online pharmacies and buying prescription drugs from countries outside the U.S. As FDA notes in a recent 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, super-potent or counterfeit."⁵⁰ These companies use sleek advertising to "give false credence to their operation."⁵¹ Whereas now, at least some consumers may understand there is no FDA-authorized importation program, opening up a closed distribution system to commercial importation of drugs from Canada would make consumers more susceptible to unknowingly importing illicit, counterfeit drugs from outside the U.S. It is likely that rogue operations will take advantage of consumer confusion to advertise that their products are "FDA-approved" as part of a Canadian importation program.

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.

⁴⁸ *Id.* at 70800.

⁴⁹ *Id.* at 70800 (emphasis added).

⁵⁰ FDA Press Release: FDA Warns CanaRx for Selling Unapproved, Misbranded, and Unsafe Imported Drugs to Unsuspecting Americans (Feb. 28, 2019).

⁵¹ *Id.*

Unsuspecting individuals may buy from these companies thinking that these products are safe, effective, and sanctioned by FDA. Legalizing commercial importation from Canada could mislead consumers, healthcare providers, pharmacists, and other healthcare entities into thinking any commercial “source” of Canadian medication is safe and part of a legally authorized program.

5. *HHS fails to demonstrate that states and other SIP entities have the capacity to ensure that drugs imported under section 804 would be safe.*

HHS should explain what States, Foreign Sellers, Importers, and other entities in a SIP proposal would need to demonstrate in terms of capacity and resources to demonstrate that they could meet all requirements under the proposed rule.

FDA proposes that States play a critical role under the proposed rule in ensuring the safety of drugs distributed under SIP programs and ensuring compliance of SIP entities. States, however, generally lack the expertise, consistency and resources to carry out the proposed rule’s responsibilities. States do not have the resources to inspect drug supply chain participants or the know-how to ensure that they are compliant with cGMP or good distribution practices. States play no role in implementing the DSCSA and do not have pharmacovigilance expertise.⁵² Yet, under the proposed rule, the SIP sponsor would be required to ensure compliance with track-and-trace requirements and post-importation pharmacovigilance, even though the States likely will not have infrastructure in place to ensure such compliance. Additionally, reliance on state participation inherently leads to variability and inconsistency in inspection, monitoring and ultimately drug safety.

Further, it is unclear how a SIP sponsor will have the capability to ensure that the drug was actually intended for sale in Canada. Products imported from Canada can pose safety risks to the American consumer because Canada’s oversight of drugs intended for export into the U.S. differs drastically from its oversight of drugs intended for Canadians and from that required for products intended for the U.S. For example, Canada does not prohibit or track the transshipment of drugs from any country into Canada and then into the U.S.⁵³ The HHS Task Force Report concluded that foreign governments are not willing or do not have the means to ensure the safety of exported products.⁵⁴ Although proposed 21 C.F.R. § 251.14(a)(2) requires the SIP sponsor to ensure that the drug was not transshipped through Canada for sale in another country, the proposed rule does not discuss how a SIP sponsor will be able to ensure

⁵² States themselves concede this point. Several states that have passed laws to allow for importation from Canada have required states to implement a program that will “ensure that the program complies with the tracking and tracing requirements . . .” Vt. Stat. Ann. Tit. 18, § 4651(a)(5); *see also* Fla. Stat. § 381.02035(3)(c) (requiring verification that Canadian suppliers “meet[] or exceed[] the federal and state track-and-trace laws and regulations.”).

⁵³ *See* Office of the United States Trade Representative, 2017 National Trade Estimate Report on Foreign Trade Barriers (2017), at 70 (noting how Canada does not inspect in-transit counterfeit goods entering Canada destined for the United States).

⁵⁴ HHS Task Force Report at XI.

that products entering the United States were actually intended for the Canadian market. SIP sponsors will be unable to show they can exercise sufficient oversight of the SIP, and FDA cannot provide adequate regulatory oversight of the drugs in Canada that are intended for export given that Canada's oversight role will be minimal.

Likewise, the responsibilities of the Foreign Seller and Importer under the proposed rule are new and much greater than the responsibilities of a typical state-licensed wholesale distributor or pharmacy. For example, many products in the market today must be maintained at a certain temperature. The rule does not discuss how Importers or other SIP entities will trace section 804 products throughout the supply chain to ensure the management and control of validated temperatures to prevent excursions. Additionally, as with states, Importers and Foreign Sellers will lack the expertise and operational capacity to carry out pharmacovigilance responsibilities, including determining whether the adverse events are serious and unexpected. Importers have no experience with or infrastructure for reporting adverse events to FDA or following-up on adverse event reports to receive more information.

Compounding these risks to patient safety is the proposed rule's 90-calendar day timeline given to the Importer within which to submit expected or non-serious adverse events that it may receive from patients.⁵⁵ The Importer could wrongly designate an adverse event as expected or non-serious, and FDA and the application holder would not be able to address the serious and unexpected adverse event for at least 90 calendar days. It is unclear how an application holder would be able to address with the necessary expediency adverse event data about its products (eventually) received from multiple sources in the face of these delays. HHS has not indicated how it will ensure that entities importing foreign drugs will have the capability to ensure that the drugs they import are safe or to timely report adverse events.

Given these limitations, SIP sponsors and Importers are likely to be overwhelmed by their responsibilities in the proposed rule. For example, FDA proposes that the testing and relabeling of a shipment, as described in the Section 804 Pre-Import Request, take place after the shipment has arrived in the U.S., but before it can be distributed in the U.S. SIP sponsors and Importers likely will struggle to ensure the testing and relabeling are done safely. In addition, if the Importer intends to place the product into further transactions in commerce, relabeling by the Importer would also need to include placing or affixing a product identifier that is tied to the section 804 serial identifier ("SSI") that the Foreign Seller assigned to the product before it sent that product to the Importer. Tying the SSI to product identifiers supports a secure supply chain but is a burdensome, manual process that an Importer would struggle to effectively and reproducibly conduct.

6. *The proposed rule undermines the protections established under the DSCSA and creates holes in the U.S. closed-drug distribution system.*

The proposed rule would exempt products imported under it from key provisions of the DSCSA – creating holes in the very framework it relies on to support the supposed safety certification of its proposed rule – and thus posing an additional risk to the public's health and safety. The importation proposal creates a separate segment of the U.S. supply chain specifically for

⁵⁵ 84 Fed. Reg. at 70837 (proposed 21 C.F.R. § 251.18(d)(5)).

imported drugs that dangerously deviates from the existing domestic supply chain. The proposed rule's alternatives cannot substitute for the DSCSA's requirements. We provide a few examples of these deficiencies below:

- There is no product identifier affixed to the drug product during the transaction between the manufacturer and the Foreign Seller and the transaction between the Foreign Seller and the Importer.⁵⁶ Changing the identification number to a product identifier after the drug product has already been through two transactions can lead to difficulties for healthcare entities trying to reconcile transaction information and potential medication/reporting errors.
- The proposed rule would require a Foreign Seller to place an SSI on each drug imported through a SIP. The SSI is inadequate to ensure identification of prescription drugs, and the proposed rule poorly describes the SSI. Although the proposed rule indicates that an SSI must be “unique,” nothing in the proposed rule would ensure that an SSI would not be duplicated between Foreign Sellers. Further, the proposed rule does not require the SSI to include a serial number of the manufacturer, meaning that unlike a product identifier, the SSI itself could not trace a product back to any manufacturer.⁵⁷
- The proposed rule could lead to substantial confusion in the U.S. supply chain regarding verification of the imported products. Products imported under the proposed rule will not include all information related to the transaction history, transaction information, and a transaction statement for prescription drugs. This missing information may lead to confusion from entities downstream from the Importer about whether section 804 products are suspect or illegitimate.
- It is unclear what a Foreign Seller would do with suspect product. The NPRM does not account for differences in how Canadian companies detect illegitimate and suspect products and has no recordkeeping requirement relating to suspect products. Although Canadian regulations do require reports of theft, loss, or suspicious transactions, these requirements discuss government notification but do not discuss quarantining the product or notifying other entities downstream in the supply chain. The proposed rule does not specify what should occur if an entity finds illegitimate or suspect product at any point along the supply chain. If, for example, a Foreign Seller is involved in multiple SIPs, it is unclear how discovery of illegitimate or suspect product would affect each SIP.
- As HHS has acknowledged, “the opportunities for adulteration increase as the distribution chain and number of entities handling the products increase.”⁵⁸ The increase in entities handling the products also increase the risks that counterfeit or substandard product enter the supply chain. The proposed rule does not account for the

⁵⁶ *Id.* at 70835.

⁵⁷ *See id.* at 70814.

⁵⁸ HHS Task Force Report at 30.

risks associated with adding new entities (including Repackagers and Relabelers) to the supply chain and the risks that drugs could be mishandled at each step of the chain.

- It is not clear if a wholesale distributor could return imported product and, if so, how the Foreign Seller/Importer would be required to handle those returns.

Entities with roles under both the importation proposal and the traditional supply chain (i.e., manufacturers and wholesale distributors) would face complications in maintaining two supply chains, especially given that the requirements and considerations for the importation proposal are distinct from their obligations under the DSCSA. For example:

- A company operating as an Importer under the proposed rule would be a wholesale distributor or pharmacist under the DSCSA.⁵⁹ Neither wholesale distributors nor pharmacists are obligated to affix/imprint product identifiers under the DSCSA, however, because this requirement is solely the responsibility of the manufacturer or repackager.⁶⁰ The importation proposal would require wholesale distributors and pharmacists to do so in their capacity as Importers.⁶¹ This obligation will present a significant challenge for wholesale distributors and pharmacists due to their lack of familiarity with the technical requirements for product identifiers under the DSCSA. Indeed, when Congress passed the DSCSA, it gave manufacturers a four-year period to comply with the product identifier requirement.⁶² FDA then delayed enforcement of the product identifier requirement by one year.⁶³ Having wholesale distributors and pharmacists carry out this task introduces additional risk to the supply chain that precludes certification.
- The importation proposal also requires an Importer to “have processes in place to, upon receipt of a drug and records from a Foreign Seller, compare such information with information the Importer received from the manufacturer, including relevant documentation about the transaction that the manufacturer provided to the Foreign Seller upon its transfer of ownership of the product for the Canadian market.”⁶⁴ The DSCSA contains no such requirement because product documentation accompanies the product each step of the supply chain. The comparison contemplated by the importation proposal would involve reconciling information from incongruous documentation, which will likely be burdensome and difficult to automate. This comparison process could

⁵⁹ 84 Fed. Reg. at 70803.

⁶⁰ FDCA § 582(b)(2).

⁶¹ 84 Fed. Reg. at 70812.

⁶² FDCA § 582(b)(2).

⁶³ FDA, Guidance for Industry: Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy (Sept. 2018).

⁶⁴ 84 Fed. Reg. at 70835.

introduce gaps in information, and the time-consuming nature of the process could lead to drugs being introduced that are closer to the date of expiration.

The proposed rule would undo progress made to secure the supply chain and should prevent HHS from certifying that importation would pose no additional risk. As in 2004, when the HHS Task Force considered section 804 importation, the U.S. supply chain is not sufficient to ensure the safety and quality of drugs contemplated for importation under section 804. The proposed rule points to the “maturation” of supply chain security as a key reason why an importation proposal can now proceed. The premise of this claim—that the U.S. supply chain is already sophisticated and well-equipped in terms of implementing security measures—both overstates the current status of DSCSA implementation and is a reason why it should not be diluted by the proposed importation scheme.

DSCSA implementation continues to be a challenge, and FDA’s efforts on the DSCSA continue to be a work in progress. Several of the guidances mandated by Congress have been issued after their statutory deadlines. As another example, the Agency has not issued even a proposed rule outlining national standards for wholesale distributors, even though it was obligated to issue a regulation within two years of the DSCSA’s enactment (i.e., by November 2015). Certain DSCSA requirements will sunset in 2023 to make way for the second phase of the statute’s implementation, which will involve the “interoperable, electronic tracking of product at the package level.” This new second phase of DSCSA implementation leaves open many questions about what will be required for U.S. supply chain security and what will be needed for successful implementation.

Moreover, the imported product would likely move through entities, such as Foreign Sellers, which likely have not been subject to DSCSA requirements. That is one of the reasons why limiting the supply chain to three entities does not sufficiently address the gaps in the DSCSA. These entities would not necessarily benefit from the progress to date in implementing the DSCSA. These entities would need to implement new processes to comply with FDA’s supply chain requirements, processes which have taken years for currently regulated entities to come into compliance. Further modifying and exempting provisions of DSCSA only weakens the overall purpose of the act.

History shows the consequences of removing the DSCSA’s protections. Before the DSCSA, thousands of small wholesalers bought and sold drugs in a virtually unregulated secondary market. Large numbers of counterfeit drugs entered the pharmaceutical supply chain through a secondary market, where drugs were bought and sold by distributors.⁶⁵ This secondary market was due in large part to lenient state licensing standards which left “a patchwork of inconsistent

⁶⁵ See Adam Fein and Dirk Rodgers, *State Drug Importation Laws Undermine the Process that Keeps Our Supply Chain Safe*, StatNews (July 11, 2019). In many cases, unscrupulous distributors have exploited the legitimate supply chain to tamper with opioid medications and fuel the opioid epidemic. See FDA Press Release: Statement from FDA Commissioner Scott Gottlieb, M.D., on Ongoing Efforts to Stop the Spread of Illicit Opioids, Further Secure the U.S. Drug Supply Chain and Forcefully Confront Opioid Epidemic (Feb. 12, 2019).

standards across the country. Unscrupulous distributors can exploit the lowest standards of some States to insert counterfeit or adulterated product in the legitimate supply chain.”⁶⁶ One state, for example, changed its prescription drug distribution rules after reports described how counterfeits entered the U.S. market when “criminals exploited buyers in a then-vibrant secondary market.”⁶⁷ By opening the U.S. distribution system back up to drugs lacking DSCSA and other protections, the proposed rule essentially guarantees that history will repeat itself.

C. FDA’s proposed scheme would fail to significantly reduce costs of the covered product for American consumers.

HHS cannot certify under section 804(l) until it can make the factual findings on cost savings, as required under section 804(l). Section 804(l) requires HHS to make a factual finding that section 804 will result in a significant reduction in cost of covered products to the American consumer for the imported product. HHS cannot punt this required fact-finding to states in the future and HHS cannot point to the punt as an excuse not to estimate costs prior to certification.

HHS admits throughout the proposed rule that it is unable to determine whether the proposed rule will result in a significant reduction in cost of covered products for the American consumer. HHS’s admission is not just a procedural defect; it is fatal to a rule that requires a finding of cost savings for purposes of certification. FDA states, “[a]s we lack information about the expected scale or scope of such programs, we are unable to estimate how they may affect U.S. markets for prescription drugs. In particular, we are unable to estimate the volume or value of drugs that may be imported under the SIPs or the savings to U.S. consumers who may participate in such programs.”⁶⁸ Likewise, a table chart on the summaries of costs and benefits of the proposed rule is blank. Instead of providing a quantitative assessment of the costs of the proposed rule, HHS explains that it lacks information to “estimate the present and annualized values of the costs and cost savings of the proposed rule over an infinite time horizon.”⁶⁹

The proposed rule acknowledges that HHS has not even determined which factors should be considered in determining whether a reduction in the cost of covered products is significant.⁷⁰

⁶⁶ H.R. Doc. No. 109-227, at 2.

⁶⁷ Adam Fein, *supra* note 65; *see also* Katherine Eban, *Dangerous Doses: A True Story of Cops, Counterfeiters, and the Contamination of America’s Drug Supply* (2006).

⁶⁸ 84 Fed. Reg. at 70798.

⁶⁹ *Id.* at 70823. Exacerbating this deficiency, HHS leaves open questions that must be addressed, and that are fully within its purview to address, in order to properly assess the cost or cost savings of this proposal. For example, FDA specifically notes that the proposed rule “is not intended to address the applicability of the Medicaid drug rebate program for drugs under a SIP, which may be addressed in further guidance or rulemaking from HHS as appropriate.” *Id.* at 70801. Clarity on this issue is essential to an accurate assessment of the proposed rule’s impact.

⁷⁰ *Id.* at 70807 (asking for comment on “the factors that should be considered in determining whether a reduction in the cost of covered products is significant.”).

Consistent with section 804, and described further in Section V.F, cost savings calculations must be based on only out-of-pocket costs and not on indirect cost savings to consumers through other routes. And there are other critical questions that HHS will need to consider before it can make a cost-savings finding. For example, it is unclear whether insurers would cover imported drugs and whether these drugs would be subject to the same cost sharing requirements.⁷¹ HHS cannot conclude that the proposed rule will result in a significant reduction in the cost of covered products to the consumer when it has not even addressed the factors it needs to consider to make such a finding, much less actually applied such factors to a factual record.

II. HHS’s Proposed Certification and FDA’s Proposed Rule Would Exceed Their Authorities Under the FDCA and Other Federal Laws.

Section 804 creates a framework under which the entire section does not “become effective” unless the Secretary makes two findings: that implementation of all of section 804 will (1) pose no additional risk to the public’s health and safety and (2) will result in a significant reduction in the cost of covered products to the American consumer. Once HHS effectuates section 804, any importation program must comply with the requirements of the section and “other applicable requirements” of the FDCA.⁷² HHS’s proposed certification and the proposed rule are inconsistent with the section 804 certification requirements, the FDCA, and other applicable federal laws.

- A. HHS’s proposed certification of temporary, limited, short-term plans under select subsections of section 804 is inconsistent with the certification requirements of section 804.

HHS’s proposed certification is inconsistent with the section 804 certification requirements. First, certification cannot be conditioned on anticipated future findings. Second, HHS proposes to certify with respect to only some section 804 subsections (e.g., commercial importation under subsections (b)-(h)) and not others (e.g., personal importation under subsection (j)) that it admits pose additional risk to the public’s health and safety, when section 804 requires that certification must be for implementation of the entire section. Third, certification must be broadly applicable and cannot be limited to specific consumers under specific plans, as FDA

⁷¹ The proposed rule would also impose a number of obligations on the Importer, Foreign Seller, and other entities involved in the SIP, the expense of which could be ultimately passed down to the consumer. Such expenses include new capital, operating, and maintenance costs associated with the drug importation paperwork requirements; costs associated with reliably recording and sharing adverse events including by SIP sponsors themselves; development of IT systems and reporting infrastructure; and new capital expenditures toward an Importer’s relabeling and repackaging requirements to begin and sustain a comprehensive relabeling and repackaging program specific to Canada drugs. Entities may also have freight, broker, storage, and other charges associated with transporting drugs through interstate commerce. *See* FDA, Preliminary Regulatory Impact Analysis, Docket No. FDA-2019-N-5711 (2019), at 13.

⁷² FDCA § 804(c)(1).

proposes HHS will do in the proposed rule. Moreover, section 804 does not allow HHS to subdelegate certification findings to third parties.

1. *Conditional certification is impermissible under section 804.*

FDA proposes that HHS will certify under section 804(l) “conditioned on each authorized SIP meeting the relevant requirements of section 804 of the FD&C Act and this rule.”⁷³ HHS’s conditional certification is impermissible. First, HHS cannot certify based on the condition that the factual findings under section 804 will be demonstrated at some indefinite future date. Instead, section 804 requires HHS to find that implementation of section 804 *will* fulfill the two certification prongs: that section 804 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. As HHS has recognized in court filings, section 804 cannot take effect until the HHS Secretary “certif[ies] to Congress that he has made these specific factual findings.”⁷⁴

HHS’s deficiencies are most visible in the proposed rule’s discussion about how section 804 would lead to cost savings to consumers. The proposed rule states that the SIP proposal would have to explain why “their program would *be expected* to result in a significant reduction in the cost of covered products to the American consumer.”⁷⁵ FDA further proposes a *post-importation* requirement that the SIP sponsor would be required to provide FDA with data and information about its SIP, including the SIP’s cost savings to the American consumer, if any.⁷⁶ Section 804 requires HHS to certify that section 804 implementation *will* result in a significant reduction in the cost of covered products. Section 804 does not provide for its implementation without this showing, yet the proposed rule allows for certification without any showing of cost savings, based on the SIP sponsor’s expectation and HHS’s post-importation review of data and information that may not actually reflect any cost savings. Under this scheme, there is no certainty that a showing of actual cost savings will ever be made. As we discuss in Section V.F, any measure of cost savings that does not go to consumers cannot be considered in the showing of actual cost savings.

Certification would also depend on safety findings which would not be available at the time of certification or even at the time that FDA approves a SIP. Each SIP proposal will contain certain information necessary for FDA to determine whether the plan would introduce additional risk to the public’s health. For example, the SIP proposal would include a compliance plan that would explain how SIP sponsors would train SIP entities to understand their compliance-related obligations and what processes and procedures are necessary for uncovering noncompliance or misconduct. Some information, including testing information to show that potentially imported

⁷³ 84 Fed. Reg. at 70803.

⁷⁴ Federal Defendants’ Motion to Dismiss Plaintiffs’ Complaint and Memorandum in Support at 10, *Vermont v. Leavitt*, 405 F.Supp.2d 466 (D. Vt. 2005).

⁷⁵ 84 Fed. Reg. at 70796 (emphasis added).

⁷⁶ *Id.* at 70797, 70803.

drugs are FDA-approved drugs, would not be available even in the SIP proposal. HHS needs this information to make certification safety findings.

HHS's certification as suggested in FDA's proposed rule would be mere tautology. HHS would be "certifying" to cost and safety findings in section 804(l), conditioned on FDA proposing to approve only SIPs that can make cost and safety findings. A contingent statute turning on contingent certification turning on contingent SIPs introduces too many unknowns. Congress could not have intended HHS to effectuate a section of the statute based on a statement without underlying factual findings. Section 804 requires HHS to make specific factual findings to issue a certification effectuating the statute, and FDA's proposed rule suggests that HHS can make no such finding when FDA issues a final rule on section 804 importation.

2. *HHS admits that implementation of section 804 is unsafe and has failed to make certification findings for all of section 804.*

Section 804(l)(1) states that section 804 becomes effective only if HHS can certify to Congress that implementation of "this section" 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. HHS fails to demonstrate through the proposed rule how implementation of all of section 804, not just sections 804(b)-(h), will meet the two required certification findings. HHS admits section 804(j) poses additional risk to the public's health and safety.⁷⁷ Certification cannot occur if HHS can certify that the two prongs are met with respect to some parts of section 804 (i.e., subsections 804(b)-(h)), but not others (i.e., subsection 804(j)). HHS cannot implement any part of section 804 if it cannot make certification findings with respect to all parts of section 804.

This interpretation is supported by the plain language of the text, case law, and HHS's prior interpretations of section 804(l). Section 804 becomes effective only if the Secretary certifies to Congress that "the implementation of *this section* will" pose no additional risk and will result in a significant reduction in cost.⁷⁸ Congress specified that certification must relate to implementation of "this section," not implementation of "certain subsections" or "of subsections (b)-(h)." In *Vermont v. Leavitt*, the district court agreed with HHS that certification findings must relate to the entirety of section 804. In doing so, the court held that interpreting section 804(l)(1) to apply to only subsections 804(b)-(h) was "a convoluted and implausible interpretation" and "is undermined by the fact that Congress used the term 'subsection' in other provisions of section [804]."⁷⁹ FDA has also concluded that the certification requirement

⁷⁷ 84 Fed. Reg. at 70800; FDA Press Release, Trump Administration Takes Historic Steps to Lower U.S. Prescription Drug Prices (Dec. 18, 2019) (discussing certification with respect to importation programs authorized by FDA for importation of certain prescription drugs approved in Canada).

⁷⁸ FDCA § 804(l)(1) (emphasis added).

⁷⁹ *Vermont v. Leavitt*, 405 F.Supp.2d 466, 475 (D. Vt. 2005). For example, section 804(l)(2) of the FDCA refers to "the regulations under *subsection (b)*." FDCA § 804(l)(2) (emphasis added). Likewise,

provides for all of section 804 so that the section “does not authorize a specific waiver for a discrete state pilot program.”⁸⁰

In the proposed rule, FDA concedes that implementation of section 804(j) will pose an “additional risk to the public’s health and safety.”⁸¹ Specifically, FDA finds that “[m]edications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers.”⁸² FDA then cites real-world examples where consumers were deceived into believing they were buying safe and effective medications when in fact, they were buying adulterated, counterfeit, and unsafe drugs from pharmacies in Canada. In many cases, “drugs promoted as being from Canada or approved by Health Canada’s HPFB” are “not actually from Canada and not approved by HPFB” and are instead illicit.⁸³ “Given these risks, and other concerns discussed in the Task Force Report,” FDA concludes, “the proposed rule, if finalized, would not implement personal importation provisions under section 804(j) of the FD&C Act.”⁸⁴

While PhRMA agrees with FDA that implementing section 804(j) would raise significant public health risks, this fact precludes any certification under 804. HHS cannot certify under section 804(l)(1) and effectuate section 804 given that it has found that personal importation under section 804(j) will pose an additional risk to the public’s health and safety.

3. *HHS must certify based on the effects of section 804 broadly, not just for Americans under particular plans.*

HHS’s proposal that certification findings be SIP-specific is impermissible under section 804. Section 804 contemplates a broad certification finding before the section can be implemented.⁸⁵

subsection (g) on suspension of importation refers to “prescription drugs being imported under subsection (b).” FDCA § 804(g) (emphasis added).

⁸⁰ *Montgomery Cty. v. Leavitt*, 445 F.Supp.2d 505, 508 (D. Md. 2006).

⁸¹ Section 804(j), if implemented, would establish a broad, personal importation scheme that is significantly more permissive of importing foreign drugs than FDA’s Personal Importation Policy, subject to enforcement discretion. See FDA, Personal Importation, <https://www.fda.gov/industry/import-basics/personal-importation#whatis> (current as of Aug. 3, 2018).

⁸² 84 Fed. Reg. at 70800.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ PhRMA believes that certification must be based on findings for American consumers broadly because certification makes section 804 effective and section 804 permits the opening of the closed U.S. drug distribution system that protects patients from counterfeit and substandard drugs. PhRMA also believes that if the requisite certification could be made as to the effects of section 804 broadly, the implementing

Under the section, HHS must find that implementation of section 804 will pose no additional risk to the public's health and safety, not just no additional risk under particular plans, and will result in a significant reduction in the cost of covered products "to the American consumer," not just for specific American consumers under particular plans.

Section 804 does not provide that certification can be based on state-specific plans for only certain state residents. The titles of the certification and termination procedures refer to one "program," and the termination procedures envision revoking certification and the effectiveness all of section 804 if the benefits of the section do not outweigh the detriment of implementation of the section. If Congress had intended for certification to be based on state-specific plans for certain state residents, Congress could have specified that the findings supporting the certification could be so limited. Instead, section 804 certification does not refer to states in any way.⁸⁶

Further, the legislative history around section 804(l) does not mention certification based on state-specific plans for certain state residents. In introducing the amendment adding section 804(l) to the Medicare Modernization Act ("MMA"), Senator Cochrane discussed how previous HHS secretaries had failed to make the two required certification findings.⁸⁷ The letters from previous HHS secretaries did not address certification under state-specific plans but discussed how HHS could not certify an open system of distribution, as contemplated by an importation scheme.⁸⁸ None of these letters made certification findings with respect to state-specific plans, or even suggested such a certification would be permissible.

HHS's interpretation departs from its prior interpretations of section 804. Historically, HHS has agreed that certification must apply broadly, not just to any temporary, limited, or short-term plan for importing prescription drugs from Canada. As FDA admits, "[p]ast analyses regarding the feasibility of implementing section 804 did not consider the possibility of implementing section 804(b) through (h) of the FD&C Act solely through plans proposed by

regulations for commercial importation could include safeguards, including requiring state involvement and limiting participation to state residents. *See* FDCA § 804(c)(3).

⁸⁶ Again, although PhRMA believes that the certification cannot be limited to findings for certain states, PhRMA does not object to state involvement if the certification findings for American consumers writ large could be made. *See* FDCA § 804(c)(3).

⁸⁷ These findings were made under a previous version of section 804 with the same certification requirement.

⁸⁸ 149 Cong. Rec. 15528–529 (2003) (statement of Sen. Cochran).

States”⁸⁹ Past analyses did not conduct state-based analyses because HHS considered certification of such plans impermissible under the statute. HHS has argued in the past:⁹⁰

There is no language in section 384(l) that authorizes or contemplates any waiver, partial certification, experiment, or other temporary, limited, or short-term program for importing prescription drugs from Canada. Section 384(l) is an explicit “all-or-nothing” provision that asks the Secretary to certify whether the law should be effective for all Americans, not just those in one particular state.

Likewise in response to a petition to approve a county’s importation program, FDA concluded that section 804 certification “does not authorize a specific waiver for a discrete state pilot.”⁹¹

Even if HHS’s new interpretation could be reconciled with the statutory text, the proposed rule must provide a basis for why section 804 should no longer be interpreted as an “all-or-nothing” provision and should be interpreted as applying to temporary, limited, short-term plans under select subsections of section 804.

4. *HHS cannot certify based on anticipated findings by third parties.*

HHS also impermissibly relies on third parties—namely, states, tribal, and other non-federal governmental entities—to make the required factual findings on its behalf. HHS’s reliance on third parties to make the certification findings is contrary to the plain language of section 804.

Section 804 requires “the Secretary” to make a certification, and only the executive identified by Congress (or perhaps a subordinate of the Secretary to whom a lawful subdelegation was made) can make certification findings. Section 804 of the FDCA does not provide any role for third parties to demonstrate that implementation of section 804 would meet the two conditions under section 804(l) following certification. Once the Secretary makes the findings under section 804, an ineffective statute becomes effective. A determination of such importance cannot be made by someone other than the Executive Branch officer to whom Congress assigned this responsibility (or perhaps a subordinate).

The proposed rule, however, would effectively subdelegate HHS’s fact-finding role to SIP sponsors. Under the proposed rule, a SIP sponsor would need to demonstrate to FDA that “importation would pose no additional risk to the public’s health and safety and would be expected to result in a significant reduction in the cost of covered products to the American

⁸⁹ 84 Fed. Reg. at 70800.

⁹⁰ Federal Defendants’ Motion to Dismiss Plaintiffs’ Complaint and Memorandum in Support at 10, *Vermont v. Leavitt*, 405 F.Supp.2d 466 (D. Vt. 2005).

⁹¹ *Montgomery Cty. v. Leavitt*, 445 F.Supp.2d at 508.

consumer.”⁹² Instead of HHS making its own cost determination and findings of fact at the time of certification, the proposed rule requires SIPs to “report their total cost savings to consumers as well as the methodology used to calculate this measure,” and cost savings calculations should rely “to the greatest extent possible” on prices paid by the intended consumer population.⁹³ These are essentially the findings that the HHS Secretary must make under section 804(l). HHS cannot subdelegate fact-finding to the states absent Congressional authorization.⁹⁴

B. FDA lacks authority to adopt certain provisions in the proposed rule.

Provisions of the proposed rule, if finalized, would impermissibly require the manufacturer to participate in importation in ways not sanctioned by the FDCA, FDA’s regulations and other statutes.⁹⁵ These provisions include proposed 21 C.F.R. § 251.16(i) (authorizing FDA to provide the Importer information contained in an NDA or ANDA), 21 C.F.R. § 251.16(b) (requiring manufacturer to supply “testing methodologies and protocols that the manufacturer has developed”), 21 C.F.R. § 251.13(a) (deeming authorization to provide labeling), 21 C.F.R. § 251.4(c)(4)(xii) (requiring manufacturer to provide attestation), 21 C.F.R. § 251.14 (requiring manufacturer to provide an Importer transaction information).

1. *FDA’s provision of the manufacturer’s trade secrets and CCI to the Importer would violate federal statutes and FDA’s own regulations.*

The FDCA and other federal statutes prohibit FDA from disclosing a manufacturer’s trade secrets and CCI submitted to the government. The FTSA makes it a federal crime for any federal employee to disclose “trade secret” information acquired during the course of governmental duties.⁹⁶ The FDCA makes disclosure of trade secrets and CCI without express written consent of the person who submitted the information a prohibited act.⁹⁷ The Freedom of Information Act (“FOIA”) exempts trade secrets and CCI from public disclosure.⁹⁸ Due to these statutes,

⁹² 84 Fed. Reg. at 70801.

⁹³ *Id.* at 70821.

⁹⁴ *See, e.g., U.S. Telecom Ass’n v. FCC*, 359 F.3d 554, 565–66 (D.C. Cir. 2004).

⁹⁵ 5 U.S.C. § 706(2)(C).

⁹⁶ 18 U.S.C. § 1905.

⁹⁷ *See* FDCA § 301(j); *see also CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1140 (D.C. Cir. 1987) (holding that trade secret in this context includes information described in FOIA’s Exemption which includes both trade secrets and CCI).

⁹⁸ 5 U.S.C. § 552(b)(4).

FDA's longstanding policy, set forth in its regulations, has been to protect against the release of information contained in an NDA or ANDA – whether it is a trade secret or CCI.⁹⁹

FDA regulations define a trade secret to include “any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities that can be said to be the end product of either innovation or substantial effort.”¹⁰⁰ Traditionally, trade secret information within NDAs and ANDAs will usually include a description of manufacturing methods, data on materials used in production of the drug, facilities and manufacturing lines used to make the drug, testing methodologies and protocols, and representative samples and summaries of the results of testing on drug samples. FDA regulations broadly define CCI as “valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.”¹⁰¹

The proposed rule would fundamentally alter FDA policy in violation of federal statutes and FDA's own regulations. As PhRMA discusses in its comments to FDA's draft guidance on importation,¹⁰² non-public details about whether a U.S.-approved product and foreign-approved product are the same – e.g., whether the release specifications and manufacturing sites for particular markets are the same – constitute trade secrets because they reveal commercially valuable elements of the manufacturing process.¹⁰³ If FDA allows imports of drugs from Canada under the proposed scheme, it would disclose proprietary information regarding the sameness of FDA-approved products to products sold in Canada. FDA's authorization of these imports would disclose that in FDA's view, the Canadian products “meet the conditions in an FDA-approved” NDA or ANDA, but for the labeling.¹⁰⁴

The proposed rule would violate federal confidentiality statutes in other, direct ways. The proposed rule indicates that in the “event that a manufacturer fails to provide information required by this proposed rule in a timely fashion, including information necessary for the Importer to conduct the Statutory Testing, authenticate the drug being tested, or confirm that

⁹⁹ 21 C.F.R. § 20.61. See also *Food Marketing Inst. v. Argus Leader Media*, 139 S.Ct. 2356, 2366 (2019) (rejecting narrow construction of CCI to require a “substantial competitive harm” requirement).

¹⁰⁰ 21 C.F.R. § 20.61(a).

¹⁰¹ 21 C.F.R. § 20.61(b).

¹⁰² PhRMA's comments to FDA's Draft Guidance on Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act, Docket No. FDA-2019-D-5743 (Feb. 21, 2020).

¹⁰³ See 21 C.F.R. § 20.61(a) (defining a trade secret as “any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product or either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.”).

¹⁰⁴ 84 Fed. Reg. at 70797.

the labeling is in compliance with the FD&C Act, FDA may provide such information to an Importer if the information is contained in the manufacturer's approved NDA or ANDA."¹⁰⁵ Under proposed 21 C.F.R. § 251.16(b), FDA would require manufacturers to disclose to Importers information that is traditionally maintained as trade secrets or CCI. And under proposed 21 C.F.R. § 251.16(i), FDA would provide that information, including testing methods, manufacturing processes, and product specifications, to the Importer if the manufacturer does not do so in a "timely fashion."¹⁰⁶

FDA must abstain from disclosing a manufacturer's trade secrets and CCI, in violation of the FDCA and other statutes as well as FDA's own regulations and policies. Section 804 does not exempt FDA from the prohibitions that bar it from releasing trade secrets or CCI.¹⁰⁷ Although section 804 includes provisions that allow a manufacturer to provide information to an Importer, section 804 does *not* allow FDA to release information to the Importer in the event that a manufacturer fails to provide the information listed under section 804(e). Instead, the FDCA contains other provisions for FDA to enforce section 804 if manufacturers do not comply with statutory requirements. FDA's provision of the manufacturer's trade secret and CCI would also raise constitutional concerns, as discussed in Section III.

2. *The proposed rule's deeming authorization is ultra vires.*

Proposed 21 C.F.R. § 251.13(a) requires a manufacturer to provide an Importer "written authorization for the Importer to use, at no cost, the FDA-approved labeling for the prescription drug. If the manufacturer fails to do so within a timely fashion, FDA may deem this authorization to have been given."¹⁰⁸

FDA should remove reference to FDA deeming authorization to have been given if the manufacturer does not provide the Importer written authorization to use FDA-approved labeling. Section 804 does not provide FDA authority to deem that the manufacturer authorized the use of its labeling. Section 804 requires the manufacturer to provide the Importer written authorization, but it does not provide any exception for an Importer to use the FDA-approved labeling without the manufacturer's written authorization. While FDA can promulgate regulations to facilitate the importation of prescription drugs, FDA would need express statutory authority to authorize the use of manufacturer labeling without the manufacturer's written authorization.

The lack of statutory authority for FDA to authorize the use of manufacturer labeling is particularly evident here because the manufacturer's labeling will include trademarks (e.g., brand names and corporate logos). By authorizing and providing a manufacturer's FDA-approved labeling to an Importer, the government would be appropriating a manufacturer's private property for the Importer's use without just compensation and without any express

¹⁰⁵ *Id.* at 70818.

¹⁰⁶ *Id.* at 70836 (proposed 21 C.F.R. § 251.16(i)).

¹⁰⁷ *See* FDCA § 804(e)(3).

¹⁰⁸ 84 Fed. Reg. at 70833 (proposed 21 C.F.R. § 251.13(a)).

statutory authorization. Such an action raises the constitutional concerns discussed in Section III.

3. *FDA has no authority to require manufacturer attestation as outlined in the proposed rule.*

Proposed 21 C.F.R. § 251.4(c)(4)(xii) requires a manufacturer to attest that but for the fact that a drug proposed for import bears Canadian labeling, the drug meets the conditions in an FDA-approved NDA or ANDA.¹⁰⁹ FDA cannot force manufacturers to provide an attestation under section 804.

Section 804(d)(1)(K) requires either an Importer or manufacturer of a prescription drug to certify that the drug is approved, not adulterated, and not misbranded, and meets all the labeling requirements under the FDCA. Section 804(d)(1)(K) does not require the manufacturer to provide information, in the form of an attestation, to the Importer to certify. In contrast, other parts of section 804 are explicit when they require manufacturers to provide information to an Importer. For example, section 804(e) allows either the Importer or the manufacturer to conduct testing on drugs for import, but if the Importer does the testing, the manufacturer has to supply information to the Importer. Likewise, section 804(h) requires a manufacturer to provide an Importer written authorization to use the approved labeling for the prescription drug. Congress knew how to require the manufacturer to supply information to an Importer to fulfill section 804 requirements, but did not do so with the 804(d)(1)(K) certification.

4. *Section 804(e) of the FDCA does not authorize FDA to require manufacturers to provide transaction information to the Importer.*

Proposed 21 C.F.R. § 251.14(b) would require the manufacturer to “provide to the Importer a copy of any transaction documents that were provided from the manufacturer to the Foreign Seller.”¹¹⁰ The preamble to the proposed rule states that manufacturers would need to provide sufficient information to the Importer about the imported drug’s movements in the pre-U.S. supply chain and “[t]o this end, this rule proposes to require, under section 804(e) of the FD&C Act, that the manufacturer provide to the Importer all relevant documentation about the transaction that it provided to the Foreign Seller, upon its transfer of ownership of the product for the Canadian market.”¹¹¹

PhRMA encourages FDA to clarify that this requirement does not stem from section 804(e), particularly because section 303(b)(6) of the FD&C Act provides for enhanced criminal penalties for failures to comply with section 804(e). Section 804(e) relates to testing, not supply chain information. Section 804(e) does not mandate a manufacturer to provide transaction information to an Importer. A manufacturer who fails to provide transaction information to an

¹⁰⁹ *Id.* at 70831 (proposed 21 C.F.R. § 251.4(c)(4)(xii)).

¹¹⁰ *Id.* at 70834 (proposed 21 C.F.R. § 251.14(b)).

¹¹¹ *Id.* at 70816-817.

Importer should not be subject to enhanced criminal penalties for failing to comply with section 804(e).

III. The Proposed Rule Forces Manufacturers¹¹² to Help Introduce Their Canadian Products in the U.S. Markets, in Violation of the Constitution and U.S. Treaty Obligations.

A. The proposed rule forces manufacturers of drugs to facilitate unauthorized sales of their own products by competitors.

Section 804(e) of the FDCA and the proposed rule require that the prescription drug manufacturer test drugs imported under section 804 or provide proprietary information, including trade secrets and CCI, needed by the Importer to conduct testing. The proposed rule would require the manufacturer to “provide an attestation to the Importer, or alternatively to FDA . . . to establish that, but for the fact that it bore the HPFB-approved labeling, the drug that the manufacturer sold to the Foreign Seller in fact met the conditions in the FDA-approved NDA or ANDA.”¹¹³ The attestation would also “need to include information needed to confirm that the labeling of the prescription drug complies with the labeling requirements” of the FDCA.¹¹⁴

In addition to the attestation, the manufacturer must provide to an Importer other information, including “the executed batch record, including the COA” for manufacturer-approved drugs. The proposed rule also requires that “the manufacturer provide to the Importer all relevant documentation about the transaction that it provided to the Foreign Seller, upon its transfer of ownership of the product for the Canadian market.”¹¹⁵ The information must also include “any testing methodologies and protocols that the manufacturer has developed that the Importer needs to conduct the Statutory Testing.”¹¹⁶ FDA recognizes that much of this information may include “proprietary test methods.”¹¹⁷ The proposed rule states that where a manufacturer fails to provide information in a timely fashion, “FDA may provide such information to an Importer if the information is contained in the manufacturer’s approved NDA or ANDA.”¹¹⁸

¹¹² As discussed below, the proposed rule defines manufacturer to mean an applicant, a person who owns or operates an establishment that manufactures an eligible prescription drug, or a holder of a drug master file (“DMF”) containing information necessary to authenticate an eligible prescription drug. FDA should define the manufacturer to be the applicant only and clarify what roles and responsibilities contract manufacturers and DMF-holders would have under the proposed rule.

¹¹³ 84 Fed. Reg. at 70818, 70831 (proposed 21 C.F.R. § 251.4(c)(4)(xii)).

¹¹⁴ *Id.* at 70818.

¹¹⁵ *Id.* at 70817.

¹¹⁶ *Id.* at 70803.

¹¹⁷ *Id.* at 70818.

¹¹⁸ *Id.*

Section 804(h) of the FDCA and the proposed rule requires that “[t]he manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.”¹¹⁹ If the manufacturer fails to do so “within a timely fashion, FDA will deem this authorization to have been given” under the proposed rule.¹²⁰ Further, the manufacturer must supply the Importer “in a timely fashion, with information needed to confirm that the labeling of the prescription drug complies with the labeling requirements” of the FDCA.¹²¹

B. The proposed rule’s requirements violate manufacturers’ First Amendment Rights.

The First Amendment to the U.S. Constitution prohibits the government from “abridging the freedom of speech[.]”¹²² The First Amendment’s protection extends to non-commercial speech and to “commercial speech.”¹²³ The manufacturer’s speech at issue would be non-commercial speech because it does “more than propose a commercial transaction.”¹²⁴ The speech that FDA proposes to force on manufacturers does not propose any transaction, so strict scrutiny would apply. The FDA cannot demonstrate that its speech-related requirements are “narrowly tailored to a compelling government interest,” and so they would necessarily fail.¹²⁵

The proposed rule would also fail to pass muster under the four-part *Central Hudson* test applied to government regulation of commercial speech. Generally, the government can regulate commercial speech to prevent the dissemination of false, misleading, or deceptive information.¹²⁶ In assessing whether the government’s regulation violates the First Amendment, courts determine: (1) “whether the expression is protected by the First Amendment[.]” and for “commercial speech to come within that provision, it at least must concern lawful activity and not be misleading[;]” (2) “whether the asserted governmental interest is substantial[;]” (3) “whether the regulation directly advances the governmental

¹¹⁹ FDCA § 804(h).

¹²⁰ 84 Fed. Reg. at 70819, 70833 (proposed 21 C.F.R. § 251.13(a)).

¹²¹ *Id.* at 70819.

¹²² U.S. Const. amend I.

¹²³ *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001).

¹²⁴ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Counsel, Inc.*, 425 U.S. 748, 762 (1976) (citation omitted).

¹²⁵ *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 680 (1994).

¹²⁶ *See Virginia State Bd. of Pharmacy*, 425 U.S. at 773.

interest asserted[;]” and (4) “whether it is not more extensive than necessary to serve that interest.”¹²⁷ The *Central Hudson* test is viewed as a form of intermediate scrutiny.

While *Central Hudson* provides the general framework for First Amendment analysis of commercial speech claims, courts may apply a different level of scrutiny or a different test in certain situations.¹²⁸ For instance, where the government has compelled commercial speech, a more demanding form of strict scrutiny may apply.¹²⁹ Similarly, where the government has compelled a subsidization of others’ speech, courts apply a form of “exacting [First Amendment] scrutiny.”¹³⁰ And where the government has restricted truthful and non-misleading commercial speech, courts may apply a heightened form of intermediate scrutiny.¹³¹

The proposed rule violates the First Amendment on at least two grounds: (1) the attestation and statutory testing requirements amount to compelled speech and a compelled subsidy; and (2) compelled authorization to use the labeling amounts to compelled speech and a compelled subsidy.

1. *Compelled attestation and provision of testing information from the manufacturer to an Importer amount to compelled speech.*

In general, the First Amendment prohibits compelled speech where “the complaining speaker’s own message was affected by the speech it was forced to accommodate.”¹³² Compelling the manufacturer to provide a false or misleading attestation would violate the First Amendment if the manufacturer has a reasonable basis to question whether the drug proposed to be imported satisfies FDA’s requirements.¹³³ Further, the compelled attestation and disclosure of testing information offend the First Amendment even if they are truthful and non-misleading because they fail to directly advance a substantial governmental interest in a manner that is not more extensive than necessary to serve that interest.

¹²⁷ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York (Central Hudson)*, 447 U.S. 557, 566 (1980).

¹²⁸ In limited circumstances, the standard applied in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), can also apply to commercial speech, but we do not believe this standard would apply here.

¹²⁹ *see Nat’l Ass’n of Mfrs. v. SEC*, 800 F.3d 518, 524 (D.C. Cir. 2015).

¹³⁰ *see Knox v. SEIU, Local 1000*, 567 U.S. 298, 310 (2012).

¹³¹ *see, e.g., United States v. Caronia*, 703 F.3d 149, 163, 165 (2d Cir. 2012) (observing that the commercial speech restrictions at issue warrant heightened scrutiny) (citing *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011)).

¹³² *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 63 (2006).

¹³³ *See generally Nat’l Ass’n of Wheat Growers v. Zeise*, 309 F.Supp.3d 842, 853 (E.D. Cal. 2018) (law requiring warnings that are “false and misleading” violates First Amendment).

Under the proposed rule, the manufacturer would be required to attest that “but for the fact that [a drug] bears the HPFB-approved labeling,” the drug “meets the conditions in the FDA-approved NDA or ANDA.”¹³⁴ In addition, the manufacturer would have to confirm that the Canadian drug was “manufactured in accordance with the specifications described in the FDA-approved drug’s NDA or ANDA” and “include the original date of manufacture or whatever date was used in calculating the labeled expiration date.”¹³⁵ The attestation would need to “confirm that the labeling of the prescription drug complies with labeling requirements” of the FDCA. Aside from the attestation, the manufacturer needs to provide the Importer with manufacturing information, such as an executed certificate of analysis and batch records.¹³⁶

The regulations do not indicate that manufacturers could refuse to provide an attestation to the Importer for any reason. Failure to provide attestation, even when the manufacturer disagrees with the content, could lead to severe penalties. FDA takes the position that failure to comply with the attestation requirements could result in civil and criminal penalties. According to FDA, a violation of a regulation promulgated under section 804 is a prohibited act under section 301(aa) of the FDCA. FDA could use its civil authorities (e.g., injunction) against a manufacturer that fails to comply with an implementing regulation of section 804(e). FDA also could invoke its general criminal authorities under section 303(a) for failures to comply with section 301(aa), such as imprisonment or a fine. In addition, enhanced criminal penalties under section 303(b)(6) for failures to comply section 804(e) are available. Under section 303(b)(6), any person who is a manufacturer or Importer of a prescription drug under section 804(b) and knowingly fails to comply with section 804(e) that is applicable to such manufacturer or Importer, respectively, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both. The potential for FDA enforcement under these provisions would loom over any manufacturer who objects or does not believe it appropriately can make the required attestation.

If the manufacturer does not provide the attestation, FDA proposes to directly provide information needed for attestation to the Importer. The proposed rule states that in the “event that a manufacturer fails to provide information required by this proposed rule . . . FDA may provide such information,” based on the information contained in the manufacturer’s approved NDA or ANDA.¹³⁷ The statement suggests that FDA could provide the information necessary for a manufacturer attestation if the manufacturer is unwilling to provide the attestation for any reason.

¹³⁴ 84 Fed. Reg. at 70831 (proposed 21 C.F.R. § 251.5(c)(4)(xii)); *see also* 84 Fed. Reg. at 70818.

¹³⁵ *Id.* at 70818. PhRMA notes that the proposed rule does not include specific provisions to ensure that expiration dates are calculated correctly. The expiration date can be affected by temperature and storage of the product, and the Importer must establish the expiration date of the imported product under those conditions.

¹³⁶ *Id.*

¹³⁷ *Id.*

Forcing manufacturers to provide false or misleading attestations would violate the First Amendment.¹³⁸ Here, the attestation itself is inherently misleading. A manufacturer cannot attest that a drug meets the conditions in an approved application unless it can confirm, among other things, that drugs are held in compliance with cGMP, which is not possible to confirm through testing alone. As we note in Section I.B.2, drugs imported under section 804 would not comply with all the conditions in an approved application. The attestation would require the manufacturer to verify a wide range of statements, which the manufacturer cannot verify. A manufacturer would likely disagree with the Importer on whether a drug meets the conditions within an NDA or ANDA. The compulsory attestation is unlikely to survive First Amendment scrutiny.

Even if manufacturers could truthfully make the required attestations, the attestation and statutory testing requirements would violate the First Amendment because FDA has not met its burden to satisfy even the *Central Hudson* test.

2. *Compelled use of manufacturer labeling amounts to compelled speech.*

Under the current plan, the implementation of section 804(h) will require manufacturers to allow Importers to use the FDA approved labeling, at no cost, and that the labeling used by the Importer must include (1) the name and place of business of the manufacturer and the Importer; (2) the product's proprietary and established name (if any); (3) a statement that "This drug was imported from Canada under the [Name of State or Other Governmental Entity and of Its Co-Sponsors, If Any] [SIP] to reduce its cost to the American consumer"; and (4) a National Drug Code specific to the imported drug.¹³⁹ It may also include the SIP website address. The labeling would include the manufacturer's trademarks.

Under the scheme, a manufacturer would be forced to engage in compelled speech by having its name, and potentially, other of its trademarks, associated with the imported product.¹⁴⁰ Individuals are accustomed to seeing a manufacturer's name and trademarks on the labels of drug products that the manufacturer has, in fact, authorized. Accordingly, without other

¹³⁸ See generally *Nat'l Ass'n of Wheat Growers*, 309 F.Supp.3d at 853 (law requiring warnings that are "false and misleading" violates First Amendment).

¹³⁹ 84 Fed. Reg. at 70819; see also *id.* at 70833 (proposed 21 C.F.R. § 251.13(b)(4)(ii), (5)) (requiring the label of the drug to include "[t]he name and place of business of the manufacturer." The container label must also include "the product's proprietary and established name . . . and the name of the manufacturer and the Importer").

¹⁴⁰ Including the manufacturer's name and marks on the label of the imported product would associate the manufacturer with the various claims also included on the label: safety, efficacy, etc. See generally *Rumsfeld*, 547 U.S. at 63 (2006) (compelled speech "resulted from the fact that the complaining speaker's own message was affected by the speech it was forced to accommodate"); *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 471 (1997) (compelled speech occurs when entities must "repeat an objectionable message out of their own mouths," "use their own property to convey an antagonistic ideological message," or regulations "require them to be . . . associated with another's message.").

clarifying labeling statements (which the proposed rule effectively forbids by not allowing a pathway for other manufacturer statements to be added), a reasonable consumer could well view inclusion of the manufacturer's name and marks on the label of an imported product as confirmation that the manufacturer is vouching for the quality of the product and the accuracy of the various statements made about safety and efficacy on the labeling, a message that the manufacturer would disagree with and not wish to communicate. Indeed, a consumer may believe the manufacturer endorses not only the health and safety claims, but the statement about how importation was conducted to reduce costs, and the importation scheme generally.

Requiring that manufacturer labeling be used for imported drugs would force a manufacturer to engage in compelled speech. The manufacturer would involuntarily associate itself with the claims made on labeling — claims with which the manufacturer would not agree.¹⁴¹

3. *Compelled use of manufacturer labeling and forced attestation amounts to compelled subsidy.*

FDA's proposed importation scheme would amount to a significant economic subsidy from the manufacturer to the Importer that would directly enable the Importer to engage in commercial speech regarding the drugs. The scheme would require the manufacturer to make available its product labeling at no charge (including its name and other trademarks), provide an attestation that the drug is FDA approved as safe and effective but for the labeling, and either conduct testing and report the results itself or disclose testing information to the Importer and Qualifying Laboratories.

A compelled subsidy is impermissible under the First Amendment unless the government can show that the compelled subsidy “serve[s] a compelling state interest that cannot be achieved through means significantly less restrictive of associational freedoms.”¹⁴² Here, FDA cannot show that this is satisfied in the context of the proposed rule. In *United Foods*, the Supreme Court invalidated a statute that mandated an assessment on handlers of mushrooms to fund advertising for generic mushrooms, in part because the brand-name mushroom growers did not wish to promote their generic competitors.¹⁴³ The Court later emphasized that “compulsory subsidies for private speech are subject to exacting First Amendment scrutiny,” even when only “mundane commercial” speech is at issue.¹⁴⁴

While there would be no direct monetary payment from the manufacturer to the Importer, the Importer would be permitted to free ride off of the manufacturer's substantial investments in

¹⁴¹ See generally *Rumsfeld*, 547 U.S. at 63 (in other cases, compelled speech “resulted from the fact that the complaining speaker's own message was affected by the speech it was forced to accommodate”); see also *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 15, 17 (1986) (plurality op.) (finding unconstitutional an “access order” that requires utility to “associate with speech with which” it “may disagree”).

¹⁴² *Janus v. AFSCME, Council 31*, 138 S. Ct. 2448, 2465 (2018) (citation omitted).

¹⁴³ *United Foods*, 533 U.S. at 405.

¹⁴⁴ *Knox*, 567 U.S. at 309–310.

developing, testing, and manufacturing the drug, including the investments made to associate the quality of the resulting product with the goodwill of the manufacturer's name and trademarks. Because the costs of developing goodwill in a new drug product are very high, a manufacturer would typically require a paid license to authorize another party's use of such name or trademarks. These considerations mean that the manufacturer would, as a practical matter, provide a significant subsidy in support of the Importer's speech. The manufacturer would be harmed because: (1) it would be supporting a message that the imported drug is equivalent in quality and other attributes to the manufacturer's drug intended for the U.S. market, a message with which manufacturers disagree; (2) it would be subsidizing economic competitors; and (3) it would lose sales by facilitating the imports.

C. Compelled disclosure of trade secrets and CCI would require payment of just compensation under the Takings Clause.¹⁴⁵

Section 804(e) and the proposed rule would constitute an unconstitutional and categorical taking of manufacturers' intellectual property. Disclosure of manufacturer trade secrets and CCI for competitor use would interfere with manufacturers' reasonable investments based on explicit guarantees in the FTSA, section 301(j), and FDA regulations. Forced disclosure for competitor use would have a significant negative economic impact on manufacturers and would harm a key right associated with their intellectual property: the right to exclude others from using the property.

The Fifth Amendment to the U.S. Constitution prohibits the government from taking private property without providing compensation: "nor shall private property be taken for public use, without just compensation."¹⁴⁶ A "regulatory taking" occurs when the government's action does not effect a permanent physical occupation of private property or entirely destroy the property's economically beneficial uses. In determining whether a regulatory taking has occurred, the courts balance the three *Penn Central* factors: (1) whether the government action interferes with "the distinct investment-backed expectations" of the property owner; (2) the economic impact of the government action; and (3) the character of the government action.¹⁴⁷ Courts may enjoin an agency action that effects a categorical taking of property from "an identifiable class" of takings victims.¹⁴⁸

In *Monsanto*, the Supreme Court held that the Takings Clause protects trade secrets and other intellectual property that a regulated party discloses to the government, where the party has a reasonable investment-backed expectation that the information protected from disclosure will

¹⁴⁵ FDA must also analyze the property implications of the proposed rule and whether these might give rise to a takings claim, as we explain in Section III.C.

¹⁴⁶ U.S. Const. amend V.

¹⁴⁷ *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

¹⁴⁸ *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 128 (1985); *Bell Atl. Tele. Cos. v. FCC*, 24 F.3d 1441, 1445 (D.C. Cir. 1994).

not be used to benefit another regulated party.¹⁴⁹ In that case, the Court addressed provisions of the Federal Insecticide, Fungicide, and Rodenticide Act that authorized EPA to use data submitted by an applicant for pesticide registration to evaluate applications submitted by *other* entities. Monsanto, which had submitted applications for registration, argued that EPA's proposed disclosure of the company's data and proposed use of these data to evaluate follow-on applications would constitute takings without just compensation.¹⁵⁰ The Supreme Court found that the data were "private property" for purposes of the Taking Clause, because the underlying state law protected them as "trade secrets."¹⁵¹ The Court then considered the case under the *Penn Central* test for regulatory takings.¹⁵² The court held that such use could amount to a taking, at least insofar as the law at the time the data was submitted provided it could not be used in such a fashion.

1. *Trade secrets and CCI in NDAs or ANDAs are private property.*

Manufacturers' trade secrets and CCI submitted under NDAs and ANDAs are private property protected by the Fifth Amendment.¹⁵³ Trade secrets consist of information that derives value from being neither generally known nor readily ascertainable by others, and that is the subject of efforts reasonably likely to maintain secrecy.¹⁵⁴ CCI consists of information that is related to commerce and is customarily and actually treated as private and provided to the government under an assurance of privacy.¹⁵⁵ FDA has acknowledged that companies have a "property right" in their trade secrets.¹⁵⁶

¹⁴⁹ *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–11 (1984).

¹⁵⁰ *Id.* at 998–999.

¹⁵¹ *Id.* at 1001–1004.

¹⁵² *Id.* at 1003–05.

¹⁵³ *See id.* at 1003–04 ("We therefore hold that to the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment."); *see also id.* at 1003 ("That intangible property rights protected by state law are deserving of the protection of the Taking Clause has long been implicit in the thinking of this Court.").

¹⁵⁴ *See* 18 U.S.C. § 1839(3).

¹⁵⁵ *Food Mktg. Inst.*, 139 S. Ct. at 2359–60 (2019) (defining CCI for purposes of Exemption 4 of the Freedom of Information Act).

¹⁵⁶ *See* 21 C.F.R. § 20.82(a) (noting FDA's discretion to disclose the Agency's records, consistent with "the property rights of persons in trade secrets," among other factors).

2. *The Penn Central factors confirm that forced use of trade secrets and CCI by competitors would amount to a taking requiring just compensation.*

The proposed rule violates the Takings Clause by allowing competitors to use manufacturer proprietary trade secrets and CCI. FDA's proposed disclosure of confidential information, if the manufacturer does not disclose in a timely fashion, would result in the same use of the protected data that would suffice for a taking.

- a) Manufacturers have a reasonable, investment-backed expectation in the confidentiality of trade secrets and CCI.

Manufacturers have a reasonable investment-backed expectation in the confidentiality of trade secrets and CCI within a drug application. The *Monsanto* Court explained that disclosure of such data, or allowing others to use it, could amount to a taking if reasonable investment-backed expectations were frustrated:

With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitute a trade secret are disclosed to others, *or others are allowed to use those data*, the holder of the trade secret has lost his property interest in the data. That the data retain usefulness for Monsanto even after they are disclosed . . . is irrelevant to the determination of the economic impact of the EPA action on Monsanto's property right. The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.¹⁵⁷

Manufacturers submit trade secret data and CCI as part of an NDA or ANDA under the reasonable expectation that the government would not use the data to benefit a competitor of the applicant. Based on the FTSA, section 301(j), FDA's regulations, and decades of agency policy, manufacturers have a reasonable investment-backed expectation that FDA will not disclose nonpublic information about the existence and status of their applications, as well as the content of those applications and correspondence with the agency about them. These provisions give manufacturers "explicit assurance"—of the type dispositive in *Monsanto*—that the agency is "prohibited from disclosing publicly . . . any data [or information] submitted by [them]" that is trade secret or CCI, including the information the Task Force now proposes to disclose.¹⁵⁸ These manufacturers reasonably relied on this assurance and, thus, had a reasonable, investment-backed expectation that this information would not be disclosed and used by competitors. Accordingly, at least one court has found a reasonable, investment-backed expectation based on an FDA regulation providing that "[a]ny reference to information

¹⁵⁷ *Monsanto*, 467 U.S. at 1011-1012 (emphasis added) (footnote omitted).

¹⁵⁸ *Id.* at 1011.

furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it.”¹⁵⁹

A manufacturers’ investment-backed expectations for the confidentiality of data submitted as part of an NDA or ANDA remained reasonable for data generated after section 804’s enactment date. Sections 804(e) and (h), by their own terms, do not take effect unless the HHS Secretary makes the required certification to Congress.¹⁶⁰ No HHS Secretary has been willing to make the certification. The HHS Task Force Report raised significant legal and practical concerns associated with certification and noted that the impact on intellectual property rights would likely be significant, including potentially raising issues under the Takings Clause.¹⁶¹ Given these circumstances, a manufacturer retained reasonable investment-backed expectations after the enactment of section 804.

Moreover, the situation here contrasts sharply with the pre-1972 situation in *Monsanto*, where the government had “taken no position on disclosure of . . . data.”¹⁶² Section 301(j) has prohibited the release of this information since 1938, and the FTSA was enacted in 1948.¹⁶³ FDA’s policy prohibiting release of trade secrets and CCI dates to 1938, and its current regulations date to the 1970s. Thus, the government has, for over seven decades, taken a firm position on the proprietary nature of the information now proposed for disclosure.

b) The other *Penn Central* factors point to a Taking.

Manufacturers would experience substantial economic losses if they were to provide this information to their competitors. As the Supreme Court recognized in *Monsanto*, “[t]he economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.”¹⁶⁴ The proposed rule would force manufacturers to provide proprietary information about its prescription drugs for use by a competitor.

The types of trade secrets and CCI that manufacturers would need to provide is troubling. For example, the proposed rule would require manufacturers to disclose batch records. Manufacturers routinely protect batch records as highly confidential business information because they include proprietary information about how the drug is manufactured. The manufacturer would likely need to disclose other highly confidential information to Importers, such as product specifications, analytical methods for each component of the formulation,

¹⁵⁹ *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 140 (3d Cir. 1987).

¹⁶⁰ See 21 U.S.C § 384(l).

¹⁶¹ See HHS Task Force Report at 96 (“For example, the MMA’s compulsory license requirement for a drug’s U.S.-approved labeling raises Fifth Amendment takings issues, potentially requiring compensation by the U.S. government for the rights holder under the Fifth Amendment.”).

¹⁶² *Monsanto*, 467 U.S. at 1008–09.

¹⁶³ See *Chrysler Corp. v. Brown*, 441 U.S. 281, 297–300 (1979) (discussing legislative history of FTSA).

¹⁶⁴ *Monsanto*, 467 U.S. at 1012.

sampling methods, and in-process controls. Further, the proposed rule likely would involve manufacturers assisting Importers to be able to conduct the manufacturer's proprietary testing methods to third-party laboratories to help ensure their proper transfer and validation.

Because competitors would be able to freely access information about a drug and rely on manufacturer data to test their products, their testing would be essentially subsidized by manufacturer data. In this context, an Importer could obtain information in a manufacturer's NDA or ANDA and utilize them to test its own product, consistent with section 804, without incurring the time, labor, risk, or expense involved in developing the methods to test these drugs independently.

Further, this highly confidential and trade secret information might also be applicable to other existing drugs, or to future drugs. In other words, the damage to the manufacturer would not be limited to only the single drug at issue. Instead, the effect of taking this information and handing it off to Importers could cascade into multiple other drugs that might use the same confidential information or trade secrets. Although FDA proposes that Importers can only use this information within an SIP program, it provides no details about what controls Importers should impose to protect this information, how FDA can enforce these protections, or whether any controls to protect the information are even workable.

3. *The proposed rule's alternative to disclosure of proprietary information, compulsory testing, does not cure the Takings Clause violation.*

The proposed rule states that a manufacturer can avoid disclosure of its intellectual property by conducting the testing itself.¹⁶⁵ Such compulsory testing would amount to a taking because it would impose significant costs and burdens on manufacturers, while benefitting their competitors. It would deprive the manufacturer of the most significant property right in the "bundle of rights" conferred by trade secret law: the right to exclude competitors from gaining the benefit of the proprietary information.¹⁶⁶ In addition, as a practical matter, Importers and wholesalers would derive the same benefit that they would derive from stealing the trade secrets and using them to conduct the tests needed to gain permission to import drugs in competition with the manufacturer. Indeed, Importers and wholesalers would not even incur the expense of conducting the tests themselves.

That compulsory testing would not cure a takings violation draws support from the patent context. There, the Supreme Court has broadly stated that any "use[] by the government itself" of a patent amounts to a taking.¹⁶⁷ In *Horne*, the Supreme Court stated that a patent "confers

¹⁶⁵ 84 Fed. Reg. at 70818.

¹⁶⁶ See *Monsanto*, 467 U.S. at 1011 ("The right to exclude others is generally 'one of the most essential sticks in the bundle of rights that are commonly characterized as property.' With respect to a trade secret, the right to exclude others is central to the very definition of the property interest.").

¹⁶⁷ *Horne v. Dep't of Agric.*, 135 S. Ct. 2419, 2427 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)).

upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser.”¹⁶⁸ If manufacturers were forced to do testing for Importers’ benefit, the government would be using manufacturer information for the benefit of a manufacturer’s competitor without just compensation.

Even if the manufacturer itself elects to conduct the testing, the testing would need to be conducted at a Qualifying Laboratory. Nothing in the regulation indicates that the manufacturer would be allowed to select the laboratory. The fact that the Qualifying Laboratory must be approved and that the SIP sponsor must identify the Qualifying Laboratory in its SIP proposal together suggest that the manufacturer would not be able to choose the Qualifying Laboratory.¹⁶⁹ Regardless, manufacturer trade secrets and CCI would still need to be disclosed to a third party (the laboratory) and used for competitors’ purposes.

D. Manufacturer trademarks in the FDA-approved labeling are private property that manufacturers are forced to allow Importers to use at no cost.

Section 804(h) and the proposed rule provide that a manufacturer of a prescription drug shall provide an Importer written authorization for the Importer to use, at no cost, the approved labeling for the prescription drug.¹⁷⁰ The approved labeling includes the manufacturer’s trademarks. Because compulsory licenses are disfavored under trademark law, the proposed rule’s compulsory license requirement raises Takings issues under the Fifth Amendment.¹⁷¹

The proposed rule would allow an Importer to use the manufacturer’s trademarks in the labeling, such as in the product’s proprietary name and the manufacturer’s name. With limited exceptions, FDA has proposed that the labeling should be the same as FDA-approved labeling. Further, the proposed rule would grant an Importer the right to use at least the prescribing information, a Medication Guide or other patient labeling (if any), and the labels on the package and product itself. These materials will likely include one or more of the manufacturer’s trademarks, including brand names, company names, logos, 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).¹⁷²

¹⁶⁸ *Id.* at 2427 (quoting *James v. Campbell*, 104 U.S. at 358).

¹⁶⁹ FDCA § 804(a)(4); 84 Fed. Reg. at 70828, 70830 (proposed 21 C.F.R. §§ 251.2 (defining “Qualifying Laboratory”), 251.3(d)(7)).

¹⁷⁰ 84 Fed. Reg. at 70819.

¹⁷¹ *See, e.g., A & H Sportswear, Inc. v. Victoria’s Secret Stores, Inc.*, 166 F.3d 197, 208 (3d Cir. 1999) (disapproving of lower “court’s award of a royalty for future sales” stating that it “put the court in the position of imposing a license neither party had requested or negotiated”).

¹⁷² *See Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 209 (2000).

Requiring manufacturers to allow Importer use of their trademarks would violate trademark principles, to the detriment of both consumers and prescription drug manufacturers. Such a broad compulsory license conflicts with the principle that confusion should be vigilantly avoided for drug products so that potential harm to consumers may be avoided.¹⁷³ A broad compulsory license also conflicts with the disfavored status of compulsory trademark licenses. Not only would a compulsory license to use a manufacturer's trademarks conflict with precedent,¹⁷⁴ such use on a directly competing product would risk facilitating the precise harms to mark owners that trademark law seeks to prevent by allowing a competitor to both benefit from, and potentially endanger, the reputation associated with the manufacturer's trademarks.¹⁷⁵

Moreover, the broad compulsory license required under the proposed rule conflicts with the overall purpose of section 804. Section 804 is premised on the importation program posing "no additional risk to public's health and safety."¹⁷⁶ Yet, mix-ups between a U.S. drug and its foreign equivalent would run directly counter to this principle, creating an additional risk to public health and safety. For example, foreign versions of U.S. drugs could bear consequential differences, including with respect to quality due to storage and handling in the Canadian market before importation.¹⁷⁷ The distinguishing statements on imported drugs are not sufficient to prevent consumers from believing that the imported drug was sponsored or approved by the manufacturer.

The compulsory license to Importers for use of manufacturers' trademarks raises Takings issues under the Fifth Amendment. In general, courts recognize trademarks as "property" entitled to protection under the Takings Clause.¹⁷⁸ Federal law has traditionally prohibited importation of foreign merchandise if the labeling bears a trademark owned by a U.S. citizen or corporation unless the Importer produces written consent from the trademark owner at time of entry.¹⁷⁹ As HHS stated in its HHS Task Force Report, "the MMA's compulsory license requirement for a drug's U.S.-approved labeling raises Fifth Amendment takings issues, potentially requiring compensation by the U.S. government for the rights holder under the Fifth Amendment."¹⁸⁰

¹⁷³ See, e.g., *Alfacell Corp. v. Anticancer Inc.*, 71 U.S.P.Q.2d 1301, 2004 WL 1631116 (T.T.A.B. 2004); *Clifton v. Plough*, 341 F.2d 934, 936 (C.C.P.A. 1965); *Morgenstern Chem. Co. v. G.D. Searle & Co.*, 253 F.2d 390, 393 (3d Cir. 1958).

¹⁷⁴ see *A & H Sportswear*, 166 F.3d at 208.

¹⁷⁵ see *Sweetarts v. Sunline, Inc.*, 380 F.2d 923, 927 (8th Cir. 1967) ("Plaintiff has the right to make and keep its own reputation without entrusting it to others over whom it cannot exercise any control.").

¹⁷⁶ FDCA § 804(l)(1).

¹⁷⁷ See HHS Task Force Report at 15.

¹⁷⁸ See, e.g., *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) (trademarks are "constitutionally cognizable property interests," because trademark owners "can exclude others from using them").

¹⁷⁹ 19 U.S.C. § 1526.

¹⁸⁰ HHS Task Force Report at 94.

Here, FDA cannot force a manufacturer to provide authorization to allow Importer use of manufacturer trademarks “at no cost.” Under the familiar *Penn Central* takings analysis, manufacturers have reasonable, investment-backed expectations that FDA would not require compulsory licenses for trademarks. The Lanham Act and the case law around trademarks have generally prohibited compulsory licenses for trademarks. Based on these assurances, manufacturers have invested in their trademarks and their brands to build a reputation around their companies and products. As discussed in Section III.C, manufacturers’ investment-backed expectations remained reasonable even after section 804 enactment because the statutory language does not suggest that importation will involve compulsory licensing, no HHS secretary has been willing to make the certification, and HHS has also raised concerns related to the Takings Clause for compulsory licenses.

If the government required a compulsory license for trademarks, manufacturers would experience economic harm. Not only would manufacturers experience increased competition from those who benefit from the marks, manufacturers would also experience reputational damages related to associating their brand with products that manufacturers cannot vouch for. The compulsory license would damage a core component of property by taking away a manufacturer’s rights to exclude others from using its property.

E. The proposed rule is inconsistent with U.S. treaty obligations under the TRIPS Agreement.

The World Trade Organization’s (“WTO’s”) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) provides an additional reason that FDA should not force manufacturers to help their competitors import section 804 drugs. The proposed rule would violate the principles of the TRIPS Agreement by failing to adequately protect manufacturers’ intellectual property rights. The proposed rule would also be inconsistent with specific provisions within the TRIPS Agreement.

Article 39.2 prevents Members from forcing a company to disclose or allow others to use trade secrets and CCI.¹⁸¹ Article 39.3 of TRIPS imposes certain obligations on Members who require “the submission of undisclosed test or other data, the origination of which involves a considerable effort” as “a condition of approving the marketing of pharmaceutical . . . products which utilize new chemical entities.”¹⁸² Specifically, Article 39.3 states that “Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”¹⁸³ Article 39.3 also requires that Members protect this data against “unfair commercial use.” An importation scheme that forces manufacturers to publicly disclose trade secrets and CCI to

¹⁸¹ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 81 (1994) (the “TRIPS Agreement”), at Art. 39.2.

¹⁸² *Id.* at Art. 39.3.

¹⁸³ *Id.*

competitors or otherwise allows FDA to disclose trade secrets and CCI to competitors or the public would be inconsistent with United States obligations under the TRIPS Agreement. FDA's importation proposal is not based on a showing that the disclosure is "necessary to protect the public" or that steps would be taken to protect against unfair commercial use.

Compulsory licenses of manufacturer trademarks would also be inconsistent with U.S.'s obligations under the TRIPS Agreement. Article 21 states that "compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs."¹⁸⁴ As discussed in Section III.D, the proposed rule would allow an Importer to use the manufacturer's trademarks in the labeling, such as in the product's proprietary name and the manufacturer's name. Requiring manufacturers to allow Importers to use their trademarks would amount to a compulsory license and is not permitted under the TRIPS Agreement.

IV. FDA Must Withdraw the Proposed Rule and HHS Must Not Certify Section 804 Without Meaningful Notice and Comment and Adherence to Procedural Requirements.

FDA must withdraw the proposed rule not only for the reasons above, but also because it was issued without an effective statutory basis and issued without reasonable and meaningful opportunity for the public to assess and comment on any future certification by the Secretary. FDA's failure to comply with numerous procedural requirements also warrants withdrawal of the rule.

A. FDA cannot issue a proposed rule under section 804 absent certification.

Section 804 provides the Secretary and FDA with an unambiguous sequence it must follow: Section 804(l) states that section 804 "*shall become effective only if the Secretary*" makes the requisite certification to Congress.¹⁸⁵ Only after certification does the provision in section 804 come into effect that supplies FDA with the power to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."¹⁸⁶ This sequence makes practical sense. First, the Secretary would make the requisite certification to Congress that the importation would be safe and result in a significant reduction in cost. After certification, section 804 would come into effect and supply FDA with a statutory basis for regulations premised in part on this pre-existing finding. FDA could then craft regulations that are informed by the Secretary's findings and the information the Secretary relied on for certification, and provide the public with an opportunity to comment.

¹⁸⁴ *Id.* at Art. 21.

¹⁸⁵ FDCA § 804(l) (emphasis added).

¹⁸⁶ FDCA § 804(b).

However, FDA did not follow this sequence. Instead, FDA issued a proposed rule, relying on legal authority from section 804 — a section that has not yet come into effect.¹⁸⁷ FDA deferred the findings and certification necessary for section 804 to come into effect to later dates.¹⁸⁸ Still more troubling is that, by failing to provide the Secretary’s certification - or even providing a detailed factual explanation of the basis for a potential certification - before issuing this proposed rule, FDA deprived interested parties and the public of the opportunity to reasonably and meaningfully comment, as discussed in Section IV.B.

FDA thus lacked statutory authority to issue the proposed rule, and no other grant of authority exists other than section 804 that might authorize the proposed rule. Although section 701 of the FDCA authorizes FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress,¹⁸⁹ this provision does not “constitute an independent grant of authority that permits FDA to issue *any* regulation the agency determines would advance the public health.”¹⁹⁰ In other words, section 701 merely grants FDA the power to promulgate rules pursuant to the procedural requirements of the Administrative Procedure Act (“APA”) § 553.¹⁹¹ But, as discussed above, FDA acted without statutory authority by issuing its proposed rule before section 804 took effect. Because section 701 does not grant the agency an independent source of authority, it provides no justification for the agency’s decision to act in express defiance of Congress’s grant of authority.

¹⁸⁷ In fact, former Acting Commissioner Brett Giroir did not have authority to sign the proposed rule on the date of filing, making the proposed rule legally invalid. Only agency officials to whom authority is duly delegated may sign proposed rules, which is part of the reason why HHS has a detailed manual setting forth delegations to the FDA Commissioner. See FDA, FDA Staff Manual Guides, Volume II – Delegations of Authority, SMG 1410.10. Indeed, the Office of the Federal Register’s Document Drafting Handbook makes clear that “[t]he signer must be a Federal employee with the authority to take action for the agency.” Office of the Federal Register, Document Drafting Handbook (Aug. 2018, Rev. 1.1 (Aug. 9, 2019)), at 1-6, <https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf>. That requirement was not satisfied here. Brett Giroir was indeed acting Commissioner when he signed the NPRM on December 11, 2019. However, Stephen Hahn was sworn in as the Commissioner on December 17, 2019. See FDA, Stephen M. Hahn M.D., <https://www.fda.gov/about-fda/fda-organization/stephen-hahn> (current as of Feb. 20, 2020) (noting that Dr. Hahn was sworn in on December 17, 2019). The NPRM was not officially filed with the Office of the Federal register until December 18, 2019. 84 Fed. Reg. at 70839. Thus, Mr. Giroir no longer had signing authority at the time the rule was filed with the Office of the Federal Register.

¹⁸⁸ See 84 Fed. Reg. at 70798 (“FDA is also issuing this proposed rule under FDA’s rulemaking authority regarding importation of prescription drugs under section 804(b) through (h) of the FD&C Act.”).

¹⁸⁹ FDCA § 701.

¹⁹⁰ *Ass’n of Am. Physicians & Surgeons, Inc. v. FDA*, 226 F.Supp.2d at 213.

¹⁹¹ See *Nat’l Ass’n of Pharm. Mfrs. v. FDA*, 637 F.2d 877, 879 (2d Cir. 1981) (“The effect [of APA § 553] is to require that rulemaking under [section 701 of the FDCA] . . . follow an informal notice and comment procedure.”).

FDA must withdraw the proposed rule because the Secretary has not made a certification to Congress, and the proposed rule was issued with no valid statutory basis. FDA can only promulgate regulations implementing section 804 after certification, and must provide the public with an opportunity to comment on the bases for certification and any later promulgated rules.

B. FDA must provide a reasonable and meaningful opportunity for notice-and-comment as to the Secretary's certification.

Notice-and-comment brings the public into the regulatory process, allowing the government access to information that may clarify the government's assumptions and providing the government with a perspective it may not have access to. Notice-and-comment also gives potentially affected stakeholders and the public an opportunity to provide the federal government with information that may bear on the government's decisions and challenge the government's assumptions to the extent that they are incorrect or invalid. However, such a process can be successful only if potentially affected stakeholders and the public are given access to the information that the government relied on. This information may include technical studies and data upon which the agency relied.¹⁹²

FDA has not indicated that it would provide *any* opportunity for notice-and-comment as to the Secretary's future certification, much less a meaningful opportunity. Instead, FDA has proposed that such certification would occur at the same time that FDA will issue the final rule. The Secretary, however, cannot certify section 804 without giving the public access to the information the Secretary relied on as to certification and without providing a meaningful and reasonable opportunity for the public to comment. FDA should withdraw the proposed rule, place in the public record any basis the Secretary has for certification, and allow the public to comment. Failure to do so is inconsistent with the statute and the Administrative Procedure Act, because the certification is a "rule" within the meaning of the APA, and no exception to the APA's notice and comment requirement applies.¹⁹³

C. In addition to all the other reasons, FDA must withdraw its proposed rule for failing to comply with numerous procedural requirements.

Congress and presidential administrations have established important procedural requirements for proposing regulations, which are designed to ensure that agencies give due consideration to a proposed rule's impacts on other governmental entities, the economy, and individual rights, as well as to provide meaningful opportunity for input from appropriate parties. As described below, FDA failed to adhere to a number of these requirements and thus cannot assure the public or governmental and private sector stakeholders that the rule was formulated using proper data and methods. To meet its legal obligations and ensure confidence in any importation program, FDA should withdraw the proposed rule for failure to comply with the

¹⁹² See generally *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240 (2d Cir. 1977).

¹⁹³ 5 U.S.C. §§ 551(4), 553; *Milk Indus. Found. v. Glickman*, 132 F.3d 1467, 1475–76 (D.C. Cir. 1998) (secretarial finding triggering contingent legislation is "a rule implementing congressional policy").

appropriate procedural requirements and, if it persists in pursuing importation, re-propose the rule in compliance with these procedural requirements.

1. *FDA failed to describe the proposed rule’s impact on small entities.*

The Regulatory Flexibility Act (“RFA”) represents a carefully crafted scheme designed to balance the goals of federal regulations with the needs and capabilities of small businesses and other entities that may be uniquely burdened by such regulations. To that end, Congress directed federal agencies that whenever an agency undertakes certain kinds of notice-and-comment rulemaking under the Administrative Procedure Act “the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.”¹⁹⁴ Further, Congress specified that “[s]uch analysis shall describe the impact of the proposed rule on small entities[,]” and then laid out in detail the requirements for an initial regulatory flexibility analysis.¹⁹⁵ Such a regulatory flexibility analysis is designed to ensure that regulations do not place a disproportionate economic burden on small entities and businesses, and give potentially affected entities a chance to comment on the agency’s estimated burdens.

The requirements for an initial regulatory analysis under the RFA, however, are not triggered unless the head of the agency certifies that the proposed rule would have a “significant economic impact on a substantial number of small entities.”¹⁹⁶ FDA, in the proposed rule, states:

We cannot anticipate if sponsors will contract with small entities to implement their authorized SIP proposals and request comment on the impact the proposed rule may have on small entities. We also lack information to quantify the total impacts of the proposed rule. Therefore, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.¹⁹⁷

FDA cannot rely on an absence of information about whether sponsors *will* contract with small entities to find no significant impact on a substantial number of entities. Indeed, when agencies publish rules, they often must estimate the impact without certainty as to the precise extent to which small entities will be involved. Nonetheless, agencies should, and do, engage in reasoned estimation of the burdens.

Agencies’ reasoned estimation and the opportunity such estimation provides for public input are particularly important, when, as here, small entities will be involved throughout as key

¹⁹⁴ 5 U.S.C § 603(a).

¹⁹⁵ See 5 U.S.C. § 603.

¹⁹⁶ 5 U.S.C. § 605(b).

¹⁹⁷ 84 Fed. Reg. at 70822. See also FDA, Regulatory Flexibility Analysis, Docket No. FDA-2019-N-5711 (2019).

stakeholders.¹⁹⁸ For instance, small-business pharmacies would likely be burdened as Importers under SIP proposals and as entities on the front lines of handling and dispensing drugs that are imported. The proposed rule does not address this latter role for pharmacies, particularly small-business pharmacies that do not import, but will still inevitably be a critical piece of any drug importation scheme under Section 804. Such non-Importer pharmacies are still likely to fill prescriptions with imported drugs, address issues of substitutability, and advise customers as to their use.¹⁹⁹ The burdens of doing so, particularly absent guidance, are made all the more acute in the context of small-business pharmacies. Yet, the proposed rule does not account for such a role nor does it provide any explicit guidance beyond the role of pharmacies as Importers. Importantly, for the purposes of the RFA, the proposed rule assumes that because it cannot estimate the burdens, such burdens should not be taken into account. FDA should withdraw the proposed rule, and if it proceeds with the proposal, FDA should estimate how small entities, like small-business pharmacies, would likely be impacted by the proposed rule and re-propose the rule to allow for public comment. To the extent that it cannot estimate the economic impact on small entities, HHS cannot certify that section 804 implementation will result in a significant reduction in the cost of covered products to the American consumer.

2. *FDA failed to properly explain its assessment of the proposed rule's costs to state, local, and tribal governments and the private sector.*

Congress passed the Unfunded Mandates Reform Act (“UMRA”) to substantially reduce the federal government’s ability to impose unfunded mandates on businesses and state, local, and tribal governments. In that vein, Congress, through UMRA, requires that before an agency may issue a notice of proposed rulemaking “that is likely to result in promulgation of any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more . . . in any 1 year, . . . the agency shall prepare a written statement containing” information such as “a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate, including the costs and benefits to State, local, and tribal governments or the private sector.”²⁰⁰

¹⁹⁸ “According to the most recent (2016) Statistics of U.S. Businesses, at least 939 of 1,017 firms classified in the pharmaceutical preparation manufacturing industry employed fewer than 1,250 workers. We observe that at least 92% of firms in this sector qualify as small businesses, which is understated due to data limitations. Similarly, at least 95% of drug wholesalers (NAICS code 424210), or 6,542 out of 6,833 firms, fall under the threshold of 250 employees to qualify as small businesses. According to data from the 2012 SUSB survey, the most recent to include revenue information, at least 98% of pharmacies and drug stores (NAICS code 446110), or 18,490 out of 18,852 firms, fall under the revenue threshold of \$27.5 million dollars and thus qualify as small businesses.” FDA, Preliminary Regulatory Impact Analysis, Docket No. FDA-2019-N-5711 (2019), at 14–15.

¹⁹⁹ Or perhaps FDA is not envisioning such a role for small pharmacies. If so, it should clarify in the proposed rule.

²⁰⁰ 2 U.S.C. § 1532.

FDA determined that “[t]his proposed rule would not result in an expenditure in any year that meets or exceeds this amount [of \$100 million].”²⁰¹ FDA, however, did not describe how it calculated that the expenditure would not meet \$100 million so that the public could comment. Further, FDA repeatedly stated in the proposed rule that it could not estimate the costs involved in the rule, yet concluded, without supporting qualitative or quantitative data, that the cost would be less than \$100 million.²⁰²

This is troubling in light of the clear substantial investments likely required to set up SIP programs. SIP sponsors and Importers, for instance, would need significant resources to put in place the pharmacovigilance responsibilities envisioned by the proposed rule and typically taken on by manufacturers. As FDA regulations lay out, adverse event reporting alone, merely one aspect of 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.²⁰³ Another costly undertaking for SIP sponsors and Importers is the role the proposed rule sets out for these entities with respect to recalls. The SIP sponsor would similarly have to develop significant medical and scientific expertise to put in place procedures to comply with the proposed rule in this regard. For example, the SIP sponsor is tasked with determining whether a recall is necessary and if it is, taking steps to ensure that the recall is carried out effectively.²⁰⁴ Effectuating a recall, a task that would involve SIP sponsors as well as all supply chain entities, requires the ability to quickly and effectively ensure that distribution of the drug stops, any potentially affected entities are notified, appropriate communications are issued to the public, effectiveness checks, disposition of the product, and the notification of regulators.²⁰⁵ FDA should withdraw the rule and if it proceeds with importation, re-propose the rule, providing an explanation of how it was able to estimate and certify that the rule would have an impact of less than \$100 million given the substantial impact on the SIP sponsors and private sector. Also, to the extent that it cannot do so, HHS cannot certify that section 804 implementation will result in a significant reduction in the cost of covered products to the American consumer.

3. *FDA failed to provide an explanation for its determination that the proposed rule is a “significant regulatory action.”*

Executive Order 12866 (“EO 12866”) was signed with the goal of promoting a more efficient regulatory process. Among the objectives EO 12866 sets forth are “enhanc[ing] planning and coordination” with respect to federal regulations; “restor[ing] the integrity and legitimacy of regulatory review and oversight;” and “mak[ing] the process more accessible and open to the public.”²⁰⁶ To that end, under EO 12866, agencies must submit their “significant” proposed and

²⁰¹ See FDA, Unfunded Mandates Reform Act Analysis, Docket No. FDA-2019-N-5711 (2019).

²⁰² Exec. Order No. 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993).

²⁰³ See 21 C.F.R. § 318.80 (b)(2)(B).

²⁰⁴ See 84 Fed. Reg. at 70802.

²⁰⁵ See generally 21 C.F.R. § 7.42.

²⁰⁶ 58 Fed. Reg. at 51735.

final rules to the Office of Information and Regulatory Affairs (“OIRA”) for review prior to publication. EO 12866 outlines a “significant regulatory action” as one that is likely to result in a rule that may:

1. “Have an annual impact on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or;
4. Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in [Executive Order 12866].”²⁰⁷

FDA had initially identified the proposed rule as “economically significant.” This means that FDA had identified the proposed rule as meeting prong 1’s requirement of having an annual impact of \$100 million or more or adversely affecting, in a material way, the economy, a sector, public health or safety, or State, local, or tribal governments. It then changed the designation to “significant” prior to issuing the rule.²⁰⁸ FDA did not provide any information for public comment that allows the public to understand what information or analysis underpinned the agency’s change as to this determination.

FDA’s preliminary regulatory impact analysis (“PRIA”) for public comment, an analysis undertaken in connection with EO 12866,²⁰⁹ lacks critical information relevant for commenters, particularly as to costs and benefits expected from the program.²¹⁰ The PRIA lacks, for example, data to support its reclassification of the regulation from “economically significant” to “significant,” and data to show that that the regulation is indeed not “economically significant.” In addition, the EO 12866 preliminary economic analysis of impacts in the proposed rule includes a blank table where it is supposed to provide the cost-benefit analysis for all rules—economically significant or significant.²¹¹

HHS cannot certify that the section 804 implementation proposal will result in a significant reduction in the cost of covered products to the American consumer when FDA has provided no support for its determination that the annual impact on the economy is not \$100 million or more and that there would not be an adverse material effect on the economy and SIP sponsors, among others. FDA should withdraw the proposed rule. If it proceeds with the importation

²⁰⁷ *Id.* at 51739.

²⁰⁸ *See generally* HHS, Guidelines for Regulatory Impact Analysis: A Primer 1 (2016).

²⁰⁹ *See* FDA, Preliminary Regulatory Impact Analysis, Docket No. FDA-2019-N-5711 (2019).

²¹⁰ *See, e.g., id.* at 5 (providing a blank table of Summary of Benefits, Costs, and Distributional Effects of Proposed Rule).

²¹¹ 84 Fed. Reg. at 70823.

proposal, FDA should re-propose the rule to provide the basis for the change in designation and to properly evaluate the benefits, costs, and distributional effects of the proposed rule so that stakeholders may have the opportunity to comment. To the extent FDA cannot do so, HHS cannot meet its certification requirements under section 804.

4. *FDA failed to consult with other federal agencies on issues implicating their policy jurisdictions and expertise.*

In addition to increasing efficiency, EO 12866 was intended to create a regulatory system in which federal agency rulemakings are the product of a coordinated process involving the input and expertise of other federal agencies, state, local, and tribal governments, and the public.²¹² To allow the public a proper opportunity for input, FDA should have conducted a thorough process of intergovernmental coordination prior to proposing the rule.

EO 12866 creates a process by which agencies consult with one another to minimize potential conflicts, and agencies are specifically instructed to “seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities” and “provide the public with meaningful participation in the regulatory process.”²¹³ Importantly, the Order instructs that “before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation.”²¹⁴ This coordination facilitates the ability of an agency to “base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation” and to ensure that “that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency.”²¹⁵

The proposed rule will have significant impact on the policy jurisdictions of other federal agencies. For example, the proposed importation program will have major implications for international trade and, according to the HHS Task Force Report, may call into question the United States’ compliance with its obligations under international trade agreements, such as the TRIPS Agreement.²¹⁶ Opening the closed supply chain for pharmaceutical products to international suppliers may impact U.S. customs procedures and could raise national security concerns. In addition, drug importation may affect the quality of pharmaceutical treatments available and in circulation in the event of threats to the public health. FDA should have provided for meaningful inter-governmental coordination on this significant and far-reaching policy change with departments and agencies such as the State Department, International Trade

²¹² See generally Exec. Order 12866, 58 Fed. Reg. at 51735–744.

²¹³ Exec. Order 12866 at §§ 1(b)(9), 6, 58 Fed. Reg. at 51736, 51740.

²¹⁴ Exec. Order 12866 at § 6(a), 58 Fed. Reg. at 51740.

²¹⁵ Exec. Order 12866 at §§ 1(b)(7), 2(b), 58 Fed. Reg. at 51736, 51737.

²¹⁶ HHS Task Force Report at 92–93.

Administration, Customs and Border Protection (“Customs”), Department of Homeland Security (“DHS”), and Centers for Disease Control and Prevention.

Moreover, the proposed rule should have been the product of inter-agency expertise. In fact, section 804 requires FDA to consult with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection before issuing a proposed rule, and there is no indication that FDA did so.²¹⁷ FDA should have consulted other agencies, such as the Centers for Medicare & Medicaid Services (“CMS”), the HHS Office of the Assistant Secretary for Planning and Evaluation (“ASPE”), and the National Institute for Standards and Technology (“NIST”). FDA should have consulted CMS and ASPE to analyze how the proposed rule (if finalized) would be expected to function for reimbursement purposes and economic planning. Likewise, NIST has experience in developing supply chain risk management practices²¹⁸, and FDA should have drawn upon this expertise when developing the supply chain requirements in the proposed rule.²¹⁹

Inter-agency consultation is particularly important where, as here, FDA must take into account the costs of implementing the program for other entities in the Federal government. These entities include the Drug Enforcement Administration, Customs, CMS, and DHS. For example, FDA and Customs would likely have increased expenditures associated with developing and overseeing multiple importation schemes and new screening procedures to prevent counterfeit drugs from entering the market. New expenditures would include increased security measures, inspections, and education and training, and increased hiring to ensure that agencies are adequately staffed to ensure the safety of imported drugs. Expenditures should also include costs related to compensation to manufacturers for effectuating a regulatory taking of private property.

The interagency review process has the ability to identify the widespread effects of a proposed rule and facilitates the public’s opportunity to engage in regulatory planning. Because the proposed rule is not the product of meaningful coordination with other agencies, the public, including state, local, and tribal governments, does not have the opportunity to comment on the proposed rule with the benefit of the interagency review. FDA should withdraw and re-propose the rule to allow for full intergovernmental coordination and to give the public an opportunity to comment in light of the issues identified by that process.

5. *FDA failed to properly account for the proposed rule’s impact on Native American tribes.*

Executive Order 13175 (“EO 13175”) is designed to ensure that agencies “have an accountable process to ensure meaningful and timely input by tribal officials in the development of

²¹⁷ See FDCA § 804(b).

²¹⁸ See, e.g., Jon Boyens, et al., Supply Chain Risk Management Practices for Federal Information Systems and Organizations, National Institute for Standards and Technology, SP 800-161 (April 2015).

²¹⁹ 84 Fed. Reg. at 70834–835 (proposed 21 C.F.R. § 251.14).

regulatory policies that have tribal implications.”²²⁰ To that end, EO 13175 prohibits, to the extent practicable or permitted by law, agencies from promulgating regulations not required by law that have tribal implications and impose substantial direct costs on tribal governments, unless the necessary funds are provided or agency consults with tribal officials and provides a “tribal summary impact statement.”²²¹

Yet, instead of publishing a tribal summary impact statement, FDA stated that it “tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.” FDA solicits comments “from tribal officials on any potential impact on Indian Tribes from this proposed action.”²²²

The proposed rule, however, contemplates a range of very substantial, direct effects on Indian Tribes, particularly given the role that tribes could play as SIP sponsors.²²³ As SIP sponsors, tribes would be responsible for a host of activities that they currently are not engaged in, including developing detailed procedures that require experience, resources, and expertise to ensure any storage, handling, and distribution practices meet the rule’s requirements; overseeing supply chain security; ensuring that the Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, or expired; and ensuring that the Importer fulfills its responsibilities to submit adverse event, medication error, field alert, and other reports.²²⁴

Under EO 13175, such a proposal warrants significant consultation and coordination with tribes, and the provision of a tribal summary impact statement that provides, as required by EO 13175, “a description of the extent of the agency’s prior consultation with tribal officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met[;]”²²⁵ soliciting comments after the fact does not satisfy this requirement. FDA should issue a tribal summary impact statement and provide an additional opportunity for stakeholders to

²²⁰ Exec. Order No. 1317 at § 5, 65 Fed. Reg. 67249 , 67250 (Nov. 9, 2000). “Policies that have tribal implications” is defined as “regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” Exec. Order No. 13175 at § 1(a), 65 Fed. Reg. at 67249.

²²¹ Exec. Order No. 13175 at § 5(b), 65 Fed. Reg. at 67250.

²²² 84 Fed. Reg. at 70825.

²²³ *Id.* at 70828 (proposed 21 C.F.R. § 251.2 (definition of “Section 804 Importation Program Sponsor”)).

²²⁴ *Id.* at 70830.

²²⁵ Exec. Order No. 13175 at § 5(c)(2), 65 Fed. Reg. at 67250.

comment. Also, to the extent that FDA cannot estimate the costs of the proposed rule on Indian tribes, HHS cannot meet its certification requirements under section 804.

6. *FDA failed to consider the takings implications of the proposed rule.*

Executive Order 12630 (“EO 12630”) lays out a series of principles and procedures designed to ensure that agencies that engage in rulemaking that may have takings implications, do so with particular attention as to the potential property implications for individuals and businesses and whether these implications might give rise to a takings claim.²²⁶ FDA, however, did not address any takings issues or implications raised in the proposed rule. This is despite the HHS Task Force Report’s conclusion that a drug importation program would likely have takings implications.²²⁷ In other rules, agencies have explained their analysis of potential takings implications before concluding that the “takings implications assessment has been completed and concludes that [the rule] does not pose significant takings implications.”²²⁸ For example, in a Fish and Wildlife Service proposed rule about critical habitat designation, the takings discussion notes that it “does not affect land ownership.”²²⁹ FDA should have engaged in a comparable analysis of whether the rule’s requirement that manufacturers give up their property rights constitutes a taking and considered whether to nevertheless proceed. Given that FDA was on notice about the potential takings implications, and the principles laid out in EO 12630, FDA should have included a takings implications assessment when it proposed the rule; having failed to do so, FDA now must withdraw and re-propose the rule and make an explicit finding as to any takings the proposed rule implicates.

7. *FDA failed to conduct a Privacy Impact Assessment for the proposed rule’s adverse event reporting requirements.*

FDA failed to conduct a Privacy Impact Assessment of the proposed rule’s adverse event reporting provisions, as required under the E-Government Act of 2002.²³⁰ The E-Government Act mandates that federal agencies undertake a Privacy Impact Assessment before the agency develops information technology that collects or maintains personal information in “identifiable form,” or the agency initiates a new collection of information using information technology that collects identifiable information when identical questions have been asked of ten or more

²²⁶ Exec. Order No. 12630, 53 Fed. Reg. 8859, 8860 (Mar. 18, 1988).

²²⁷ See HHS Task Force Report at 94-95 (“In any case, the MMA’s requirement, under which imported drugs presumably must be relabeled to bear the U.S.-approved labeling, may preclude pharmaceutical companies from asserting copyright protections to prevent the use of the labeling or to collect damages under copyright law. However, as with trademarks, this requirement raises Fifth Amendment takings issues of ‘just compensation’ for the lost property right associated with the copyright.”).

²²⁸ Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Suwannee Moccasinshell, 84 Fed. Reg. 65325, 65339 (Nov. 27, 2019).

²²⁹ 84 Fed. Reg. at 65339.

²³⁰ See E-Government Act of 2002, Pub. Law No. 107-347, § 208(b), 116 Stat. 2899, 2921–922 (2002).

private citizens.²³¹ Information is considered identifiable when it is “any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means.”²³²

The proposed rule requires Importers to submit individual adverse event reports to FDA.²³³ While the rule specifies that patient names and addresses should not be included in the reports, the reporter name is to be included, even if the reporter is the patient.²³⁴ Thus, reports may contain sensitive and identifiable patient information. Under the proposed rule, this information must be “submitted in an electronic format that FDA can process, review, and archive, as described in [21 C.F.R.] § 314.80(g)(1).”²³⁵ FDA has not, however, specified precisely how FDA will receive, process, review, and archive the adverse event information submitted by the Importer under the proposed rule or how the current adverse event reporting system will be modified to accommodate this new collection of information. Because the proposed requirements contemplate submission of sensitive patient information by Importers—entities previously not covered by adverse event reporting requirements—FDA is required to conduct a Privacy Impact Assessment to determine, among other things, how the information will be used or stored, and to identify privacy risks.²³⁶ The Agency should withdraw the rule to allow a Privacy Impact Assessment to be conducted.

8. *FDA failed to evaluate the proposed rule’s risks to child health.*

Executive Order 13045 places certain procedural requirements on an agency engaged in an “economically significant” rulemaking under EO 12866²³⁷ that “concern[s] an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.”²³⁸ These risks include “risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest.”²³⁹ In these circumstances, the agency must prepare and make public “an evaluation of the environmental health or safety

²³¹ *Id.*

²³² *Id.* at 2923.

²³³ 84 Fed. Reg. at 70837 (proposed 21 C.F.R. § 251.18).

²³⁴ *Id.* at 70838 (proposed 21 C.F.R. § 251.18).

²³⁵ *Id.* at 70837 (proposed 21 C.F.R. § 251.18(d)(6)(i)).

²³⁶ *See* E–Government Act of 2002 at 2921–922.

²³⁷ Under Executive Order 12866, a rule is economically significant if it may “[h]ave an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.” Exec. Order No. 12866 §2(f)(1); *see also* Exec. Order No. 13045 § 2(a).

²³⁸ Exec. Order No. 13045, § 2.

²³⁹ *Id.*

effects of the planned regulation on children” and “an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.”²⁴⁰

As discussed more fully in Section IV.C, FDA changed its classification of the proposed rule from “economically significant” to “significant” without providing any supporting data for this conclusion.²⁴¹ It is vital that FDA provide data to justify this change, because the applicability of Executive Order 13045 turns on FDA’s classification of the proposed rule. Should the data show that the proposed rule is economically significant, FDA would be required to evaluate its impact on child health and safety.

Such an analysis is important considering the proposed rule’s potential to pose health risks to vulnerable pediatric populations. The proposed rule increases the potential for adulterated drugs to enter the U.S. market,²⁴² including drugs intended for children. Florida, one of the first states to release an importation plan, has included among its list of qualifying drugs for importation drugs indicated for pediatric patients, including two epilepsy drugs.²⁴³ Pediatric patients, particularly those with serious illnesses, are more vulnerable to suffering serious adverse health effects as a result of ingesting an adulterated product. Given that the level of supply chain security of an importation program is yet unknown, and pediatric medications may be among the first medications imported, the proposed rule may have significant implications for child health. For example, differences in child resistant packaging and containers between Canadian and U.S. drugs could lead to safety concerns. In light of this risk and the lack of data to support a conclusion that the rule is only “significant,” the agency should conduct an assessment of the proposed rule’s impacts on child health, including an evaluation of policy alternatives that would minimize risks.

V. HHS Should Abandon Section 804 Implementation and FDA Should Withdraw the Proposed Rule. Nevertheless, if FDA Proceeds with the Proposal, It Must Address Critical Legal and Safety Concerns.

Because of the safety, cost, and legal concerns raised for this ill-conceived path, HHS should abandon section 804 implementation and FDA should withdraw the proposed rule. If FDA nevertheless persists in moving forward with its importation proposal, PhRMA identifies critical issues highlighting the safety, cost, and legal concerns that HHS and FDA must address. We respond to FDA’s requests for questions in the proposed rule Federal Register notice in the sections below.

²⁴⁰ *Id.* at § 5.

²⁴¹ *See* Section IV.C.

²⁴² *See infra* Section I.B.2.

²⁴³ State of Florida, Canadian Prescription Drug Importation Concept Paper, at § VI.

A. FDA Request: FDA asks for comment on what elements should be included in a SIP's compliance plan.²⁴⁴

As an initial matter, PhRMA believes that each SIP and any appropriations necessary to carry out the state's obligations as a SIP sponsor must first be approved by the state legislature and signed by the state's governor (or similar authorities for tribal or territorial governments) before FDA can authorize a SIP. Establishing and then implementing a SIP takes a tremendous amount of resources as states would assume new responsibilities related to drug manufacturing and distribution that could impact the health of millions of patients. Legislative support for a SIP could reduce the possibility that a SIP receives inadequate resources from the state throughout the life of the program. Legislation to establish a SIP may also provide an additional level of oversight to ensure that state agencies are complying with federal and state regulations.

PhRMA agrees that the items listed in FDA's preamble to the proposed rule must be included in a SIP compliance plan. The listed components, however, fall short of the components typically included in manufacturers' compliance plans. Manufacturer compliance plans typically include the development of a compliance committee to develop, monitor, and oversee the SIP; a program for internal monitoring and auditing of compliance; and well-established processes for disciplinary actions for noncompliance. We note that SIPs should be fully compliant with federal laws, including laws outside of the FDCA.

Further, a SIP compliance plan currently does not include information on how SIP sponsors and entities will comply with federal and state laws related to the sale and promotion of the products they import for distribution. To the extent that SIP sponsors or entities wish to promote the SIPs or products imported under the proposed rule, they should comply with all federal laws related to manufacturer promotion of medical products.²⁴⁵ For example, SIP sponsors should ensure that any information communicated about the SIP program or about imported prescription products not be false or misleading. SIP programs should have internal promotion compliance programs to ensure that any communications with external entities do not violate federal and state laws. This includes interactions with healthcare professionals, patient advocacy organizations, and other contacts with healthcare consumers.

B. FDA Request: FDA is interested in receiving comments on what the division of responsibility between co-sponsors should be and whether there are certain arrangements that should not be permitted. FDA seeks comment on whether it could be possible for a pharmacist or wholesaler to be a SIP Sponsor without a State, tribal, or territorial government co-sponsor, while posing no additional risk to the public's health and safety.²⁴⁶

PhRMA does not believe that a pharmacist or wholesaler should be able to be both a SIP co-sponsor and an Importer within the same SIP. In the proposed approach, state governments play an important role in monitoring entities to ensure that all supply chain members comply

²⁴⁴ 84 Fed. Reg. at 70811.

²⁴⁵ See FDCA § 502; 21 C.F.R. § 314.81. *see also* FDCA § 201(m) (defining labeling).

²⁴⁶ 84 Fed. Reg. at 70801, 70802.

with FDA regulations. For the same reasons, PhRMA does not believe that a pharmacist or wholesaler should be a SIP sponsor without a government co-sponsor. The SIP sponsor will need to ensure SIP compliance with federal laws and regulations, as well as be responsible for auditing and monitoring SIP entities and overseeing SIP activities. Allowing an Importer to also be a sponsor would remove a key layer of oversight where a third-party could monitor SIP entity activities. Entities participating in SIP programs, including Importers, will be adopting new, unfamiliar responsibilities and implementing new compliance programs. They will lack the expertise and experience of manufacturers who routinely oversee pharmaceutical compliance. An additional layer of compliance and monitoring is necessary to ensure that SIP entities are appropriately complying with federal regulations and to ensure that issues can be discovered quickly. If a pharmacist or wholesaler could be both an Importer and SIP sponsor or co-sponsor, FDA would be relying on self-monitoring for compliance. Because of the increased risk of counterfeit and unlawful drugs that come through the program and because of entities' unfamiliarity with regulatory compliance programs, self-accountability is not enough to ensure that actors comply with federal laws.

- C. FDA Request: FDA seeks comment on its proposed definitions. FDA seeks comments on its product-by-product approach to determine whether a product falls into categories that pose heightened safety concerns in the context of specific SIP proposals.²⁴⁷

A number of FDA's proposed definitions are problematic. In particular, FDA should revise definitions of the following terms:

- Manufacturer: PhRMA proposes that FDA define "manufacturer" to be solely the holder of the NDA or ANDA for the relevant FDA-approved product. The types of responsibilities assigned to the "manufacturer" in the proposed rule cannot be carried out by the other entities included in the "manufacturer" definition (i.e., a person who owns or operates an establishment that manufactures an eligible prescription drug or a holder of a drug master file containing information necessary to authenticate an eligible prescription drug). For example, only the holder of the NDA or ANDA for the relevant FDA approved product could make the attestation stating that but for the fact that it bears the HPFB-approved labeling, the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA. Only the NDA or ANDA holder would be able to provide written authorization allowing an Importer to use the manufacturer's FDA-approved labeling. If a drug needs to be recalled, an NDA or ANDA holder would be best positioned to respond to a SIP entity's questions about the recall.

Defining the "manufacturer" as the holder of the NDA or ANDA for the relevant FDA-approved product would also avoid complications associated with entities other than the application holder attempting to provide the attestation. The global pharmaceutical landscape is complex, and collaboration arrangements have proliferated where drug development and commercialization roles differ by jurisdiction. It is possible, for example, that the entity developing, manufacturing, and commercializing any given drug

²⁴⁷ *Id.* at 70804.

in the U.S. could be wholly separate from the entity developing, manufacturing, or commercializing the same drug in Canada. These entities could make independent decisions about the development, manufacturing, and commercialization of their drugs. In these situations, the manufacturer selling a drug directly to a Foreign Seller in Canada would not have the information or ability to confirm that the Canadian drug is the same as the U.S. drug, but for the labeling if this were even possible.

- Eligible prescription drug: PhRMA agrees that drugs with REMS and intrathecally and intraocularly injected drugs should be excluded from the definition of an eligible prescription drugs. These drugs have known safety risks that rely on strict manufacturing and distribution controls to mitigate risks. Use of Foreign Sellers and Importers with little to no experience manufacturing, testing, and distributing drugs under tight controls would introduce gaps that could significantly increase the risks associated with such drugs.

For these same reasons, FDA should categorically exclude products identified as potentially having heightened safety concerns from the definition of an eligible prescription drugs. These drugs include drug-device combination products (e.g., auto-injectors with epinephrine, transdermal patches), inhaled drugs, modified-release drugs, sterile drugs, ophthalmic drugs, narrow therapeutic index drugs, drugs with boxed warnings, and drugs requiring special storage conditions (e.g., cold storage). As FDA notes, these “categories of products could pose potentially heightened safety concerns” that are exacerbated by inexperienced entities, such as Foreign Sellers and Importers, handling, testing, and storing these drugs.²⁴⁸ It would more be difficult to discern problems with these drugs due to their inherent complexity. Patients receiving these drugs are at heightened risk by relying on an untested foreign supply chain.

FDA likewise should categorically exclude products for which a Medication Guide is required under 21 C.F.R. § 208.24(a). By definition, such drugs present serious risks relative to their benefits, are important to health, and require certain disclosures to patients to “help prevent serious adverse effects.”²⁴⁹

In addition to these categories, PhRMA asks FDA to revise the definition of eligible prescription drug to include the following considerations:

- Drugs subject to remaining Orange Book listed patents or exclusivities. Drugs subject to remaining patents or exclusivities listed in the Orange Book must be excluded from the definition of an eligible prescription drug.²⁵⁰ As we discuss in

²⁴⁸ *Id.* at 70804.

²⁴⁹ 21 C.F.R. § 208.1(c)(1).

²⁵⁰ See FDA, Statement by FDA Commissioner Scott Gottlieb, M.D., on the Formation of a New Work Group to Develop Focused Drug Importation Policy Options to Address Access Challenges Related to Certain Sole-Source Medicines with Limited Patient Availability, but No Blocking Patents or Exclusivities

Section I.B.2, FDA should apply its well-established procedures for drug approval under the FDCA and FDA's implementing regulations to drugs imported under section 804. A person may file an application under 505(b)(1) if it contains full reports of investigations of safety of effectiveness that the applicant owns or has a right of reference to use. Alternatively, a person may file a 505(b)(2) application where there is no right of reference, relying on another application for at least some of the information required for approval. A person may also file an ANDA under section 505(j) for a drug product that is a duplicate of a previously approved drug product. The specific process and timeline laid out for the acceptance, review, and approval of 505(b)(2) or 505(j) applications are subject to listed patents and exclusivity terms.

More generally, allowing entities to import foreign versions of drugs with remaining patents or exclusivities would upend the Hatch-Waxman Act's successful balance between promoting innovation and fostering drug competition. Importing foreign versions of drugs with remaining patents or exclusivities could lower the incentives for manufacturers to innovate in certain disease areas and lower the incentives for generic manufacturers to submit ANDAs once the branded drugs' patents or exclusivities expire.

- Sole-source drugs. Any importation should be limited to sole-source drugs for which there are no remaining patents or exclusivity. As FDA has recognized in the past, the public health need for alternatives to sole-source drugs is higher than those of other drugs because sudden changes in the supply chain could lead to a shortage. As former FDA Commissioner Scott Gottlieb suggested, importation of sole-source drugs might be appropriate to “help meet near-term patient need in the U.S. until new competition is able to enter the domestic market.”²⁵¹
- Drugs that use recombinant technology. Drugs produced using recombinant technology pose heightened safety risks for the same reason that biologics do. These products are subject to special handling procedures and have the potential to cause immune system reactions and infection risks, particularly if adulterated. For these reasons, drugs produced using recombinant technologies are considered biologic drugs in Canada.²⁵²

(July 19, 2018) (stating that FDA's “ultimate goal is to seek multiple FDA-approved and marketed versions of each medically important drug for which there are no blocking patents or exclusivities”).

²⁵¹ FDA, Statement by FDA Commissioner Scott Gottlieb, M.D., on the Formation of a New Work Group to Develop Focused Drug Importation Policy Options to Address Access Challenges Related to Certain Sole-Source Medicines with Limited Patient Availability, but No Blocking Patents or Exclusivities (July 19, 2018).

²⁵² Canada Food and Drugs Act, R.S.C. 1985, c. F-27, at Schedule D.

In fact, FDA has not explained why drugs treated as biologics in Canada do not pose the same safety risks as biologics in the U.S. Canada considers biologic products to derive from living organisms or from their cells.²⁵³ In contrast, FDA does not consider a drug to be a biologic if it contains 40 amino acids or less in size, regardless of how these products are manufactured.²⁵⁴

The same safety concerns that led Congress to exclude biologics from the definition of an eligible prescription drug apply to products considered biologics in Canada. Drugs produced using recombinant technology pose heightened safety risks for the same reason that biologics do. These products are subject to special handling procedures and have the potential to cause immune system reactions and infection risks, particularly if adulterated.

- Drugs subject to postmarketing commitments and requirements. The definition of eligible prescription drug should exclude drugs subject to postmarketing commitments and requirements because importation of such drugs would interfere with subject enrollment and interpretation of results from post-marketing studies.
- Other drugs with potential heightened safety or efficacy concerns. Certain drugs can have increased risk due to the diseases they treat. For example, antimicrobial, antiviral, or oncology drugs could have a high potential for resistance or death if misbranded, adulterated or otherwise unsafe or ineffective. As with other drugs with heightened safety concerns, patients receiving these drugs could be at increased risk of serious harm by relying on an untested foreign supply chain.
- Foreign Seller: PhRMA agrees that the definition of “Foreign Seller” should be limited to wholesaler distributors. A Foreign Seller should not be a specialty pharmacy or other pharmacy that also dispenses prescription drugs. It is possible that potentially problematic online pharmacies could register as wholesalers to participate in a state-run importation SIP program. The definition of Foreign Seller should exclude entities that have not been inspected by FDA.
- Importer, Relabeler, Qualifying Laboratory: PhRMA agrees that Foreign Sellers, Importers, Relabelers, and Qualifying Laboratories must be registered with FDA before participating in a SIP program. As with the Foreign Seller, PhRMA proposes that the definitions of Importer, Relabeler, and Qualifying Laboratory exclude entities that have not been inspected by FDA.

²⁵³ See Health Canada, Biosimilar Biologic Drugs in Canada: Fact Sheet (Aug. 23, 2019).

²⁵⁴ 21 C.F.R. § 600.3(h)(6).

- D. FDA Request: FDA seeks comment on whether the rule should require additional or alternative background information and on whether the background information requirement should cover additional or alternative individuals or entities.²⁵⁵

To the extent FDA can implement section 804 through SIPs, PhRMA strongly recommends that FDA ensure that drugs imported through SIPs are not broadly distributed throughout the U.S. supply chain. The SIP proposal should identify which entities and individuals would receive section 804 imported drugs downstream from the Importer. Entities and individuals receiving imported drugs should fall within the jurisdiction of the state sponsoring each SIP. States that have passed laws providing for an importation program expressly state this as a requirement and SIPs also should as well. For example, a Florida-sponsored SIP proposal should only be able to distribute drugs imported through the SIP to Florida residents. Doing so would limit supply chain disruptions in the U.S. and ensure that states have jurisdiction to act against bad actors diverting section 804 drugs into the general U.S. market. Without such a restriction, the ability for an imported product to leave the control of the SIP creates additional risks in the supply chain and the possibility for a gray market of imported products.

FDA should also require background information for all entities identified in the SIP proposal. If the Importer intends to distribute the drug to corporate entities rather than directly to a patient, the SIP Sponsor should provide an attestation to FDA containing a complete disclosure of any past or pending civil penalties or violations, or criminal convictions or violations, of applicable state or federal laws regarding drugs or devices against downstream entities. As with attestations related to Foreign Sellers and Importers, the attestation would need to include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager. The attestation should also include a list of all disciplinary actions against each entity.

Background information for downstream entities is essential to ensuring the safety of imported drugs. Each SIP proposal depends on assumptions related to safety and costs of drugs imported under the program. Because application holders no longer have oversight over section 804 drugs, there is a greater danger that these drugs could be improperly handled further down the supply chain. There is also a chance that section 804 drugs could be diverted and provided to individuals not originally intended within SIP proposals. Because assessments of safety and cost within each SIP proposal depend on assumptions related to who would receive the drug and how they drug would be distributed, FDA should require background checks for downstream entities who would receive the drug to decrease the risks associated with the drugs and their potential introduction into a gray market.

²⁵⁵ 84 Fed. Reg. at 70806.

- E. FDA Request: FDA seeks comment on whether a SIP proposal should also be required to describe the SIP Sponsor’s plan for ensuring that the FDA-approved patient labeling is dispensed to patients with the drug.²⁵⁶

PhRMA agrees that the SIP proposal should describe the plan for ensuring that FDA-approved patient labeling is dispensed to patients. This is particularly important given that the prescribing information or package insert (“PI”) is not intended for patients and is not routinely dispensed to patients at the point of sale. FDA should consider adopting regulations akin to the Medication Guide regulations requiring Importers to provide FDA-approved patient labeling or the means to produce such patient labeling to dispensers.²⁵⁷

The product labeling dispensed to patients should be either product-specific or product-unspecific depending on labeling associated with the U.S.-marketed product. Product labeling dispensed to patients should be product-specific if the relevant U.S.-marketed product has FDA-approved patient labeling. This labeling should include additional information regarding the SIP and the disclosure statements discussed in Section V.R, including a clear statement that the product was not imported by the U.S. manufacturer and was not within its control. On the other hand, product labeling would be product-unspecific if the U.S. product does not have FDA-approved patient labeling. FDA should develop product-unspecific templates to communicate information pertaining to importation under a SIP generally or under a particular SIP.

Given the public health risks emphasized throughout the proposed rule, and the steps FDA is proposing to take to attempt to mitigate those risks, FDA should ensure that SIP sponsors and entities associated with the SIP do not communicate false or misleading information about drugs imported under section 804. The SIP proposal should contain a promotional compliance plan with policies and procedures to ensure that the SIP sponsor, Foreign Seller, and Importer communicate truthful and non-misleading information about the SIP programs and the products imported through the SIPs. FDA should implement similar promotional submission requirements to that of accelerated approval products.²⁵⁸

Sponsors and other entities marketing products under section 804 could have incentives similar to manufacturers to promote the use and uptake of products imported through their SIP program. For example, these entities could falsely claim that their testing shows that the products are cGMP-compliant. These entities will not be as experienced as manufacturers with federal regulations governing the communication of drug product information. FDA should implement similar promotional submission requirements to that of accelerated approval products.²⁵⁹ Pre-dissemination review would allow FDA to review promotional information for communication by the Sponsor, Foreign Seller, Importer, and downstream wholesalers before

²⁵⁶ *Id.*

²⁵⁷ See 21 C.F.R. § 208.24.

²⁵⁸ See generally FDCA § 506(c)(2)(B); 21 C.F.R. § 314.550; 21 C.F.R. § 601.45.

²⁵⁹ See generally FDCA § 506(c)(2)(B); 21 C.F.R. § 237 314.550; 21 C.F.R. § 601.45.

such information is disseminated. Failure to implement pre-dissemination review could increase the risk that consumers would receive false or misleading information about imported products and increase the confusion around any importation program.

F. FDA Request: FDA seeks comment on the factors that should be considered in determining whether a reduction in the cost of covered products is significant.²⁶⁰

Section 804(l) of the FDCA requires HHS to certify that implementation of section 804 “will . . . result in a significant reduction in the cost of covered products to the American consumer.”²⁶¹ Any factors HHS considers in calculating cost savings should be consistent with the statutory language.

HHS should consider only cost savings that go to consumers. In the healthcare setting, the “consumer” is the patient. Congress enacted section 804 with the clear intention that the section would not go into effect unless “patients” would realize cost savings.²⁶² Consistent with the statute, “cost” should be calculated based on an individual patient’s out-of-pocket costs. HHS should ensure that patient out-of-pocket costs go down at the individual and aggregate level. In other words, HHS should find a reduction in the out-of-pocket cost that an individual would pay for each imported drug that the individual purchases and an overall reduction in out-of-pocket costs for all drugs in an importation program.

Consideration of any measure of cost savings that does not go to patients would be inconsistent with the requirements of the statute. For example, cost savings that accrue to a healthcare provider or payer should not be calculated in the demonstration of cost savings under section 804(l). Most Americans are covered by some form of insurance that requires them to pay a share of a drug’s total cost. It would be appropriate to consider savings that lower the cost sharing that patients pay for drugs or the amounts that uninsured patients pay out of pocket. It would be inappropriate, however, to consider savings that accrue to an insurance company due to the price of imported drugs. These calculations thus should take into consideration whether insurers will reimburse for drugs imported under the proposed rule, as it affects how much actual savings will occur at the individual patient level.

HHS must not calculate how cost savings accrue to consumers in other ways, such as increasing the number of people who can be covered by a State program. Such calculations are too tenuous to directly attribute a program to savings to consumers. Moreover, the statute requires that the savings relate to the cost for covered products, and not, as HHS suggests whether implementation of section 804 would “increas[e] the availability of drugs covered by the program.”²⁶³

²⁶⁰ 84 Fed. Reg. at 70807.

²⁶¹ FDCA § 804(l)(1).

²⁶² See, e.g., 149 Cong. Rec. 15531-532 (2003) (statement of Sen. Dorgan).

²⁶³ 84 Fed. Reg. at 70807.

G. FDA Request: FDA solicits comments on the process for reviewing and prioritizing SIP proposals.²⁶⁴

The process for reviewing and approving or denying SIP proposals must provide opportunities for public notice and comment. SIP proposals will likely implicate a number of entities across the pharmaceutical supply chain. As the proposed rule notes, a SIP proposal's demonstration that each SIP meets the relevant requirements of section 804, including the section's safety and cost savings requirements, is critical to HHS's ability to certify under section 804(l) and to FDA's ability to implement the section. Receiving public comment on each proposal is essential to ensuring that FDA does not inadvertently authorize a SIP proposal that could result in increased risk to the public's health or would not result in significant cost savings to the consumer.

In particular, as a matter of the Administrative Procedure Act and principles of due process, NDA or ANDA holders listed in any SIP proposal must have an opportunity to comment on any SIP proposal before FDA makes a determination. Under the proposed rule, application holders are significantly impacted by approval of a SIP and are entitled to participate in FDA's process of review. As noted above, those impacts include potential violations of application holders' First Amendment and property rights. Accordingly, both the APA and the Due Process Clause require FDA to provide NDA and ANDA holders a meaningful opportunity to participate in the SIP approval process.²⁶⁵ Under no circumstances should SIP approval proceed before the application holder has an opportunity to seek judicial review.

Moreover, providing a meaningful opportunity for application holder input would be important for other reasons. Holders are often most knowledgeable about their prescription drugs and their distribution and could provide information to help FDA assess any assumptions and uncertainty included in SIP proposals. For example, certain drugs have increased risk due to the diseases they treat. For example, antimicrobial, antiviral, or oncology drugs could have a high potential for resistance or death if misbranded or adulterated. Allowing application holders to comment on each proposal would allow FDA to receive input on appropriate drugs throughout implementation of the SIP program and save agency resources as it corrects mistaken assumptions early in the proposal process before SIP sponsors and federal agencies have spent resources implementing an unworkable or dangerous proposal.

²⁶⁴ *Id.*

²⁶⁵ *See, e.g.*, 5 U.S.C. § 551(4) (rules include agency statements of "particular applicability"); Attorney General Manual on the APA at 13 (1947) (noting that "rules" under the APA include approvals of reorganizations by the SEC and the prescription of rates for a utility); *Buckeye Power, Inc. v. EPA*, 481 F.2d 162 (6th Cir. 1973); *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Even if a SIP approval were deemed an informal adjudication, it would have much more than "some tangential impact on other entities," *Neustar, Inc. v. FCC*, 857 F.3d 886, 895 (D.C. Cir. 2017), and so due process principles and 5 U.S.C. § 555(b) would entitle a manufacturers to participate in those proceedings, *Block v. SEC*, 50 F.3d 1078, 1085 (D.C. Cir. 1995).

H. FDA Request: FDA seeks comment on whether a Pre-Import Request would cover subsequent shipments of the eligible prescription drug identified in the Agency's grant of that request.²⁶⁶

PhRMA disagrees with FDA's proposal that a Pre-Import Request should cover subsequent shipments. PhRMA believes that each shipment is different and that a manufacturer's attestation may cover only a specific shipment, not subsequent shipments of unknown quantity. Failing to associate a Pre-Import Request with each shipment would mean that FDA would not have proof of the supply chain for subsequent shipments. Given the increased risks of counterfeiting and potential transshipments that could enter through the section 804 system, FDA should require a Pre-Import request associated with each shipment of section 804 drugs.

In the preamble to the proposed rule, FDA states that drugs refused for admission under section 804 programs should "be exported or destroyed by the Importer within 90 days of refusal."²⁶⁷ PhRMA requests that FDA instead require drugs that appear to be adulterated, misbranded, unapproved or otherwise inadmissible under section 801(a) of the FDCA be rejected for importation and be destroyed after refusing them at the Foreign Trade Zone or at the secured warehouse. Allowing an Importer to re-export a drug that did not meet the requirements for importation would introduce another opportunity for harmful and potentially counterfeit product to enter the U.S. supply chain. PhRMA agrees that a discovery of importation by an Importer of drugs that are counterfeit or in violation of the proposed rule should result in a suspension and potential termination of importation.²⁶⁸

I. FDA Request: FDA seeks comment on whether 2 years is the appropriate initial period of time for a SIP, whether 2-year reauthorization periods are appropriate, and whether there should be a limit on the number of re-authorization periods.²⁶⁹

FDA should not allow reauthorization for a 2-year period and instead require each SIP proposal to seek new authorization for each SIP proposal. PhRMA anticipates that SIPs will likely evolve throughout the experience of the program so that relying on information submitted two years ago will likely be outdated. Sponsors who have had experience with prior SIP programs should include assessments based on the experience of prior programs. To the extent that a new SIP proposal relies on a prior version of a SIP program, FDA should not authorize the program unless the sponsor reanalyzes whether the SIP program would "pose no additional risk to the public's health and safety" and would "result in a significant reduction in the cost of covered products to the American consumer." Changes in the healthcare system since the initial

²⁶⁶ 84 Fed. Reg. at 70808.

²⁶⁷ *Id.* at 70809.

²⁶⁸ *See id.* at 70811.

²⁶⁹ *Id.*

authorization, including introduction of any therapeutically equivalent products, may mean that importation of drugs under the proposed rule would no longer be permissible under the statute.

J. FDA Request: FDA seeks comment on what additional standards should be imposed or qualifications should be required of Foreign Sellers.²⁷⁰

PhRMA believes that Foreign Sellers must comply with cGMP and all requirements expected of establishments registered as “relabelers” in the U.S. A Foreign Seller would be responsible for “relabeling the drug product” to affix or imprint an SSI on each package. Drug relabeling is a manufacturing process that should be conducted in accordance with applicable cGMP requirements. Foreign Sellers should be held to the same standards as domestic labelers to reduce the risk of misbranding and adulteration as a drug moves through the supply chain.

FDA should ensure that Foreign Sellers can comply with FDA requirements and can hold prescription drug products in safe conditions. As we note in Section V.C, FDA should inspect each facility where the Foreign Seller will hold an imported drug before registration.

K. FDA Request: FDA seeks comment on the feasibility and sufficiency of screening to ensure that imported eligible prescription drugs are not adulterated, counterfeit, damaged, tampered with, or expired.²⁷¹

PhRMA believes that in addition to a “visual comparison” of a sample of a section 804 drug to a sample of the HPFB-approved drug, FDA should conduct periodic audits of shipments of section 804 drugs to determine whether the shipments are not adulterated, counterfeit, damaged, tampered with, or expired.

L. FDA Request: FDA seeks comment on whether there are qualifications Importers should be required to have, beyond being licensed as a pharmacist or wholesaler, given their responsibilities.²⁷²

The Importer may hold drugs imported under section 804 for long periods of time as the drugs are tested for authenticity and quality. FDA should ensure that the Importer handles the drugs in compliance with cGMP and maintains effective product security controls. Therefore, FDA should inspect each facility where an Importer may hold prescription drugs imported under section 804 to reduce the risk of adulteration.

²⁷⁰ *Id.* at 70812.

²⁷¹ *Id.*

²⁷² *Id.* at 70813.

- M. FDA Request: FDA seeks comment on whether there actually are safeguards that could be put in place that would enable FDA to authorize a SIP with multiple Foreign Sellers in a single supply chain in Canada.

FDA should not authorize a SIP with multiple Foreign Sellers in a single supply chain in Canada. PhRMA agrees with FDA that it cannot see how “a longer supply chain would not pose additional risk to the public’s health and safety.”²⁷³ Allowing for additional Foreign Sellers in a supply chain would undermine any claim that FDA could ensure that its proposed approach poses no additional risk. As the HHS Task Force Report notes, each step in the supply chain creates additional opportunities for unscrupulous activity.²⁷⁴ The more complex a supply chain becomes, the more opportunities exist for counterfeit and illicit drugs to enter the supply chain or for drugs to be diverted out of the supply chain. This is particularly true given FDA’s limited resources and limited ability to monitor multiple Foreign Sellers to ensure compliance.

- N. FDA Request: FDA welcomes comments on whether FDA should include exemptions from additional DSCSA requirements.²⁷⁵

FDA must not include exemptions from additional DSCSA requirements. In fact, PhRMA is concerned that the exemptions in the proposed rule would open up new pathways for counterfeit drugs to enter the closed U.S. system and undermine security improvements under the DSCSA. As we note in Section I.B.6, the DSCSA’s requirements provide important safeguards for drugs distributed in the United States. The proposed rule exempts several DSCSA requirements and imposes alternative track-and-trace requirements on Foreign Sellers and Importers. These safeguards do not fully realize the benefits of a single track-and-trace distribution system in the U.S.

Drugs imported into and held in Canada present a higher level of risk and safety concerns than drugs originally intended for the U.S. supply chain. The importation proposal overlooks issues resulting from (1) differences between the two legal frameworks; and (2) limitations to the Canadian government’s jurisdiction over drugs intended for export to the U.S. Unlike the U.S., Canada does not have legal requirements comparable to the DSCSA to ensure the security of the drug supply chain. As a result, drugs purchased by the Foreign Seller — then imported to the U.S. — are subject to a higher level of risk than drugs originally intended for the U.S. supply chain. The importation proposal fails to account for this risk.

The importation proposal would undercut existing surveillance measures that can be used to secure the U.S. supply chain. The preamble says:

To address the substantial public health risks associated with counterfeits of their prescription drugs, manufacturers around the

²⁷³ *Id.*

²⁷⁴ HHS Task Force Report at 37.

²⁷⁵ 84 Fed. Reg. at 70816.

world now use a number of technologies to detect whether a certain drug is legitimate or fake. These technologies include both overt and covert security technology to enable identification of their authentic drug. Technological enhancements that support verification of these overt and covert security features have enhanced the ability to detect counterfeits at the border and prevent their introduction into U.S. commerce.²⁷⁶

Although it is unclear which “technologies” the preamble is referring to here, to the extent they are tied to the DSCSA, it seems the manufacturer and the Foreign Seller would not be utilizing these technologies for drugs imported under the proposed rule. These drugs would not bear the same information as DSCSA-compliant drugs (e.g., product identifier) because they are intended for the Canadian market and instead would bear a DIN and an SSI affixed using a stamp or adhesive sticker.²⁷⁷

- O. FDA Request: FDA seeks comment on whether there are other requirements all laboratories should meet before FDA approves them for use by a SIP.²⁷⁸

As we note in Section V.C, FDA should inspect Qualifying Laboratories and ensure that they are capable of testing the drugs included in an SIP proposal before they are approved as part of a SIP proposal.

- P. FDA Request: FDA seeks comment on whether any other provisions are needed to protect the information that manufacturers would need to provide to Importers under this rule. We seek comments on what testing would be appropriate at this stage and comment on what would be considered timely for the manufacturer to provide necessary information to the Importer for testing.²⁷⁹

PhRMA disagrees with forcing manufacturers to provide proprietary information to Importers for testing. As we note in our comments in Section III, compelled disclosure of manufacturer information for competitor use raises significant constitutional and statutory concerns. If FDA implements the proposed rule, disclosure of trade secrets and confidential information raises complex legal issues that may require negotiations between the manufacturer and the Importer. The trade secrets and CCI would likely differ based on the particular circumstances of each situation, and is not amenable to implementing a fixed timeframe. FDA should not impose any arbitrary time frame by which the manufacturer should provide information to an Importer. Under no circumstances should FDA permit importation before an application holder has had an adequate opportunity to seek judicial review.

²⁷⁶ *Id.* at 70801.

²⁷⁷ *Id.* at 70814.

²⁷⁸ *Id.* at 70817.

²⁷⁹ *Id.* at 70818, 70819.

- Q. FDA Request: FDA seeks comment on whether having multiple otherwise identical drugs in the marketplace with different National Drug Codes (NDCs) will create any issues, such as with pharmacy dispensing or otherwise.²⁸⁰

PhRMA does not agree that drugs imported under FDA's proposed importation scheme would otherwise be identical to drugs sold under an approved NDA, with the authorization and under the control of the manufacturer. As we note in Section I.B.2, drugs imported under section 804, as contemplated under the proposed rule, would be unapproved new drugs because they are subject to processes by entities not described in the application and have labeling that departs from the FDA-approved labeling. Drugs imported under section 804 will also fall outside of manufacturer control, meaning that the drugs will not have the usual assurances of safety from a manufacturer.

PhRMA believes that different NDCs for drugs imported under section 804 are necessary (though not sufficient). Different NDCs may help reduce the risk that pharmacies would inadvertently dispense the imported drug when it intends to dispense the drug originally intended for the U.S. market. Moreover, they are essential to providing some avenue to avoid misattribution. Data show that misattribution of adverse events exists upon generic drug entry. That degree of misattribution exists even where the generic product does not carry the same tradename, packaging, and manufacturer identifiers as would be the case of products imported under the proposed rule. Here, drugs imported under the proposed rule would have the exact same packaging, non-proprietary name, and trade name as the reference product. Further, the same manufacturer will be identified in the labeling and packaging. The only real way of differentiating between the two products, particularly in healthcare databases, will be the NDC. There will likely be a high degree of misattribution upon entry of section 804 drugs into the market and NDCs are rarely used in adverse event reporting in practice, but identifiable adverse event reporting would be impossible without different NDCs.

Different NDCs are also essential to detecting potential supply chain issues, such as the introduction of counterfeit or adulterated products in the supply chain. If application holders cannot reliably attribute adverse events to imported product, they cannot detect potentially problematic drugs within the supply chain. Separate NDCs would also help FDA determine whether drugs imported through section 804 are being diverted outside of the defined patient population. Moreover, if quality or safety issues associated with an imported product increase adverse events or quality reports for an FDA-approved product, FDA would be jeopardizing the overall U.S. drug supply system based on only problems with imported supply.

In addition, different NDCs will be necessary for components of HHS outside FDA, for example, for reimbursement, coverage, and Medicaid purposes.²⁸¹

²⁸⁰ *Id.* at 70819.

²⁸¹ For these reasons and others, FDA should consult with other agencies before issuing this proposed rule, as we discuss in Section IV.C.4.

R. FDA Request: FDA seeks comments on the content of the disclosure statement, whether such a statement is necessary, and whether more information is necessary.²⁸²

PhRMA believes it is necessary to provide the name of the SIP, the SIP sponsor, the Foreign Seller, and the Importer in a way that would be understandable and meaningful to prescribers, pharmacists, and patients. However, FDA should remove the statement that the drug is intended “to reduce its cost to the American consumer.”²⁸³ FDA’s proposed disclosure statement should not include a discussion of cost because inclusion of a such a statement would not be consistent with FDA regulations and the purpose of labeling, which is to provide safety and effectiveness and use information.²⁸⁴

Disclosing that a drug was imported under a section 804 program is important for consumers to properly attribute the drug to the entity responsible for ensuring the quality and safety of the drug. As we note in our comment in Section V.Q, a significant amount of misattribution occurs when a product is introduced into the market that is substantially similar to another drug already on the market. Without any disclosure statement, patients, caregivers, or healthcare professionals may mistakenly attribute an adverse event for an imported drug to the FDA-approved drug, which could hamper accurate reporting. Differentiating SIP-imported drugs from drugs intended for the U.S. market would make it easier for FDA to evaluate whether the SIP programs pose additional risk to the public’s health. Accordingly, PhRMA encourages FDA to prominently display disclosure statements on drugs imported under the proposed rule.

That said, the proposed disclosure statement does not sufficiently communicate that manufacturers cannot guarantee the safety of these products due to lack of information about how the product was stored or tested. Drugs imported through SIP programs are no longer subject to the strict quality control standards that manufacturers impose on their products. Therefore, manufacturers cannot vouch for how the product was handled through the supply chain, including whether the product was stored or tested properly. Because the manufacturer’s name must be on labeling for a drug imported under the proposed rule, consumers could mistakenly assume that the manufacturer vouches for the safety and quality of the imported product. In fact, consumers could mistakenly assume that the manufacturer authorized importation of the products under a SIP program.

Therefore, in addition to FDA’s proposed disclosure statement, FDA should clarify that manufacturers would have the ability to expressly disclaim liability on labeling and disclaim any representation of regulatory compliance associated with drugs imported under section 804. For example, a drug manufacturer could require that drug labeling include a disclaimer that “This

²⁸² 84 Fed. Reg. at 70820.

²⁸³ *Id.* at 70819.

²⁸⁴ See FDA, Press Release: FDA Takes Steps to Encourage More Informative Labeling on Prescription Drug and Biological Products’ Indications and Usage (July 6, 2018) (stating that “FDA-approved labeling is the primary communication tool for providing information on the safe and effective use of drugs to the medical community”).

drug was not authorized for importation into the U.S. by [insert manufacturer].” Explicit disclaimers allows pharmacists, healthcare providers, and patients to understand who is importing the drug, to make choices regarding what drugs are appropriate for a patient, and to accurately report adverse events or quality concerns with the drug.

Prohibiting manufacturers from adding disclaimers would raise significant First Amendment concerns if manufacturers cannot dissociate themselves from products imported under FDA’s proposed rule. Currently, the proposed rule does not provide any avenue by which manufacturers can review the Importer’s proposed labeling and require the Importer to add truthful, non-misleading language, in order to distance manufacturers from the product. Disclaimers are necessary to cure confusion related to whether products are distributed by the manufacturer and imported with the manufacturer’s authorization.

S. FDA Request: FDA seeks comment on how a SIP Sponsor, Foreign Seller, or Importer would effectuate a recall in the United States.²⁸⁵

PhRMA believes the rule should assign the roles and responsibilities of the SIP Sponsor, Foreign Seller, and Importer, including which entities evaluate the complaint or conditions, make the decision to institute a recall, identify the implicated products, notify affected parties and FDA, remove affected products from the market, and assess effectiveness of the recall. FDA should review and revise any recall plan that the SIP Sponsor puts forth and ensure that recalls, if necessary, are implemented properly. More broadly, FDA should oversee a SIP program’s pharmacovigilance measures, including reviewing adverse event reports, medication error reports, and product quality complaints about a drug imported under the proposed rule to determine, for example, whether an event should be attributed to the product itself or to an entity’s mishandling of the product. Insofar as the rule takes control over labeling and distribution away from the application holder, FDA is best positioned to conduct this oversight.

Even with these provisions, there are significant risks to the public’s health related to SIP sponsors effectuating a recall. As with adverse event reporting and other pharmacovigilance activities, SIP sponsors and Importers do not have experience implementing recalls of prescription drug products. If a recall is not timely and correctly instituted, conducted, and concluded, a recall could result in patient harm. All of these risks would be outside the control of the application holder, and the application holder would not have chain of custody of the product.

In addition, improperly executed recalls can cause negative brand and reputation impact. Any recall resulting from a mistake in SIP plan importation could extend to an application holder’s distribution and sale of other products. Taken to the extreme, if a SIP sponsor were unable to narrow the scope of a recall due to the errors made in the SIP importation, FDA may seek to institute a recall of products authorized by the application holder (thereby also putting supply to Canadians at risk, as such imported product by virtue of its Canadian origin would also still require reporting to Canada). Issues with the recall, or even steps involved in assessing the

²⁸⁵ 84 Fed. Reg. at 70822.

necessity of a recall, could significantly and unnecessarily disrupt the supply of FDA-approved drugs and increase the risk of drug shortages due to improper recalls in the U.S. (and Canada).²⁸⁶

VI. Conclusion

In conclusion, PhRMA appreciates HHS's and FDA's consideration of our comments on this important matter. PhRMA believes the importation proposal is unsafe, costly, and unlawful. As HHS has articulated for nearly twenty years, section 804 importation would lead to adverse consequences to patient safety and the public's health and not deliver any cost savings for prescription drugs to the American consumer. Moreover, implementation of the proposed rule would violate the FDCA, other federal laws, and the Constitution. HHS and FDA must withdraw the proposed rule and abandon its importation proposal. PhRMA hopes to continue to collaborate with the Agency to help advance our shared goal of bringing safe and effective drugs to American consumers.

Sincerely,

_____/s/
James C. Stansel
Executive Vice President and General Counsel

_____/s/
Richard Moscicki, MD
Executive Vice President, Science and Regulatory Advocacy, and Chief Medical Officer

_____/s/
Kelly Falconer Goldberg
Vice President, Law and Senior Counsel for Biopharmaceutical Regulation

²⁸⁶ The drug supply can be affected by steps involved in determining whether a recall is even necessary. For example, the Importer will need to hold prescription product and not release the product while conducting product testing.