UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PARTNERSHIP FOR SAFE MEDICINES, and THE COUNCIL FOR AFFORDABLE HEALTH COVERAGE,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; U.S. FOOD AND DRUG ADMINISTRATION; and JANET WOODCOCK, in her official capacity as Acting Commissioner of Food and Drugs,[1]

Defendants.

Case No. 1:20-cv-03402-TJK

FIRST AMENDED COMPLAINT

Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA"), an association representing the country's leading innovative pharmaceutical research companies; the Partnership for Safe Medicines ("PSM"), an association of organizations and individuals with interests in protecting consumers from counterfeit, substandard, or otherwise unsafe medicines; and the Council for Affordable Health Coverage ("CAHC"), a broad-based advocacy alliance with a focus on increasing competition, bringing down the cost of health care for all Americans, and expanding private, affordable health insurance coverage, bring this action for declaratory and

[1] Secretary Becerra and Acting Commissioner Woodcock are substituted for their predecessors in office under Rule 25(d) of the Federal Rules of Civil Procedure.

injunctive relief. At issue are actions by the Department of Health and Human Services ("HHS") and Food and Drug Administration ("FDA") that would permit pharmacists and wholesalers to import certain prescription drugs from Canada into the United States without drug manufacturers' authorization or oversight, presenting significant safety risks. *See* Alex M. Azar, II, Sec'y, HHS, Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020) (the "Certification"), Exhibit 1 to Defendants' Motion to Dismiss, No. 1:20-cv-3402, ECF No. 26-1 (May 28, 2021); Final Rule, 85 Fed. Reg. 62,094 (Oct. 1, 2020) (the "Final Rule").

To ensure the safety of the U.S. drug supply, Section 801(d)(1)(A) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 381(d)(1)(A), broadly prohibits reimportation of a drug that is manufactured in the United States and exported unless the drug is imported by the drug's manufacturer. Section 801(d)(1)(B), 21 U.S.C. § 381(d)(1)(B), prohibits importation of a drug for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States. One exception to both Section 801(d)(1) prohibitions is Section 804 of the FDCA, 21 U.S.C. § 384. Section 804 authorizes HHS to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution ("commercial importation") and the importation of drugs by individual patients ("personal importation"). Section 804 is effective, however, only if the HHS Secretary certifies to Congress "that the implementation of this section will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products [(*i.e.*, certain prescription drugs)] to the American consumer." § 384(*l*)(1).

In light of the risks inherent in importation outside the drug manufacturer's control and the likelihood that such importation will yield little to no savings for American consumers, HHS

Secretaries of both political parties have consistently declined for two decades to certify importation. As recently as May 2018, then-HHS Secretary Alex Azar II derided importation as a "gimmick" that would have "no meaningful effect" on drug prices and could not "be safely achieved." Alex M. Azar II, Remarks on Drug Pricing Blueprint (May 14, 2018).[2]

On the eve of the 2020 Presidential election, then-Secretary Azar wrote to Congress to certify that implementation of Section 804's commercial-importation provisions "poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer." Certification at 1. At the same time, HHS and FDA (together, the "Agencies") promulgated a Final Rule to implement the commercial-importation provisions of Section 804 through "Section 804 Importation Programs" ("SIPs") sponsored and overseen by States and Tribes. 85 Fed. Reg. 62,094. At least two States—Florida and New Mexico—submitted such SIPs to FDA for approval after the Final Rule was promulgated. *See* The State of Florida's Preliminary Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada (Nov. 2020);[3] N.M. Dep't of Health, Section 804 Drug Importation Program Application.[4] Neither FDA nor any of the applicant states have indicated whether these applications have been authorized, but Florida Governor Ron DeSantis relayed at a May 28, 2021 conference that Florida's SIP proposal had been "under review now for

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[2] *Available at* https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[3] *Available at* https://www.safemedicines.org/wp-content/uploads/2019/09/SIP-Proposal-to-HHS-11-23-2020.pdf.

[4] New Mexico's final SIP proposal is available at http://www.safemedicines.org/wp-content/uploads/2019/09/NM-Finalized-Application-1.pdf. A draft of the proposal is available at https://www.safemedicines.org/wp-content/uploads/2019/09/Prescription-Drug-Importation-Program-Application.pdf.

six months," and the state had "been told that if it wasn't denied last week"—*i.e.*, by late May—"that we should assume it's going to be approved."[5]

The actions Defendants have taken to allow the importation of Canadian drugs into the United States violate the FDCA, the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* ("APA"), and the U.S. Constitution. The HHS Secretary's Certification is contrary to Section 804 and unsupported by the record. The Final Rule disregards key protections of the FDCA that are designed to ensure patient safety. There is no indication that the Final Rule will reduce costs to actual American patients. And aspects of the Final Rule are contrary to the FDCA in multiple respects, each of which requires vacating the Rule in its entirety; violate manufacturers' First Amendment rights; and raise serious questions under the Fifth Amendment Takings Clause.

Accordingly, Plaintiffs ask this Court to hold unlawful, set aside, and permanently enjoin implementation of the Certification and Final Rule.

PARTIES

1. PhRMA is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA serves as the pharmaceutical industry's principal policy advocate and represents its members' interests before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives, and they together account for approximately 70 percent of

[5] Video of the press conference is available at *Florida Gov. Ron DeSantis holds news conference at logistics center in Lakeland*, YouTube.com (May 28, 2021), https://www.youtube.com/watch?v=5YQtPxSP3Y4 at 3:35–3:41.

the sales of the prescription drugs in the United States. A full list of PhRMA's members is available at http://www.phrma.org/about/members.

2. PSM is a voluntary, nonprofit association made up of associations representing the nation's leading health care supply chain participants that handle pharmaceuticals from the factory floor to the patient. Representing patients, pharmacists, wholesalers, manufacturers, and families victimized by counterfeit drugs, these associations are committed to the accessibility of safe prescription drugs, and protecting consumers against counterfeit, substandard, or otherwise unsafe medicines. PSM represents its members' interests before Congress, state regulatory agencies and legislatures, and the courts. A list of PSM's members is available at https://www.safemedicines.org/about-us/members, and includes PhRMA. In addition, PSM teaches patients and medical professionals how to buy medication safely, and how to avoid criminals' attempts to infiltrate the closed, secure U.S. drug supply chain.

3. PSM supports quality assurance programs and establishment of an uncompromising drug distribution system in the hope of reducing the number of counterfeit drugs that render ineffective therapies for alleviating suffering and saving lives. PSM's unique and groundbreaking research on the spread of counterfeit medicines in America has been cited by U.S. government agencies, including the Drug Enforcement Administration. Many PSM members are directly involved in procuring, distributing, and selling medications to persons and entities in the United States, and thus stand to be directly and adversely affected by the Final Rule. Indeed, PSM advocates on behalf of individual families that have suffered death due to counterfeit medicines.

4. CAHC is a broad-based advocacy alliance with a focus on expanding competition, bringing down the cost of health care for all Americans, and expanding private, affordable health insurance. Its members include medical providers, patient groups, insurers, retail pharmacies,

pharmaceutical manufacturers, and employers, many of whom will be adversely affected by the Final Rule. CAHC members believe that the cost of health coverage is too high and growing too fast. CAHC promotes policies that lower health costs through increased competition, informed consumers, and more choices to help promote access to affordable coverage.

5. Defendant HHS is a federal agency with its headquarters at 200 Independence Avenue SW, Washington, District of Columbia 20201. HHS issued the Certification and Final Rule at issue in this suit.

6. Defendant Xavier Becerra is the Secretary of HHS and is ultimately responsible for HHS's operations, including the implementation of the Final Rule. Furthermore, under the FDCA, Secretary Becerra is principally responsible for, among other things, (a) the Certification at issue in this suit, 21 U.S.C. § 384(*l*)(1); and (b) regulations governing the commercial importation of prescription drugs from Canada, *id.* § 384(b). Secretary Becerra maintains an office in HHS's Washington, D.C., headquarters, and is sued in his official capacity only.

7. Defendant FDA is a federal agency located within HHS and headquartered at 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993. FDA is the primary federal regulator of prescription drugs, among other things. Along with HHS, FDA issued the Final Rule at issue in this suit and is responsible for approving SIP applications.

8. Defendant Dr. Janet Woodcock is Acting Commissioner of Food and Drugs and is principally responsible for FDA's operations, including its development and implementation of the Final Rule and its review and approval of SIP applications. Dr. Woodcock maintains an office in FDA's headquarters at White Oak in Silver Spring, Maryland, and is sued in her official capacity only.

JURISDICTION AND VENUE

9. This action arises under the FDCA, the APA, and the U.S. Constitution. This Court has jurisdiction under 28 U.S.C. § 1331 and is authorized to grant declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02.

10. This Court may hear this action under the APA because Plaintiffs seek review of final agency actions—the Certification and the Final Rule—for which there is no other adequate remedy.

11. Plaintiffs PhRMA and PSM, and several of Plaintiffs' members, submitted comments on the Agencies' Notice of Proposed Rulemaking, 84 Fed. Reg. 70,796 (Dec. 23, 2019) (the "NPRM"),[6] and all Plaintiffs submitted citizen petitions asking that FDA not approve the Florida or New Mexico SIP applications. *See* Docket Nos. FDA-2021-P-0034 (Jan. 7, 2021) (Florida), FDA-2021-P-0307 (Mar. 18, 2021) (New Mexico).

12. Venue in this Court is proper under 28 U.S.C. § 1391(e)(1) because Defendants Secretary Becerra and the U.S. Department of Health and Human Services are principally located in the District of Columbia, and a substantial part of the events or omissions giving rise to the claims asserted arose in this District. Venue in this Court is also proper because PhRMA resides in this District and no real property is involved in this action.

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[6] *E.g.*, Letter from PhRMA to FDA Regarding Docket No. FDA-2019-N-5711: Importation of Prescription Drugs (Mar. 9, 2020), https://downloads.regulations.gov/FDA-2019-N-5711-1236/attachment_1.pdf ("PhRMA Comment Letter"); Letter from PSM to FDA Regarding Docket No. FDA-2019-N-5711: Importation of Prescription Drugs (Feb. 11, 2020), https://downloads.regulations.gov/FDA-2019-N-5711-0055/attachment_1.pdf.

STATUTORY AND REGULATORY BACKGROUND

I. THE FDCA CREATES A CLOSED DRUG DISTRIBUTION SYSTEM.

13. As HHS has explained, "[t]he drug distribution network for legal prescription drugs in the U.S. is a 'closed' system that involves several players (*e.g.*, manufacturers, wholesalers, pharmacies) who move drug products from the point of manufacture to the end user, and provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor quality medications. This system evolved as a result of legislative requirements that drugs be treated as potentially dangerous consumer goods that require professional oversight to protect the public health. The result has been a level of safety for drug products that is widely recognized as the world's 'gold standard.'" HHS Task Force on Drug Importation, Report on Prescription Drug Importation 35 (2004) ("Task Force Report").[7]

14. To maintain the "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective, *see id.*, the FDCA limits drug imports into the United States. *First*, the FDCA prohibits the importation into the United States of drugs that are unapproved, misbranded, and/or adulterated. 21 U.S.C. §§ 331(a), (d), 355(a); *see* FDA Information on Importation of Drugs ("interstate shipment . . . includes importation").[8] These provisions apply with equal force to any drugs imported under Section 804. *See* 21 U.S.C. § 384(c)(1) (regulations implementing Section 804 "shall . . . require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of the prescription

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[7] *Available at* http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf.

[8] Sections 501 and 502 of the FDCA, 21 U.S.C. §§ 351 and 352, define, respectively, adulterated and misbranded drugs. Section 505, 21 U.S.C. § 355, prohibits the introduction into interstate commerce of unapproved drugs.

drug), with sections 351 and 352 of this title, and with other applicable requirements of this chapter"); *see generally* 21 U.S.C. § 384 (not exempting drugs from the premarket approval, misbranding, or adulteration provisions of the FDCA). *Second*, Section 801 of the FDCA also specifically directs that any drugs "being imported or offered for import into the United States" that appear to be unapproved, misbranded, or adulterated "shall be refused admission" to this country. *Id.* § 381(a)(3). This provision is mandatory, and FDA has "no discretion to make an exception" by allowing the importation of drugs that appear to violate this prohibition. *Cook v. FDA*, 733 F.3d 1, 8–9, 12 (D.C. Cir. 2013). Section 804 also does not exempt drugs from Section 801(a).

15. Drugs must be approved by FDA before they may be lawfully introduced into interstate commerce in the United States. *See* 21 U.S.C. §§ 331(d), 355(a).[9] This ensures that any drug that is imported into the United States adheres to the "gold standard" of safety and efficacy expected from FDA-approved drugs. Task Force Report at 10. FDA approval encompasses not only the composition of the drug itself, but also, among other things, the "methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug" and the "labeling proposed to be used for such drug," *id.* § 355(b)(1), FDA approval of which is necessary to ensure that those drugs are safe for consumers and that prescribers and consumers are adequately apprised of their risks. Any drug not manufactured in accordance with and pursuant to an FDA-approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") is an "unapproved new drug" that may not be introduced to interstate commerce unless

[9] This requirement does not apply to investigational new drugs, *see* 21 U.S.C. § 355(i); 21 C.F.R. Part 312, or to compounded drugs, *see* 21 U.S.C. §§ 353a, 353b.

it is exempt from premarket approval. *See* FDA, Div. of Import Ops. & Pol'y, Information on Importation of Drugs (last accessed Oct. 19, 2020).[10]

16. In addition, the FDCA prohibits the misbranding of drugs and the introduction of misbranded drugs into interstate commerce. *See* 21 U.S.C. § 331(a)–(c). A drug is "misbranded" when, among other things, its "labeling is false or misleading in any particular." *Id.* § 352(a)(1). A drug's labeling can be misleading when it "fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug under its conditions of use. *Id.* § 321(n); *see also* 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii). A drug is also "misbranded" "[i]f in package form, unless it bears a label containing . . . the name and place of business of the manufacturer, packer, or distributor." *Id.* § 352(b); *accord* 21 C.F.R. § 202.1(a).

17. The FDCA also prohibits the adulteration of drugs, the introduction into interstate commerce of adulterated drugs, and the receipt in interstate commerce of adulterated drugs. 21 U.S.C. § 331(a)–(c). A drug is "adulterated" when, among other things, it has been packed or held under insanitary conditions that may have rendered the drug injurious to health, or its manufacture does not conform to "current good manufacturing practice" ("CGMP"); or if the drug's strength differs from, or its quality or purity fall below, the standard set forth in an official compendium, or that which the drug purports or is represented to possess. *Id.* § 351(a)(1)–(2), (b)–(c).

18. The FDCA prohibits the importation of foreign-manufactured drugs and the reimportation of U.S.-manufactured drugs that are exported abroad unless the drug is authorized for importation by the drug's manufacturer or reimported by that manufacturer, with limited

[10] *Available at* https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importations-drugs.

exceptions. A drug subject to 21 U.S.C. § 353(b)(1)—that is, a prescription drug—manufactured outside the United States may be imported for commercial use only if the drug's manufacturer has authorized the drug to be marketed in the United States and caused it to be labeled accordingly, unless the drug appears on the official drug shortage list, *see* 21 U.S.C. § 356e, or is imported under Section 804, allowing importation of certain drugs from Canada when the HHS Secretary has made the requisite certification as to public health and safety and consumer savings. 21 U.S.C. § 381(d)(1)(B). And a prescription drug that is manufactured in the United States and exported may be reimported into the United States only by the drug's manufacturer, or pursuant to Section 801(d)(2), 21 U.S.C. § 381(d)(2) (drugs deemed required for emergency medical care) and Section 804. 21 U.S.C. § 381(d)(1); *see also id.* § 331(t) (prohibiting "importation of a drug in violation of section [801](d)(1)"). Manufacturers invest heavily in seeking and obtaining FDA approval for their drugs and controlling their supply chains to help ensure that the U.S. drug distribution system is "closed."

II. BACKGROUND ON CANADIAN DRUGS

19. Under the Canadian Food and Drugs Act, the production, transportation, and sale of prescription drugs in Canada are primarily regulated by Health Canada. The statutory requirements enforced by Health Canada differ in meaningful ways from U.S. statutory requirements governing drugs marketed in the United States. For example, Canada does not have a statute comparable to the Drug Supply Chain Security Act, 21 U.S.C. § 360eee to 360eee-5 ("DSCSA"), which establishes robust track-and-trace requirements for prescription drugs throughout the pharmaceutical distribution supply chain. Health Canada also has not prioritized regulatory oversight of drugs intended for export to the United States. *See* Task Force Report at 60–61.

20. Prices that manufacturers can charge for patented medicines in Canada are regulated by the Patented Medicine Prices Review Board, an independent, quasi-judicial body, established under the Canadian Patent Act, which sets maximum permissible drug prices using a complex formula that includes the prices charged for comparable drugs in other countries.[11] Because of Canada's specific pricing regime (among other factors), the retail list prices of certain (but not all) patented medications, as sold in Canada, are lower than the prices of brand-name counterparts, as sold in the United States.[12] However, use of generic drugs is much more widespread in the United States than in Canada.[13]

21. The Canadian market for prescription drugs is significantly smaller than the U.S. market. In 2015, Canadian physicians wrote fewer than 630 million prescriptions—fewer than one-seventh the more than 4.3 billion prescriptions written in the United States. *Id.* at 2. As a result, even if the same prescription drugs were actually sold in the United States and Canada, Canada could not come close to satisfying U.S. demand for those drugs. Even assuming that Canadian distributors and pharmacists have ample reserves of drugs on hand and could obtain greater supplies from manufacturers or distributors (respectively), it is estimated that filling only 10 or 20 percent of U.S. prescriptions in Canada would exhaust the Canadian prescription drug

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[11] More information about the calculation of maximum drug prices in Canada can be found at http://www.pmprb-cepmb.gc.ca/CMFiles/Compendium_Feb_2017_EN.pdf.

[12] Measuring the difference in retail list prices for patented medications is methodologically difficult, as some Canadian drugs have different dosage forms and strength than comparable U.S. drugs. Moreover, differences in retail list prices between U.S. and Canadian brand-name medications do not necessarily indicate differences in prices paid by U.S. and Canadian consumers: Retail list prices do not necessarily incorporate rebates and discounts, and typically lower-cost generic medications are much more prevalent and lower cost in the U.S. market than in the Canadian market.

[13] In 2015, 88.7% of prescriptions filled in the United States used a generic drug, compared to only 68.6% of Canadian prescriptions. Marv Shepherd, *U.S. Drug Importation: Impact on Canada's Prescription Drug Supply*, Health Econ. & Outcome Res.: Open Access 3 (2018).

supply in less than a year. *Id.* at 4–5; Marv Shepherd, *The Effect of U.S. Pharmaceutical Drug Importation on Canadian Pharmaceutical Supply*, 143 Can. Pharmacists J. 226 (2010).

22. Canada already lacks adequate supplies of prescription drugs to satisfy its domestic demand. As Canada's official website for mandatory reporting of drug shortages and discontinuations in that country makes clear, many Canadian drugs are currently in "shortage." *See* Drug Shortages Canada, https://www.drugshortagescanada.ca/. One recent study found shortages in the supply of 13.3% of drug "markets" (comprised of drugs with the same active ingredient, dosage form, route of administration, and strength).[14]

III. FOR TWO DECADES, HHS REPEATEDLY REFUSED TO AUTHORIZE IMPORTATION OF PRESCRIPTION DRUGS UNDER SECTION 804, DUE TO SAFETY RISKS AND COST.

A. HHS DECLINED TO ALLOW IMPORTATION UNDER THE MEDS ACT.

23. In 2000, Congress enacted the Medicine Equity and Drug Safety ("MEDS") Act, which added Section 804 to the FDCA. Pub. L. 106-387, § 745, 114 Stat. 1549, *codified as amended at* 21 U.S.C. § 384. The MEDS Act directed the Secretary of HHS, in consultation with the U.S. Trade Representative and Commissioner of Customs, to "promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products," consisting of prescription drugs other than biologicals and certain controlled substances, and subject to regulations intended, among other things, to protect public health. § 384(a), (b), (k)(1)(A) (2000). The MEDS Act provided, however, that these provisions would "become effective only if the Secretary [of HHS] demonstrates to the Congress that the implementation of

[14] Wei Zhang et al., *Factors Associated with Drug Shortages in Canada: A Retrospective Cohort Study*, 8(3) CMAJ Open E535 (2020).

[§ 384] will—(1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer." § 384(*l*) (2000).

24. On December 26, 2000, then-HHS Secretary Donna Shalala stated in a letter to President Clinton that "flaws and loopholes in the design of the new drug reimportation system . . . . undermine[d] the potential for cost savings associated with prescription drug reimportation and could pose unnecessary public health risks." Letter from Sec'y Donna E. Shalala to Pres. William J. Clinton (Dec. 26, 2000), *reprinted at* Cong. Rec. S6910 (daily ed. July 17, 2002) (statement of Sen. Cochran). Among other things, Secretary Shalala noted that Congress had appropriated money to implement the provision in the first year but not to fund the increased monitoring and enforcement that would be required during the anticipated five-year life of the program "to implement [it] in a way that protects the public health."

25. On July 9, 2001, then-HHS Secretary Tommy Thompson likewise declined to certify importation under § 384(*l*), noting that "[a]fter a thorough review of the law, FDA has concluded that it would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people." Letter from Sec'y Tommy G. Thompson to Sen. James Jeffords (July 9, 2001), *reprinted at* Cong. Rec. S6910–11 (daily ed. July 17, 2002) (statement of Sen. Cochran). Secretary Thompson observed that opening the currently closed U.S. drug supply chain to drugs imported from abroad "would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions." Such drugs would be difficult to detect, and even chain-of-custody documentation and the sampling and testing of imported drugs could not eliminate the increased "public health risk . . . and a loss of

confidence by Americans in the safety of our drug supply" and would tax FDA's oversight and enforcement resources.

B. HHS DECLINED TO ALLOW IMPORTATION UNDER THE MMA.

1. The MMA Creates the Section 804 Importation Framework.

26. Congress subsequently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which replaced the MEDS Act's importation provisions with Section 804 in substantially the same version that exists today. Pub. L. 110-329, 117 Stat. 2066, 2464 ("MMA").[15]

27. As with the MEDS Act, these provisions do not take effect automatically. Instead, Congress preserved the essential balance it struck in the MEDS Act: The Executive Branch may authorize importation of certain drugs, but only if the HHS Secretary can certify that implementation of Section 804 meets the exacting standard in the statute—*i.e.*, that implementation of this section "will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer," and subject to a variety of additional statutory requirements and conditions. 21 U.S.C. § 384(*l*)(1). Congress thus continued to take a highly protective position with respect to public health and safety, specifying that importation would be authorized only if the HHS Secretary affirmatively

[15] The MMA amended Section 804 in several respects, including by limiting imports to drugs from Canada, 21 U.S.C. § 384(b); requiring importers to certify that the imported drugs are not adulterated or misbranded, § 384(d)(1)(K)(i); requiring Canadian sellers to register with the U.S. Government, § 384(f); requiring drug manufacturers to allow importers to use FDA-approved labeling at no cost, § 384(h); giving the HHS Secretary authorities with respect to personal as well as commercial importation, § 384(j); requiring the Secretary to "certify" to Congress (not simply "demonstrate") the economic benefits and lack of health risks of importation to certify the statute, § 384(*l*); and replacing the MEDS Act's provision that this section would sunset five years after it was implemented, *see* § 384(m) (2000), with the provision that the Secretary may render the section ineffective by certifying to Congress that the benefits of implementation do not outweigh its costs, § 384(*l*)(2).

found that it could be implemented in a way that significantly reduces the cost of prescription drugs for consumers without even slightly compromising public health and safety.

28. Should a valid certification take effect, the MMA, like the MEDS Act, directs the Secretary of HHS, after consultation with the U.S. Trade Representative and the Commissioner of U.S. Customs and Border Patrol, to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." § 384(b).[16]

29. The MMA specifically requires the Secretary to act via rulemaking, and provides that these commercial-importation regulations must, among other things, "require that safeguards be in place to ensure that each prescription drug imported . . . complies with [§] 355 (including with respect to being safe and effective for [its] intended use)" and with FDCA provisions regarding adulterated and misbranded drugs, § 384(c)(1); and must "contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health," § 384(c)(3). Additionally, these regulations must also require that a drug shipped directly to the United States from its first foreign recipient (as under the importation scheme at issue in this action) be tested by the drug's manufacturer or importer "for authenticity and degradation." § 384(d)(1)(J), (L), 384(e).

30. The MMA also requires the importer of a prescription drug from Canada to submit to HHS specified information about the drug. This information includes not only certain information about the drug (such as the name and quantity of the drug's active ingredient and the process by which the drug was produced), § 384(d)(1), but also a "[c]ertification from the importer

[16] The definition of "prescription drug" excludes controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs if the Secretary makes a finding that such parenteral drugs pose a public health threat. § 384(a)(3).

or manufacturer of the prescription drug that the prescription drug—(i) is approved for marketing in the United States and is not adulterated or misbranded; and (ii) meets all labeling requirements under this chapter," § 384(d)(1)(K).

31. The MMA also states that a prescription drug manufacturer "shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug." § 384(h).

32. In addition to creating a procedure by which the HHS Secretary can legalize commercial importation of certain prescription drugs from Canada, the MMA also contains several provisions relating to personal importation. Most notably, Section 804(j)(2)–(3) authorizes the Secretary to grant individuals waivers of the prohibition against importation of prescription drugs; directs the Secretary to issue guidance describing when HHS will consistently grant case-by-case waivers; and directs the Secretary to issue regulations granting individual waivers to import prescription drugs from Canada under specified circumstances and under such other conditions as the Secretary determines to be necessary to ensure public safety.

33. The MMA did not displace existing prohibitions against the importation of unapproved, misbranded, or adulterated drugs. There are no exemptions in Section 804 from the premarket approval, misbranding, or adulteration provisions of the FDCA or from the Section 801(a) prohibition on importation of drugs that are unapproved, misbranded, or adulterated. To the contrary, the Act states that it leaves untouched existing provisions relating to the importation of such drugs: "Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section [801](d)(1) of this title as provided in this section." 21 U.S.C. § 384(k). Moreover, the Act affirmatively requires that any regulations implementing commercial importation must "require that safeguards be in place to

ensure that each prescription drug imported under the regulations complies with section [505] . . . (including with respect to being safe and effective for the intended use of the prescription drug), with sections [501] and [502] . . . , and with other applicable requirements of this chapter." *Id.* § 384(c)(1).

2. The HHS Task Force Finds Importation Is Unlikely to Satisfy Section 804(*l*)(1) and Raises Numerous Additional Problems.

34. The MMA required HHS to undertake a comprehensive study of importation of drugs into the United States pursuant to § 384. MMA § 1122. To fulfill that statutory requirement, HHS convened a Task Force on Drug Importation. The Task Force was chaired by the Surgeon General and included representatives from HHS—including then-General Counsel Alex Azar and then-Administrator of the Centers for Medicare & Medicaid Services Mark B. McClellan—FDA, and other agencies.

35. In December 2004, the HHS Task Force released its Task Force Report, which cast significant doubt on whether importation under Section 804 could satisfy the patient-safety and consumer-savings criteria identified by Section 804(*l*)(1).

36. As the Task Force explained, the U.S. drug distribution system is a "closed" system that is subject to extensive regulation at every step, from the approval of newly developed drugs to their manufacture, distribution, and, ultimately, administration to patients. *Id.* at 37–38. This system has proved "very effective in protecting public safety," despite threats from, for example, counterfeit and adulterated medications. *Id.* at xii. Importation would create an opening in this closed system, "increa[sing] the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system." *Id.* at x; *accord id.* at 35 ("Legalized importation of drugs in such a way that creates an opening in the 'closed' system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation

and the distribution system have been exploited. For example, doing so would increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system.").

37. In light of these risks and the limited monitoring and enforcement resources available to FDA, the Task Force noted that it would be "extraordinarily difficult" to ensure that individual importation could be made safe for consumers, as certification under Section 804(*l*)(1) requires. *Id.* at xiii. Further, implementing commercial importation in a way that protects patient safety "would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported." *Id.* at xiii; *see also, e.g.*, *id.* at 32, 51, 53–54 (noting that FDA already lacks adequate resources to monitor shipments of imported drugs, which would likely increase if importation were legalized). Simply testing samples of drugs scheduled for importation would be no panacea: Although simple chemical analysis could ascertain whether a sample contained a drug's active ingredient, it could not identify the purity and potency of the product, determine whether it was manufactured appropriately, had expired, was stored in adverse or inappropriate conditions, or was counterfeit. *Id.* at 21. Even if such testing were available, it would be prohibitively expensive and resource-intensive, and testing all imports would be logistically impossible. *Id.*

38. The Task Force also cast significant doubt on whether importation could yield significant savings for consumers. As the Task Force noted, the disparity between U.S. and international prescription drug prices is frequently overstated, as U.S. generic drugs—which account for a significant share of U.S. prescription drugs by volume—are often cheaper than comparable foreign medications. *Id.* at 65. Further, approximately 30 percent of drug spending would be unchanged by importation because that spending goes to drugs that are cheaper in the

United States (*e.g.*, many generics) or that are unsuitable for importation (*e.g.*, injectable drugs and biologics, *see* 21 U.S.C. § 384(a)(3)). Even with respect to the remaining 70 percent of drug spending, the savings from commercial importation were likely to prove largely illusory. The Task Force predicted that foreign governments would potentially impose export restrictions to maintain their own citizens' access to medications. Task Force Report at 67. Moreover, even for drugs that were practically capable of being imported into the United States, intermediaries would likely capture at least half of the potential difference in price between U.S. and foreign drugs. *Id.* Importation thus threatened to reduce manufacturers' revenues—and thus their research and development spending, *id.* at 88–89 & fig. 8.2—and enrich intermediaries without yielding significant savings in the costs of covered products to American consumers. All told, the Task Force estimated that commercial importation would likely reduce total drug spending by only *one to two percent*. *Id.*

39. The Task Force also identified numerous other flaws with importation. Among other things, importation would not only reduce incentives to develop new drugs, but also reduce revenues that manufacturers use to fund their research and development spending. *Id.* at 83–86. The likely result of importation would be to deprive U.S. patients of between 4 and 18 new drugs per decade. *Id.* at 86. The Task Force estimated that importation would likely cost consumers as much as $2 billion per year in lost benefits from new drugs, and this figure did not even include benefits associated with access to future generic versions of those drugs. *Id.* at 88–89 & fig. 8.2. Moreover, any attempt to implement importation would trigger "[a] host of legal and constitutional challenges." *Id.* at xiii. That was in part because many imported drugs would be unapproved new drugs or misbranded under provisions of the FDCA that Section 804 left in place unaltered. *See id.* at 26, 28. Moreover, the Task Force observed that importation raised serious questions under

the U.S. Constitution's Takings Clause and under both U.S. and international intellectual property law, such as the World Trade Organization ("WTO") Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). *Id.* at 91–97. By requiring manufacturers to allow importers to use the approved labeling for a prescription drug at no cost, Section 804 essentially mandates that manufacturers license their trademarks to importers.

3. HHS Secretaries Repeatedly Refused to Certify Section 804.

40. Consistent with the conclusions of the Task Force Report, four different Administrations representing both political parties declined to certify Section 804 importation under the MEDS Act and the MMA for nearly 20 years. All told, none of the six HHS Secretaries who served between enactment of the MEDS Act and 2018 certified Section 804 importation. For example, in 2007, then-HHS Secretary Leavitt warned that "[a]llowing the importation of drugs outside the current safety system would pose an immediate and significant risk to the public health in the United States." Lynne Taylor, *US Senate Kills Drug Importation Moves*, PharmaTimes (May 8, 2007).[17] Indeed, prior to proposing the scheme at issue here, then-Secretary Azar derided importation, noting that the Congressional Budget Office had already determined that importation would have "no meaningful effect" on drug prices, given limits on the availability of drugs from Canada and that there was no way to ensure that the imported drugs were not counterfeits. Azar, Remarks on Drug Pricing Blueprint. As then-Secretary Azar put it, "[t]he last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved." *Id.*

41. In the face of efforts by state and local governments to force them to authorize importation, the Agencies consistently and successfully maintained the position that importation

[17] *Available at* http://www.pharmatimes.com/news/us_senate_kills_drug_importation_moves_989824.

could not be implemented in a way that results in significant consumer savings without increasing public health risks.

42. In *Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005), the Court upheld the Agencies' denial of a citizen petition seeking to authorize the importation of certain drugs. In that case, the Agencies had explained that Section 804 does not—

> authorize[] or contemplate[] any waiver, partial certification, experiment, or other temporary, limited, or short-term program for importing prescription drugs from Canada. Section [804](*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. Accordingly, in the absence of a certification by the Secretary, section [804](*l*) of the MMA does not authorize the issuance of regulations to legalize individual state-sponsored importation programs like the one proposed in the State's Citizen Petition.

Federal Defts.' Mot. to Dismiss, 2004 WL 3211273 (D. Vt. filed Nov. 29, 2004).

43. In *Montgomery County, Maryland v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006), the court likewise upheld the Agencies' denial of a request for a limited certification under the MMA. Once again, the Agencies explained:

> 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 allows the Secretary to certify only whether the law is effective for all Americans, not just those in one particular [S]tate or county. . . . Accordingly, absent a certification by the Secretary, section [384(*l*)] of the MMA does not authorize individual state-or county-sponsored importation programs like the one proposed in the County's waiver request.

Federal Defendants' Mot. to Dismiss, 2006 WL 1451757 (D. Md. filed Apr. 26, 2006).

FACTUAL BACKGROUND

I. THE NPRM

44. On December 18, 2019, the Agencies issued a notice of proposed rulemaking (the "NPRM") soliciting comments on a proposal to authorize commercial—but not personal—importation of certain prescription drugs from Canada under Section 804. 84 Fed. Reg. 70,796 (Dec. 23, 2019).

45. The NPRM proposed that States, Tribes, and other nonfederal government agencies could sponsor SIPs to facilitate the importation of certain prescription drugs from Canada. A SIP Sponsor would designate the drugs to be included in the SIP. For a drug to be included in a SIP, it would have to be approved by Health Canada's Health Products and Food Branch ("HPFB"), and would supposedly qualify for sale in the United States under an existing FDA-approved NDA or ANDA but for the fact that the drug bears HPFB-approved labeling when marketed in Canada. The SIP Sponsor would also designate a Canadian wholesaler that would purchase the drug directly from its manufacturer[18] (the "foreign seller") and deliver the drug to a U.S. pharmacy or wholesale distributor (the "importer"). If FDA approved such a "SIP proposal," the importer would be responsible for submitting a "Pre-import Request" identifying, among other things, the drugs covered by the request and their destination. If FDA approved this request, the foreign seller could ship the drugs to a U.S. Customs port of entry, where samples would be tested for authenticity, degradation, and other factors.[19] If the testing were successful, the importer would

[18] Except in describing the Final Rule, this Complaint uses the term "manufacturer" specifically to refer to the applicant of the approved NDA or ANDA, *see* 21 C.F.R. §§ 3.2(c), or the person who owns or operates an establishment that manufactures an eligible prescription drug ("physical manufacturer")—not, as in the Final Rule, also a holder of a drug master file ("DMF holder").

[19] As HHS has previously acknowledged, "no testing scheme is foolproof." Task Force Report at 30; *see supra* ¶ 37. Because testing is necessarily done on samples, not every drug

be responsible for removing the drugs' Canadian labeling and replacing it with the labeling approved by FDA for the comparable U.S. drugs, along with additional labeling statements.

46. The NPRM contemplated that the manufacturer would need to take a series of burdensome steps to facilitate importation of its drug, including by either testing the imported drug for authenticity, degradation, and other attributes, or providing the importer with all information—including potentially proprietary testing protocols—necessary to authenticate the drug and confirm that its labeling complies with all labeling requirements under the FDCA. The NPRM also proposed that manufacturers would be required to attest that "but for the fact that it bears the HPFB-approved labeling, [the drug] meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing." The imported drug would bear the labeling of the comparable FDA-approved drug, except that the imported drug's labeling would also include other information, including 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] Section 804 Importation Program to reduce its cost to the American consumer."

47. The NPRM proposed that the Secretary of HHS would certify that this commercial importation scheme would "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," as required

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product, it can indicate whether the particular drugs tested contained active ingredient (for example) but cannot by itself ensure that products were manufactured with adequate quality controls. *See* FDA, Facts About the Current Good Manufacturing Practices (CGMPs) (June 25, 2018), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps. Thus, FDA does not allow manufacturers to rely on testing alone, but requires them to show that the drugs they produce have the quality, identity, purity, potency, and other characteristics they are purported to possess. As FDA often says, "quality cannot be tested into products; it should be built in by design." *E.g.*, FDA/Center for Drug Evaluation and Research, New Drug Quality (Sept. 18, 2012), https://www.fda.gov/media/84457/download.

by Section 804(*l*)(1), in conjunction with publication of a final rule. The NPRM did not, however, identify what about the proposed SIP scheme would ensure public health and safety while delivering significant cost benefits.

48. Instead, with respect to public health, the NPRM pointed to the DSCSA and U.S.-Canada cooperation as bases for the Secretary being able to certify safety today. 84 Fed. Reg. at 70,800–801. Enactment of the DSCSA does not address the host of supply chain-related safety issues associated with Section 804 importation. Section 804-imported drugs cannot comply with the DSCSA, which is why the NPRM proposed to exempt imported drugs from several of the DSCSA's key requirements and replace them with less protective substitutes, on which the Final Rule continues to rely. *See* PhRMA, Comment Letter on NPRM at pp 23-27, Docket No. FDA-2019-N-5711 (Mar. 10, 2020);[20] *see generally* 21 C.F.R. § 251.14. Canada's purported cooperation also does not support certification because, among other reasons, Canada *opposes* importation. 84 Fed. Reg. at 70,816; Government of Canada, Comment Letter on NPRM at pp.1, 3, Docket No. FDA-2019-N-5711 (Mar. 10, 2020).[21]

49. With respect to cost, the Agencies acknowledged that they were "unable to estimate the cost savings from this proposed rule" without more information about "the likely size and scope of SIP programs and about the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the United States, and which SIP eligible products are produced by U.S. drug manufacturers." 84 Fed. Reg. at 70,823. Table 1 of the NPRM, *id.*, underscores the Agencies' total lack of data and analysis of the costs and benefits of the NPRM:

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[20] *Available at* https://phrma.org/public-communication/PhRMA-Comments-on-Administrations-Proposed-Rule-on-Drug-Importation.

[21] *Available at* https://www.regulations.gov/document?D=FDA-2019-N-5711-1208.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
Annualized Quantified	.....	.....	.....	2019	7	10	
				2019	3	10	
Qualitative	Potential cost savings to consumers and third-party payers or entities			.....	.....	10	
Costs:							
Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
Annualized Quantified	.....	.....	.....	2019	7	10	
				2019	3	10	
Qualitative	Potential costs to Federal Government, SIP sponsors, importers, and manufacturers of imported drugs			.....	.....	10	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
From/To	.....	From:			To:		
Other Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
From/To	From: U.S. drug manufacturers			To: Importers and U.S. consumers			Not Quantified.
Effects:							
State, Local or Tribal Government: Potential costs and cost savings to State, tribal, and territorial government entities from sponsoring SIPs							
Small Business:							
Wages:							
Growth:							

50. Instead, the Agencies proposed that the HHS "Secretary's certification will be conditioned on each authorized SIP meeting the relevant requirements of section 804 of the [FDCA] and this rule." 84 Fed. Reg. at 70,803.

51. The NPRM did *not* propose certifying personal importation under Section 804(j), which, the Agencies noted, posed certain risks to public health and safety. As the NPRM explained, "[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." 84 Fed. Reg. at 70,800. In particular, there are "many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by [licensed] pharmacies." *Id.* According to the Agencies, such pharmacies are run by criminal networks, and there have been numerous instances in which disreputable online "Canadian"

pharmacies have sold American consumers drugs that originated elsewhere and were fraudulently represented as Canadian. In one high-profile incident, the Canadian online pharmacy CanadaDrugs.com, through a subsidiary, distributed counterfeit cancer drugs containing no active ingredients to U.S. patients. *See* Dep't of Justice, Press Release, Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States (Apr. 13, 2018).[22] In another, Canadian online pharmacy pioneer Andrew Strempler—a licensed Manitoba pharmacist—sold foreign and counterfeit drugs to U.S. patients, ultimately pleading guilty to conspiracy to commit mail fraud and serving time in U.S. federal prison. *See* Christopher Weaver, Former Internet Pharmacist Sentenced in Fake Drug Case, Wall St. J. (Jan. 9, 2013).[23]

52. Indeed, many supposedly "Canadian" drugs are anything but that: As the NPRM observed, "drugs promoted as being from Canada or approved by . . . HPFB that are offered to U.S. citizens in many instances are not actually from Canada [or] approved by HPFB" and are "[i]nstead . . . obtained from ever-evolving illicit sources of supply." 84 Fed. Reg. at 70,800. Indeed, "[a] 2005 FDA analysis of drugs imported through International Mail Facilities revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, *85 percent* of those drugs originated elsewhere and were fraudulently represented as Canadian." *Id.* (emphasis added). Such drugs were typically smuggled into the United States after being shipped from their countries of origin into Canada or other third-party countries "in an effort to avoid detection and create a more trustworthy appearance." *Id.*

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[22] *Available at* https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs.

[23] *Available at* https://www.wsj.com/articles/SB10001424127887324442304578232133556180830.

53. The Government of Canada submitted comments opposing the NPRM. In particular, the Government of Canada noted that its drug market was "too small to meet American consumer demand for prescription drugs or have an impact on high drug prices." Government of Canada, Comment Letter on NPRM at pp.1, 3. The Government of Canada predicted that importation would increase "pressure on the Canadian drug supply, exacerbating drug shortages and limiting access to needed medicines in Canada." *Id.* at 2. Accordingly, the Government of Canada warned that it would "employ all necessary measures to safeguard its drug supply and preserve access for Canadians to needed prescription drugs." *Id.* at 3.

54. PhRMA and PSM also submitted extensive comments on the NPRM, which can be accessed at https://phrma.org/public-communication/PhRMA-Comments-on-Administrations-Proposed-Rule-on-Drug-Importation and https://www.safemedicines.org/wp-content/uploads/2019/09/PSM-HHS-Comment-2-11-2020.pdf.

II. THE EXECUTIVE ORDER

55. On July 24, 2020, President Trump signed an executive order directing the Agencies to take certain actions, "as appropriate and consistent with applicable law," to facilitate the "safe importation of prescription drugs." Exec. Order 13938, Increasing Drug Importation to Lower Prices for American Patients (July 24, 2020), 85 Fed. Reg. 45,757 (July 29, 2020). The stated goal of the Executive Order was to "expand safe access to lower-cost imported prescription drugs."

56. With respect to commercial importation, the Executive Order directed the HHS Secretary, to "complet[e] the rulemaking process" regarding the NPRM. Exec. Order § 2(c).

57. With respect to personal importation, the Executive Order further directed the HHS Secretary to "facilitat[e] grants to individuals of waivers of the prohibition of importation of

prescription drugs, provided such importation poses no additional risk to public safety and results in lower costs to American patients," under Section 804(j)(2). Exec. Order § 2(a).

III. THE FINAL RULE

58. The Final Rule was publicly released on September 24, 2020, and published in the Federal Register on October 1, 2020. The Final Rule nowhere indicates that the HHS Secretary consulted with the United States Trade Representative or the Commissioner of U.S. Customs and Border Protection before promulgating the Rule.[24]

59. In promulgating the Final Rule, FDA largely followed the same flawed approach set forth in the proposed rule.

60. Under the Final Rule, States or Tribes can sponsor SIPs to facilitate the importation of certain prescription drugs from Canada.[25] A SIP Sponsor such as a State or Tribe can designate the drugs to be included in the SIP. To be imported by a SIP, a drug must be approved by Health Canada's HPFB, and supposedly must qualify for sale in the United States under an existing FDA-approved NDA or ANDA, but for the fact that it bears HPFB-approved labeling when marketed in Canada. The SIP Sponsor must also designate a foreign seller (a Canadian wholesaler that will purchase the drugs directly from the drugs' manufacturers) and an importer (a U.S. pharmacy or wholesaler that will receive delivery of the drugs from the foreign seller).

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[24] PhRMA raised in its comment the Secretary's need to consult with the Trade Representative and Customs and Border Protection Commissioner, but Defendants did not respond to that comment in the preamble to the Final Rule. *See* PhRMA Comment Letter at 59–60. In September 2020, PhRMA's counsel filed a Freedom of Information Act ("FOIA") request seeking information relating to this consultation but to date Defendants have provided no such information.

[25] After SIPs operate for two years, the HHS Secretary could determine that private parties could be allowed to operate SIPs without state or tribal sponsorship. 21 C.F.R. § 251.1 ("Section 804 Importation Program Sponsor ('SIP Sponsor')").

61. The Final Rule authorizes FDA to approve, modify, or extend a SIP based on its review of a SIP proposal. 21 C.F.R. § 251.4. If FDA approves such a SIP proposal, the importer will be responsible for submitting a "Pre-import Request" identifying, among other things, the drugs covered by the request and their destination. If FDA approves this request, the foreign seller can ship the drugs to a Customs port of entry, where they will supposedly be tested for authenticity, degradation, and other factors. A manufacturer can either conduct this testing itself for free or turn over to the importer "all information needed to conduct the Statutory Testing, including any testing protocols, Certificate of Analysis, and samples of analytical reference standards that the manufacturer has developed," along with formulation information about the Canadian drug, and stability-indicating assay, and the FDA-approved drug. If the testing is successful, the importer is responsible for removing the drugs' Canadian labeling and replacing it with the labeling approved by FDA for comparable U.S. drugs.

62. The Final Rule does not provide for any public notice or opportunity for interested persons to submit comments before FDA acts upon a SIP. Nor does the Final Rule provide any other means for interested persons to intervene or be heard by the agency during SIP proceedings. Indeed, interested persons will not even have notice that a SIP is pending before the agency, much less notice of the SIP's contents or amendments thereto, unless the Sponsor chooses to publicly release that information. In addition, review of a SIP occurs entirely behind closed doors, meaning interested parties may not know the status of a SIP review or even whether an application has been denied or authorized.

A. THE FINAL RULE POSES ADDITIONAL RISKS TO PUBLIC HEALTH AND SAFETY.

1. The Final Rule weakens existing regulations that create a closed drug-distribution system to assure manufacturer oversight and keep patients safe.

63. Ordinarily, a manufacturer is responsible for drugs distributed pursuant to its applications, including ensuring that the drugs are safely handled; implementing systems for identifying adverse effects or drug-related problems; and proposing changes to drug labeling. *See* 2 James T. O'Reilly & Katherine A. Van Tassel, Food and Drug Admin. §§ 13–15 (4th ed. 2020). Under the SIP scheme, however, no single entity is responsible for the imported drugs. As a result, the manufacturer lacks visibility into the supply chain, and the manufacturer's responsibilities instead are scattered among SIP Sponsors, foreign sellers, and importers. A scheme in which the manufacturer lacks full oversight over the drug and no one entity is accountable for any issues with the drug inevitably adds public health and safety risks.

2. The Final Rule increases the risk that patients will receive unapproved, misbranded, and adulterated drugs.

64. *Unapproved*: The SIP scheme permits unapproved drugs to be imported into the United States. Ordinarily, as part of its approval process, FDA scrutinizes everything about the drug, including not only the composition of the drug, but also the method of its manufacture, its packaging, and its labeling. *See* 21 C.F.R. § 314.50. Drugs imported under SIPs, however, will differ from drugs approved in the respective applications. For example, imported drugs will have been shipped, stored, relabeled, and repackaged in ways that the approved drugs are not. Likewise, the parties responsible for relabeling and repackaging a drug imported under a SIP and the relabeling and repackaging processes will not be identified in the NDA or ANDA of the comparable FDA-approved drug. Accordingly, the Agencies admit that "for drugs imported under

section 804 there will not be 'an approval of an application' under section 505(a) of the FD&C Act [21 U.S.C. § 355]." 85 Fed. Reg. 62,114.

65. *Misbranded*: The SIP scheme also permits misbranded drugs to be imported into the United States. The Final Rule requires drugs imported under SIPs to bear the labels of FDA-approved drugs (with certain additions). Such labeling will likely mislead consumers that the drugs have been approved by FDA (which they have not) and have the assurances associated with FDA-approved drugs (which they do not). Drugs imported under the Final Rule are therefore misbranded.

66. *Adulterated*: Drugs imported under a SIP scheme pose a significant risk of adulteration. A drug is adulterated if it is not manufactured and held in conformance with CGMP, 21 U.S.C. § 351(a)(2)(B), and the SIP scheme increases the risk that the imported drug will not conform with CGMP. As the HHS Task Force observed, "there is no way to assure that [drugs imported under Section 804] have been appropriately stored, processed, and packaged." Task Force Report at 29. That is because the Final Rule, among other things, shifts relabeling and repackaging from FDA-inspected facilities that are identified in an application to other facilities that FDA has not necessarily inspected and refuses to commit to inspect; loosens restrictions on the drug supply chain by exempting supply chain members from DSCSA requirements; and increases the number of entities that are in the supply chain and which test drugs.

3. <u>The Final Rule places important responsibilities on entities that lack the experience or resources to handle them.</u>

67. The Final Rule also threatens public health and safety by imposing significant responsibilities on entities that lack the expertise and resources to carry out these responsibilities.

68. *SIP Sponsors*: The Final Rule assigns SIP Sponsors responsibility for administering SIPs. But States and Tribes lack the know-how to ensure that the drug supply chain

participants are compliant with CGMP and good distribution practices. They generally do not have the systems in place to inspect drug supply chain participants. Under current law, they play no role in implementing the DSCSA. These entities also lack expertise with pharmacovigilance, which requires significant expertise and operational capacity.[26] And they do not inspect drugs at border ports of entry. Insofar as States and Tribes currently exercise *any* of the regulatory responsibilities committed to them under the Final Rule, they do so predominantly through boards of pharmacy that are neither empowered nor equipped to take on importation (especially the importation of drugs for resale to out-of-state buyers). *See* National Association of Boards of Pharmacy, Comment Letter on NPRM at 3–4, Docket No. FDA-2019-N-5711 (Mar. 5, 2020).[27] Moreover, States and Tribes will often lack jurisdiction to take action against non-compliant foreign sellers and out-of-state (or off-reservation) entities. PSM Comment Letter at 3, Docket No. FDA-2019-N-5711 (Mar. 5, 2020).

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[26] For example, adverse event reporting, which is merely one aspect of pharmacovigilance, alone requires a number of complex steps in which entities take in adverse event information and make assessments that require medical and scientific expertise as to whether the event is serious and unexpected and was, in fact, medically caused by the drug—a determination about causation that requires the input of medical professionals.

[27] *Available at* https://www.regulations.gov/document?D=FDA-2019-N-5711-1082. Indeed, States that have attempted to facilitate their residents' personal importation of drugs from Canadian "pharmacies" and other sources have found that they have no practical ability to ensure that genuine drugs are being correctly dispensed and shipped. *See, e.g.*, FDA Staff, Letter to Gov. Tim Pawlenty at 1 (Feb. 23, 2004), *available at* http://www.safemedicines.org/wp-content/uploads/2019/03/Letter-to-Honorable-Tim-Pawlenty_-February-23-2004-1.pdf (noting that Canadian online pharmacies "were observed engaging in dangerous practices on a single voluntary, pre-announced 'visit' by Minnesota State officials who have no regulatory authority over the foreign businesses" that were fulfilling online drug orders); *see also* William G. Holland, Auditor Gen., State of Ill., Management Audit of the Flu Vaccine and the I-SaveRx Program at i, xiii (Sept. 2006), *available at* http://www.safemedicines.org/wp-content/uploads/2015/08/Illinois-Auditor-General.pdf (state contracted with Canadian pharmacy benefits manager to facilitate consumers' purchase of foreign drugs but did not know whether prescriptions were being fulfilled by approved pharmacies).

69. *Foreign Sellers and Importers*: Likewise, the Final Rule vests foreign sellers and importers with new responsibilities that greatly exceed those of typical state-licensed wholesale distributors or pharmacies. These include carrying out pharmacovigilance responsibilities, tracing imported products throughout the supply chain to ensure CGMP compliance, and relabeling or repackaging drugs. Assigning such tasks to foreign sellers and importers, which lack the expertise and operational capacity to carry them out—and, with respect to foreign sellers, may not be subject to U.S. federal and state or tribal authorities' jurisdiction—will increase safety risks and require substantial investments, the recoupment of which would reduce or offset any purported cost savings from importation.

4. The Final Rule undermines the DSCSA's safeguards for the drug-supply chain.

70. Despite citing the DSCSA, *see, e.g.*, 85 Fed. Reg. at 62,106, the Final Rule undermines the very protections that the DSCSA provides, by opening the closed U.S. drug-distribution system to drugs not subjected to rigorous supply-chain security requirements. The minimal supply chain security measures adopted as part of the Final Rule are no substitute for the rigorous protections of the DSCSA. For example:

- Although the Final Rule requires a foreign seller to place a Section 804 serial identifier ("SSI") on each drug imported through a SIP, the SSI does not include a unique serial number assigned by (and traceable back to) the manufacturer, nor does the Final Rule impose other standard technical requirements for an SSI that would help prevent counterfeiting. *See* 21 C.F.R. § 251.14(c)(4)(ii).

- Under the Final Rule, no product identifier is 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; a product identifier is added only after the drug product has already been through two transactions, one of which involves importation into the United States. 21 C.F.R. § 251.14(d)(3)(i).

- Products imported under the SIP scheme will not include the transaction history, transaction information, or a transaction statement for prescription drugs required by the DSCSA, which increases the risk that unscrupulous actors will smuggle counterfeit or other illegitimate drugs into the United States and may make entities or individuals downstream

from the importer question whether the drugs they receive are genuine. 21 C.F.R. § 251.14(d)(7)(i).

- Differences between the requirements under Canadian and U.S. law for detecting and handling suspect and illegitimate products mean that foreign sellers will not be equipped to address suspect and/or illegitimate foreign product. *Compare* 21 U.S.C. § 360eee-1(c)(4)(D) (DSCSA), *with* 85 Fed. Reg. at 62,102 (Final Rule).

71. Moreover, the Final Rule's drug-tracing provisions will lead to administrative and operational problems that undermine public health and safety. For instance, a wholesale distributor or pharmacist that is also an importer under the Final Rule must affix or imprint product identifiers to drugs imported under Section 804, which they need not do for DSCSA-compliant drugs that already include the product identifier. An importer must also piece together the transaction documentation for a drug imported under the SIP scheme by reconciling information received from the foreign seller (regarding the foreign seller's transfer of product to the importer) with records received from the manufacturer (regarding the manufacturer's transfer of the product's ownership to the foreign seller for the Canadian market). This step—which seemingly could be accomplished only manually and with difficulty—is unnecessary under the DSCSA, which requires transaction information to be exchanged at each step of the supply chain through an electronic, interoperable system. Such gaps may conceal lapses in supply chain security that would render a product "unfit for distribution." *See* FDA, Draft Guidance: Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act (Mar. 2018).

5. <u>The SIP scheme introduces risks of consumer confusion and increased medication errors.</u>

72. Section 804-imported drugs will be labeled with FDA-approved labeling, including the proprietary name of the FDA-approved drug, the name of the imported drug's manufacturer, the name of the imported drug's importer, and a statement that the imported drug was distributed under a SIP. FDA acknowledges that product labeling could lead to confusion between products

with the same name. 84 Fed. Reg. at 70,819. Consumers will not understand the distinction between Section 804-imported drugs and FDA-approved drugs. If a patient experiences an adverse event, a patient, caregiver, or healthcare professional may not know which entity to contact, which increases the risk of delays or gaps in adverse event reporting.

B. THE FINAL RULE COMPROMISES MANUFACTURERS' INTELLECTUAL PROPERTY AND SPEECH RIGHTS.

73. The Final Rule also requires manufacturers to facilitate importation by taking a variety of steps that would harm the manufacturers.

74. A drug's manufacturer is required to facilitate importation by assisting importers with the testing required by Section 804, and faces the Hobson's choice of either conducting the testing itself for free or turning over all information necessary to authenticate the drug and to confirm that its labeling complies with all labeling requirements under the FDCA, "including any testing protocols Certificate of Analysis, and samples of analytical reference standards that the manufacturer has developed" and "formulation information about the HPFB-approved drug, a stability-indicating assay, and the FDA-approved drug to facilitate authentication." 21 C.F.R. § 251.16(b); *see also* 21 U.S.C. § 384(e)(2)(A) (describing the information the manufacturer would be required to provide to facilitate testing conducted by the importer); 85 Fed. Reg. at 62,119 (rejecting the suggestion that manufacturers should be able to recoup testing costs from importers, on the grounds that Section 804 requires manufacturers to provide their *labeling* for use by importers at no cost and that "[i]f manufacturers were permitted to charge it would directly undermine section 804's cost-reducing goal").

75. If a manufacturer does not agree to conduct the testing itself, the information it must turn over includes highly confidential trade secrets and confidential commercial information ("CCI"). 21 C.F.R. § 251.16(g). If the manufacturer does not provide such information within 30

days of a request for it by an importer, any person who is a manufacturer, such as a corporate officer, faces potential criminal liability. 85 Fed. Reg. at 62,103; *see* 21 U.S.C. § 333(b)(6) ("[A]ny person who is a manufacturer or importer of a prescription drug under section [804](b) . . . and knowingly fails to comply with a requirement of 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.").

76. In addition, a manufacturer must provide the importer executed batch records, including the certificates of analysis, for recently manufactured, commercial-scale batches of the HFPB-approved drug. *See* 21 C.F.R. §§ 251.5(e)(2). Manufacturers routinely protect batch records as highly confidential, because they contain proprietary information regarding the production and control of each batch. *See* 21 C.F.R. § 211.188. Certificates of analysis contain commercially valuable information typically kept in strict confidence, including product specifications, analytical methods for each component of the formulation, and actual results obtained from testing performed.

77. Moreover—and despite the absence of any provision in Section 804 authorizing such a requirement—the manufacturer is required either to attest to the importer (or to FDA, if the manufacturer conducts testing itself), that the drug sold to the foreign seller met the conditions in the NDA or ANDA approved by FDA for the drug's U.S. counterpart, but for the fact that the drug bore HPFB-approved Canadian labeling, or to explain with specificity why it could not make this attestation. The attestation, which itself is a trade secret and CCI that is disclosed through the Final Rule's importation scheme, includes:

- "[A]ny process-related or other requirements for which compliance cannot be established through laboratory testing," 21 C.F.R. § 251.5(c)(4)(xii);

- "Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug's NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug," 21 C.F.R. § 251.5(c)(4)(xii)(B);

- "Confirmation that the HPFB-approved drug was manufactured in accordance with the specifications described in the FDA-approved drug's NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with [CGMP] requirements set forth in [the FDCA and implementing regulations]," 21 C.F.R. § 251.5(c)(4)(xii)(C);

- "[The] [o]riginal date of manufacture or the date used to calculate the labeled expiration date based on the HPFB-approved or scientifically validated expiration period, the expiration period set forth in the FDA-approved drug's NDA or ANDA, and any other information needed to label the drug within the expiration dating period determined by stability studies in the FDA-approved drug's NDA or ANDA," 21 C.F.R. § 251.5(c)(4)(xii)(D);

- "[I]nformation needed to confirm that the labeling of the prescription drug complies with labeling requirements under the [FDCA]," 21 C.F.R. § 251.5(c)(4)(xii)(E); and

- "[A] copy of all transaction documents that were provided from the manufacturer to the Foreign Seller," 21 C.F.R. § 251.14(b)."

78. The Final Rule does not expressly address what happens if the manufacturer believes it cannot make the attestation described in this section and explains so with specificity to FDA, but FDA disagrees with the manufacturer. 21 C.F.R. § 251.5(d). The FDCA does, however, criminalize "any . . . violation of regulations" under Section 804, and make such violations subject to a prison sentence of up to one or three years (depending on, among other things, whether the violation was "commit[ted] with the intent to defraud or mislead"). 21 U.S.C. §§ 331(aa), 333(a).

79. Section 804 requires a manufacturer to "provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug." 21 U.S.C. § 384(h). The Final Rule interprets that requirement to mean that imported drugs must bear the same labeling as comparable FDA-approved drugs, except that the imported drug's label must also display a National Drug Code, unique serial number, the importer's name and place of business,

and the statement that "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program." 21 C.F.R. § 251.13(b)(4)(iv). If the SIP maintains a website, the statement could also include the website address. 21 C.F.R. § 251.13(b)(4)(iv). Drugs must also include the Importer's name and telephone number as contact information for adverse event reporting. 21 C.F.R. § 251.13(b)(4)(vi). The labeling for drugs sold under NDAs typically includes trademarked information, such as drugs' brand names and logos. If the manufacturer does not authorize the importer to use its labeling within 30 days of a request, the Final Rule deems the manufacturer to have consented to the use of the labeling. 21 C.F.R. § 251.13(a). By requiring the imported product to bear the approved drug's labeling with limited, specified exceptions, the Final Rule directs importers to use manufacturers' trademarks on imported drugs, regardless of the manufacturer's consent to such use.

80. The Final Rule contains a non-severability provision providing that "[t]he provisions of this part are not separate and are not severable from one another. If any provision is stayed or determined to be invalid or unenforceable, the remaining provisions shall not continue in effect." 21 C.F.R. § 251.20.

IV. THE CERTIFICATION

81. In a letter dated September 23, 2020, then-Secretary Azar wrote to congressional leaders to certify "that implementation of section 804(b)-(h) through the final rule Importation of Prescription Drugs . . . poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer." The Secretary emphasized that this Certification was "limited to implementation of section 804(b)-(h) through the final rule and does not authorize any other method of implementing section 804."

82. Both that letter and the Final Rule are devoid of information about the actual effects of implementing Section 804(b)–(h) on public health and safety or costs to American consumers. Instead, the Final Rule asserts that the Certification is proper because, in the future, "it will be the Secretary, acting through FDA, who will find that a particular SIP proposal meets the certification requirements based on the information received as part of the proposal." 85 Fed. Reg. at 62,112. In other words, the Certification defers HHS's consideration of the effects of importation on public health and safety and costs of covered products to American consumers until FDA reviews specific SIP applications. And FDA has stated that "it is the responsibility of the SIP sponsor to ensure cost savings." FDA, Final Regulatory Impact Analysis, Importation of Prescription Drugs, Docket No. FDA-2019-N-5711, at 12–13 (2020).[28]

83. As with the NPRM, the Final Rule acknowledges that the Agencies are "unable to estimate the cost savings from this final rule, because we lack information about the likely size and scope of SIPs, the specific eligible prescription drugs that may be imported, the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States, and which eligible prescription drugs are produced by U.S.-based drug manufacturers." 85 Fed. Reg. at 62,123. Underscoring the absence of any analysis of the potential savings (if any) to American consumers from the Certification, the Agencies provided another blank cost/benefit analysis table in the Final Rule:

[28] *Available at* https://www.fda.gov/media/142408/download.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential cost savings to consumers and third-party payers or entities						
Costs	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential costs to Federal Government, SIP Sponsors, Importers, and manufacturers of imported eligible prescription drugs. This framework does not consider the potential implications of private and government insurance and reimbursement as well as other purchasers in the supply chain including hospitals and physicians. We cannot predict the types and volumes of eligible prescription drugs that will be imported under the final rule, which will influence these payors. Moreover, the prices paid by multiple payors, including those affected by discounts, may be different, unobservable, or both.						
Transfers						7%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Federal Annualized Monetized $millions/year					3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From: U.S. drug manufacturers			To: Importers and U.S. consumers			Not Quantified
Effects	State, Local or Tribal Government: Potential costs and cost savings to States and Indian Tribes from sponsoring SIPs Small Business: Potential costs to drug manufacturers; potential costs and cost savings to pharmacists and wholesale distributors Wages: Growth:							

84. In implementing the Certification, the Final Rule also casts an impermissibly broad net in defining what kinds of savings could be used to demonstrate that the SIP supposedly satisfies the statutory criteria for certification. Section 804(*l*)(1) requires the Secretary to certify that implementation of Section 804 "will," among other things, "result in a significant reduction in the cost of covered products to the American consumer." Rather than focusing exclusively on savings in the cost of prescription drugs *to American consumers*, the Final Rule leaves open the possibility that FDA would approve a SIP application based on a showing of savings to other parties if the sponsor "submit[ted] information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program." 85 Fed. Reg. at 62,101; *see also* 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

85. HHS has also claimed in the Final Rule that a certification need not "cover all of section 804," but instead that HHS may issue separate certifications for each of "two importation pathways: (1) commercial importation of drugs from Canada under subsections (b)-(h), and (2) personal importation under subsection (j)." 85 Fed. Reg. at 62,112.

86. Nothing in the statute authorizes this bifurcation, which is contrary to the position the Agencies have taken in prior cases. The statute requires the Secretary to certify that implementation "of this section"—not of separate pathways or subsections—meets the certification criteria. 21 U.S.C. § 384(*l*)(1).

V. THE STATE SIPs

87. Multiple States have answered Defendants' call. Six States have enacted laws directing state authorities to arrange for importation of Canadian drugs and have submitted some form of SIP proposal to Defendants. At least two States—Florida and New Mexico—have

submitted final SIP proposals which are awaiting Defendants' approval. And, on information and belief, at least one State, Florida, has been informed that it should expect its proposal to be approved. Because all information about SIP applications has come from voluntary disclosures by applicant States, it is unclear whether other SIP applications are pending before FDA or if FDA has authorized any SIP applications.

A. THE FLORIDA SIP

88. In 2019, Florida Governor Ron DeSantis signed into law an act establishing the Canadian Prescription Drug Importation Program within Florida's Agency for Health Care Administration ("AHCA"), with the stated goal of importing Canadian prescription drugs "which have the highest potential for cost savings to the state." *See* 2019 Fla. Sess. Law Serv. 2019-99 (C.S.H.B. 19) (West), *codified at* Fla. Stat. § 381.02035. The Act requires AHCA to contract with a vendor that would be responsible for, among other things, "develop[ing] a Wholesale Prescription Drug Importation List identifying the prescription drugs that have the highest potential for cost savings to the state," identifying Canadian suppliers, and contracting with those suppliers to import drugs under the program. Fla. Stat. § 381.02035(3). The Act also contemplates that a variety of state-affiliated pharmacies or wholesalers could import drugs from Canadian suppliers under the program. *Id.* § 381.02035(7). The Act required AHCA to submit a request for approval of the program by July 1, 2020, and to begin operating the program within six months of receiving that approval. *Id.* § 381.02035(9).

89. On August 20, 2019, Florida submitted a concept paper to HHS "to demonstrate the ability of a state to safely and effectively import prescription drugs into the U.S." and to provide

information on the State's proposed commercial prescription drug importation program design.[29] As anticipated by the Florida statute, the concept paper proposed that the program that would be administered on a day-to-day level by a third-party vendor. Concept Paper at 3. Florida would seek federal approval for its program based not on savings to consumers, but based on savings to the State itself—for example, in its role as sponsor of a Medicaid plan, or as purchaser of drugs for prison inmates. *Id.* at 16. The concept paper provided a sample list of the sort of drugs that might be imported under its SIP. *Id.* at 14.

90. On November 23, 2020, the State of Florida submitted its SIP proposal to FDA.[30]

91. The Florida proposal followed the basic structure suggested by the State's earlier concept paper. Under the Florida proposal, two state agencies—AHCA and the Department of Business and Professional Regulation ("DBPR")—will co-sponsor a SIP to facilitate the importation of prescription drugs for individuals who receive services from the State itself, such as Medicaid beneficiaries, county health department patients, state prison inmates, and state mental-hospital and disability-treatment-facility patients. Florida Proposal 3. "Because of the intricacies involved in operating an importation program, the State will enter into contractual relationships with entities to meet all requirements of the program." *Id.* at 3. The Department of Health Central Pharmacy will be the State's designated importer.

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[29] Florida's Canadian Prescription Drug Importation Paper (Aug. 20, 2019), https://www.safemedicines.org/wp-content/uploads/2019/08/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf.

[30] Gov. Ron DeSantis, *Governor DeSantis Announces Florida's Submittal of Drug Importation Proposal to Federal Government* (Nov. 23, 2020), https://www.flgov.com/2020/11/23/governor-ron-desantis-announces-floridas-submittal-of-drug-importation-proposal-to-federal-government/.

92. The State has contracted with a third-party, private logistics firm—Life Science Logistics, LLC ("LSL")—to "perform[] many duties on behalf of the importer and State." *Id.* at 35. Under the terms of its contract, LSL will receive up to approximately $38 million from the State over the next two years to purchase and import drugs from Canada.[31] On information and belief, LSL hired Barry Fishman, former chief executive officer of TEVA Canada, as its managing director for Canada.

93. Florida has also identified a foreign seller for its SIP. Although the proposal did not initially identify a foreign seller, LSL CEO Richard Beeny disclosed at the May 21, 2021, press conference that "we've identified that foreign seller" as "part of the recent submittal back to FDA." LSL officials report that they are working with Methapharm Specialty Pharmaceuticals ("Methapharm"), which will act as the SIP's foreign seller. Methapharm is registered with FDA as a "SIP Foreign Seller" through the end of 2021. *See* FDA, Drug Establishments Current Registration Site, https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm (June 30, 2021) (search: "Methapharm").

94. Florida's SIP focuses initially on approximately 100 drugs used to treat chronic conditions, such as asthma and chronic obstructive pulmonary disease, diabetes, Hepatitis C, HIV/AIDS, and psychiatric disorders, but will be subsequently expanded. *Id.* 3, 8–14. Of the drugs Florida initially plans to import, most are manufactured under NDAs or ANDAs held directly or indirectly by Abbvie, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb, Eli Lilly and Company, Gilead Sciences, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., Otsuka America Pharmaceutical, Inc.

[31] A copy of the contract is available at https://khn.org/wp-content/uploads/sites/2/2021/01/MED214_CPDIP_New-Contract_12.29.2020_Redacted.pdf.

(OAPI), Sunovion Pharmaceuticals Inc., and Teva US Specialty Medicines. All these companies are members of PhRMA, and AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, and Johnson & Johnson are also members of CAHC.

95. On May 28, 2021, the same day that the government filed its motion to dismiss, Governor DeSantis issued a press release calling on HHS to approve the State's SIP proposal.[32] The press release stated that Florida is "ready to launch" and "ready to move forward" with the SIP, and that "[w]ithin 90 days of approval, [the State] will be able to physically import prescription drugs and ensure that customs inspections are complete and that proper testing has taken place."

96. On the same day, Governor DeSantis held a press conference at a warehouse in Lakeland, Florida, newly constructed by LSL to store drugs imported under the SIP. Although the warehouse was empty, Governor DeSantis reiterated that Florida stood ready to begin importing drugs within 90 days of approval of the Florida proposal, and told reporters that if they came back within 90 days, reporters "[wi]ll start to see the shelves stocked with the prescription medications."

97. At the May 28 press conference, Governor DeSantis stated that Florida's SIP proposal "ha[d] been under review now for six months" and that the State "was told that if it wasn't denied last week" (*i.e.*, by late May), "we could assume it was going to be approved." Later in the press conference, Governor DeSantis reiterated that the State had been told its SIP application would be approved: "[F]rom the Biden Administration, yeah. And look, we, we were told 'still under review,' if it's not nixed by last week, then they said we were going to be okay."

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[32] Gov. Ron DeSantis, Press Release, Governor Ron DeSantis Calls on Biden Administration to Approve Florida's Canadian Prescription Drug Importation Program (May 28, 2021), https://www.flgov.com/2021/05/28/governor-ron-desantis-calls-on-biden-administration-to-approve-floridas-canadian-prescription-drug-importation-program/.

98. In keeping with Florida's apparent belief that SIP approval was imminent, as well as its obligation under Florida law to implement the SIP promptly after approval, the Florida Legislature has allocated substantial funding to the SIP. On June 2, 2021, Governor DeSantis signed into law Florida's 2021–22 appropriations bill, which specifically appropriated $15 million to implement the Florida proposal. Fla. Laws ch. 2021-36, Specific Appropriation 189. Numerous provisions of the appropriations bill authorize state agencies to expend funds from other sources to purchase Canadian prescription drugs from the State's importer and to fund programs under the SIP. *See id.* Specific Appropriations 210–11, 332, 478, 699–701.

B. THE NEW MEXICO SIP

99. In March 2020, the State of New Mexico enacted legislation requiring the State's Department of Health to design a "wholesale prescription drug importation program" to allow for the importation of prescription drugs from Canada. Wholesale Prescription Drug Importation Act, 2020 N.M. Laws ch. 45, *codified at* N.M. Stat. § 26-4-1 *et seq*. The New Mexico Act requires the program design to, among other things, "contract with one or more state drug wholesalers to seek federal certification and approval" to import Canadian drugs. N.M. Stat. § 26-4-4. The Act gave the State until December 15, 2020, to submit a formal request for HHS to approve its proposed program, *id.* § 26-4-6, and required the State to begin implementing and operating the program within six months of receiving that approval, *id.* § 26-4-7.

100. On or before December 15, 2020, New Mexico submitted its SIP application to FDA.

101. The vast majority of the drugs New Mexico seeks to import are manufactured under NDAs or ANDAs held directly or indirectly by Abbvie, AstraZeneca Pharmaceuticals LP, Bayer Corporation, Biogen, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb, Gilead Sciences, Inc., GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., Novartis

Pharmaceuticals, Novo Nordisk, Inc., Pfizer Inc., Sunovion Pharmaceuticals Inc., and Teva US Specialty Medicines. All these companies are PhRMA members, and AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, and Johnson & Johnson are also members of CAHC.

C. OTHER STATES' SIP PLANS

102. Even before Defendants issued the Final Rule, at least four other States—Colorado, Maine, New Hampshire, and Vermont—enacted legislation providing for the importation of Canadian drugs. *See* Colo. Rev. Stat. Ann. § 25.5-2.5-201 *et seq.*; Me. Rev. Stat. tit. 5, §§ 2041–-2044; N.H. Rev. Stat. Ann. § 126-CC: 2; N.M. Stat. Ann. § 26-4-4; 18 Vt. Stat. Ann. § 4651(a). The Colorado, Maine, and Vermont legislation requires each State to begin operating its SIP within six months of receiving federal approval. Colo. Rev. Stat. § 25.5-2.5-205(1), Me. Rev. Stat. title 5, § 2042(2)–(3), 18 Vt. Stat. § 4653.

103. At least three of these States have released draft importation proposals for review and comment by HHS or the general public. See Colo. Dep't of Health Care Pol'y & Financing, Colorado's Drug Importation Program-Draft Application, attached to Comment Letter on NPRM at pp. 15, Docket No. FDA-2019-N-5711 (Mar. 10, 2020);[33] Maine Dep't of Health & Human Servs., Application to Operate a Section 804 Prescription Drug Importation Program (submitted May 1, 2020);[34] Vermont's Canadian Wholesale Importation Program for Prescription Drugs (submitted July 1, 2020).[35]

104. Colorado's draft importation proposal seeks to import 168 drugs, the vast majority of which are manufactured under NDAs or ANDAs held directly or indirectly by Abbvie, Amgen

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[33] *Available at* https://www.regulations.gov/document?D=FDA-2019-N-5711-1238.

[34] *Available at* https://www1.maine.gov/dhhs/sites/maine.gov.dhhs/files/inline-files/Maine%20Section%20804%20Importation%20Program%20Application_0.pdf.

[35] *Available at* http://www.safemedicines.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf.

Inc., AstraZeneca Pharmaceuticals LP, Bayer Corporation, Biogen, BioMarin Pharmaceutical Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb, Eisai Inc., Eli Lilly and Company, Genentech, Gilead Sciences, Inc., GlaxoSmithKline, Incyte Corporation, Johnson & Johnson, Lundbeck LLC, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Novo Nordisk Inc., Otsuka America Pharmaceutical, Inc. (OAPI), Pfizer Inc., Sanofi, Sunovion Pharmaceuticals Inc., Takeda Pharmaceuticals USA, Inc., Teva US Specialty Medicines, and UCB. All of these companies are members of PhRMA, and AstraZeneca Pharmaceuticals LP, BioMarin Pharmaceutical Inc., GlaxoSmithKline, and Johnson & Johnson are also members of CAHC.

105. Colorado released its Invitation to Negotiate in January 25, 2021, seeking two or more vendors to manage the oversight of its importation program. Colo. Dep't of Health Care Pol'y & Fin., HCPF Invitation to Negotiate Solicitation #RFP UHAA 2021000117.[36] Bids were due April 26, 2021. Colorado plans to award contracts in July 2021 and to submit a final application to FDA in early 2022. Colo. Dep't of Health Care Pol'y & Fin., Drug Importation Program Update (Oct. 15, 2020) at 6.[37]

106. Because FDA does not make SIPs public, it is unclear how many SIPs are currently pending before the agency. The government has stated that "FDA has received two *publicly announced* SIP Proposals, from the states of Florida and New Mexico." Memorandum in Support of Defendants' Motion to Dismiss, No. 1:20-cv-3402, ECF No. 26-1 (May 28, 2021), at 13 (emphasis added). Plaintiffs have no means of determining whether there are additional SIPs

[36] *Available at* https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20ITN%201-22-2021.pdf.

[37] *Available at* https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20Drug%20Importation%20Program%20Update%2010-15-2020.pdf.

pending before the agency that have not been publicly announced, or the number, contents, or current status of any such SIPs. Due to the lack of public notice and process, Plaintiffs have been denied the ability to submit comments to the agency regarding any such SIPs. As to the two SIPs that have been publicly disclosed, FDA's attorneys have represented that "no SIPs have been authorized." *Id.* at 9. Yet the FDA does not refute that the SIPs could be granted any day.

INJURIES RESULTING FROM THE CERTIFICATION AND FINAL RULE

107. The Certification and Final Rule are inflicting, and are substantially likely to inflict, serious harms on Plaintiffs' members.

I. INJURIES TO ALL PLAINTIFFS' MEMBERS

108. Upon information and belief, federal officials have informed at least one SIP applicant, the State of Florida, that authorization of its application was certain and imminent as of May 2021, so the harms to Plaintiffs and their members enumerated herein are likewise certain and imminent.

109. Plaintiffs and their members have interests and responsibilities affecting many facets of ensuring the provision of safe and affordable medications to patients, including manufacturing, distributing, and dispensing drugs; lowering the cost of drugs; and protecting patients from counterfeit and substandard medicines. Plaintiffs and their members, comprised of NDA holders and organizations representing drug manufacturers, wholesale distributors, pharmacies and pharmacists, patients, and law enforcement, have been harmed by the process by which Defendants promulgated the Certification and Final Rule.

110. The HHS Secretary issued the Certification without providing interested parties advanced notice and an opportunity to comment on the proposed Certification, let alone on any data or analyses on which the Secretary proposed to rely. Plaintiffs and their members were thereby deprived of a meaningful opportunity to comment on the Certification before Defendants

promulgated the Final Rule. Instead, HHS's tautological approach to the Certification effectively deprived Plaintiffs of any opportunity to comment on why the Section 804(*l*)(1) prerequisites to certification had not been satisfied, because HHS's approach deferred consideration of cost and patient safety to a SIP-review process in which—as noted below—Plaintiffs have no ability to participate. Had HHS delayed issuance of a final certification until after it had issued and received public comments on a proposed certification supported by actual cost and safety information, the agency likely would not have issued the Certification at all.

111. FDA issued the Final Rule before the Secretary made a valid certification that implementation of Section 804 would reduce costs to the American consumer without increasing risks to patient health and safety. Had FDA delayed issuance of the Final Rule until such time as the Secretary made a valid certification supported by actual data, it likely would not have issued the rule at all, or at a minimum would have issued a narrower rule that does not pose the same threats to Plaintiffs' and their members' interests.

112. The Final Rule also harms Plaintiffs and their members by denying them a right to participate in SIP proceedings, even though the SIPs will impose burdensome obligations upon them. Plaintiffs and their members, including those enumerated herein, would comment on SIP proposals and/or intervene in proceedings regarding those proposals if afforded the opportunity. Indeed, where SIP Sponsors have made SIP proposals public, Plaintiffs have submitted Citizen Petitions detailing the serious flaws with those proposals. However, Citizen Petitions are not a substitute for the APA right to notice and an opportunity to comment. Plaintiffs and their members have no means of obtaining information in a timely fashion or submitting timely and informed Citizen Petitions where SIP Sponsors do not choose to make their proposals and amendments thereto publicly available. Further, FDA need not act on Citizen Petitions within a

given timeframe, and often takes years to respond. *See* 21 C.F.R. § 10.30(e)(2)(iv). And because Citizen Petitions are separate agency proceedings, there is no procedural guarantee that FDA will consider or act upon a Citizen Petition before authorizing a SIP; FDA could instead authorize a SIP and then simply deny a related Citizen Petition as moot. *See id.* § 10.30(e)(2)(iii).

II. INJURIES TO PHRMA MEMBERS

113. Both the Certification and the Final Rule threaten patient safety. The Certification opens the closed U.S. distribution system by providing for commercial importation under a scheme that will pose additional risk to the public's health and safety and will not result in significant cost reductions. Likewise, the scheme described in the Final Rule undermines important regulatory protections provided by manufacturer oversight that keep consumers safe; exposes patients to the risks associated with unapproved, misbranded, and adulterated drugs; imposes responsibilities on the States and other SIP entities when they do not have the capacity to ensure that Section 804-imported drugs would be safe; undermines the protections established under the DSCSA; and introduces risks of consumer confusion and increased medication errors. By dispensing with many of the critical safeguards that are designed to ensure the safety of imported drugs, the Final Rule significantly increases the risk that patients will be injured.

114. Any harms to patients will, in turn, harm manufacturers, whose names and labeling information are required to be included on the product, regardless of whether a manufacturer authorizes the importation. Under the Final Rule, manufacturers face a heightened risk that drugs that bear their trademarks but which are counterfeit, of substandard quality, or otherwise adulterated will be imported into the United States. The importation of such drugs will reduce manufacturers' goodwill in their drugs and force them to defend themselves in products-liability litigation brought by individuals injured by counterfeit or adulterated drugs. To address increased

adverse events and medication errors associated with Section 804-imported products, manufacturers will need to make substantial investments in pharmacovigilance. Manufacturers will also need to invest significantly in consumer education to address confusion about Section 804-imported products and to drug supply chain members, such as pharmacies, which are unaccustomed with handling both DSCSA-compliant and DSCSA-exempt products. These investments are in addition to the substantial investments the industry has already made and will continue to make to increase supply chain security, including developing and adopting new technologies, equipment systems, and processes to ensure compliance with its statutory obligations and facilitate the interoperable exchange of information across supply chain entities.

115. Moreover, the Final Rule intrudes on (and may be an uncompensated taking of) various intellectual property rights PhRMA members have in their drugs, drug-development and testing systems, and trademarks.

a. *Trade secrets*: The Final Rule purports to require "manufacturers"—which the Final Rule defines to include not only entities that hold FDA-approved NDAs or ANDAs, but also third parties that produce drugs on a contract basis ("contract manufacturers") and Drug Master File ("DMF") holders—either to conduct the required testing of imported drugs at the border (which will impose costs on these entities), or to turn over to importers all information necessary to authenticate the drugs and their labeling (specifically including any testing protocols developed by those entities, which contain highly sensitive trade secret information). S*ee* 21 C.F.R. § 251.16(b). As a result, the Final Rule will diminish or eliminate the value of these trade secrets not only in the short term, but also in the long term and potentially with broad impact.

b. *Trademarks*: Section 804 and the Final Rule purport to require the manufacturer of a drug proposed to be imported under a SIP to turn over the drug's labeling for use at no cost by the importer, or FDA will deem the manufacturer to have authorized the use of its labeling. *See* 21 C.F.R. § 251.13(a). Drug labeling and packaging typically include trademarks, including drug brand names and logos, so these provisions would thus require manufacturers to cede rights in (and would dilute the value of) these properties.

c. *Patents and Exclusivity*: The FDCA and FDA's implementing regulation provides a manufacturer of a new brand-name drug with "exclusivity," a period in which those drugs are protected from certain competition. *E.g.*, 21 U.S.C. § 355(b)(2); 21 C.F.R. § 314.108. Importation would interfere with this exclusivity by subjecting manufacturers' FDA-approved U.S. drugs to competition from Canadian counterparts that fall under a different exclusivity regime. Similarly, any patent protections afforded to the manufacturers' FDA-approved U.S. drugs would be diminished by such importation of drugs that fall under a different set of patent laws. In both instances, market conditions are created under Canadian laws, but then applied to the United States under a different set of laws. Further, insofar as manufacturers' drug-testing protocols rely on patented inventions, the requirement that the manufacturer conduct testing for importers' benefit, provide testing protocols to importers, or risk having FDA provide those testing protocols to importers, abrogates the manufacturer's patent protections in those inventions. Allowing entities to import foreign versions of drugs with remaining U.S. patents

or exclusivities would upend the Hatch-Waxman Act's successful balance between promoting innovation and fostering drug competition.

116. As implemented, the Final Rule will adversely affect PhRMA members' expectation of and reliance on the protections guaranteed by our patent system and other exclusivities, which allow recoupment of investment over a limited time period. Under the Final Rule, PhRMA members would be forced to compete with importers that sell lower-cost Canadian versions of those drugs during the time period where this type of competition was not expected, reducing their sales from U.S. drugs. The Final Rule acknowledges that manufacturers face the prospect of financial losses due to competition from imported Canadian drugs, explaining that "it is possible that U.S.-based drug manufacturers may experience a transfer of U.S. sales revenues" to importers due to this rule. 85 Fed. Reg. at 62,123. Any increased revenues from the sale of drugs to Canada for reimportation to the United States will not offset lost revenues from U.S. drugs. This transfer of revenue to importers will undermine PhRMA members' ability to invest in research and development into new medicines and additional uses for existing medicines, to the detriment of future patients. Nor will this lost research and development funding result in substantial savings to current consumers, as markups by foreign sellers and importers (including to cover the costs of relabeling and testing conducted by importers) will likely absorb most, if not all, of the difference between the cost of comparable U.S. and Canadian drugs.

117. As implemented, the Final Rule will also deprive PhRMA members of speech rights protected by the First Amendment, by compelling them to make certain statements about the drugs with which they may disagree and which involve disputed issues of fact and opinion, and by preventing them from adding statements to their labels explaining the differences between FDA-

approved drugs and drugs imported under Section 804, and disassociating themselves from the latter.

118. PhRMA members have already been forced to incur costs to ensure compliance with Section 804 and the Final Rule. Under the Final Rule, upon an importer's request, the manufacturer must provide the importer with its attestation, information necessary to conduct the statutory testing (if the manufacturer is not conducting that testing itself), batch records, and transaction information. These requirements are onerous and will in many cases require significant employee time to collect, prepare, and provide the requested information. But the Final Rule gives a manufacturer only 30 days from the importer's request—which could be made as soon as a SIP is approved—before the manufacturer must provide that information. In order to comply with these requirements within the extremely limited time provided by the Final Rule, PhRMA members have taken reasonable but costly preparatory steps in advance of approval of any SIP, such as developing work flows and processes for responding to importer requests; engaging counsel to provide guidance on responding to such requests; identifying which documents would be responsive to such requests and what information in those documents would need to be designated as confidential; analyzing whether to conduct the testing in-house or to provide the information needed to conduct that testing; identifying and compiling the information needed to conduct the testing; and ascertaining whether there are external labs that could conduct that testing. Given the extent of the actions that will be necessary to comply with importer requests, PhRMA members have reasonably begun making plans and taking steps now to be able to satisfy importer requests within 30 days.

119. PhRMA and its members are also harmed by the lack of notice and an opportunity to comment or otherwise participate in SIP proceedings. PhRMA and its members, including

Bristol-Myers Squibb Company, Gilead Sciences, Inc., Merck & Co., Inc., and Sanofi, would very likely comment on SIP proposals and/or intervene in proceedings regarding those proposals if afforded the opportunity. They have frequently submitted comments to regulatory agencies in the past, and certain members, including Gilead Sciences, Inc., submitted comments on the NPRM that preceded the Final Rule at issue here.

III. INJURIES TO PSM MEMBERS

120. The Certification and Final Rule also harm PSM members—especially member organizations with a shared interest in the safety of the U.S. drug supply. The Final Rule eliminates many of the critical safeguards needed to ensure drug (and thus, patient) safety.

121. For example, the Certification and Final Rule will harm patient advocacy organizations, such as PSM members Health HIV, Rx Outreach, and Rx Partnership, which will be exposed to increased risk that U.S. consumers will receive unapproved, misbranded, and adulterated drugs. The Certification and Final Rule will also injure organizations combatting the misuse of prescription drugs, such as PSM member National Association of Drug Diversion Investigators, which will be forced to expend additional resources to curtail the circulation of unapproved, misbranded, and adulterated drugs.

122. PSM's distributor and pharmacy association members, including the American Pharmacists Association, Healthcare Distribution Association, National Association of Chain Drug Stores, and state-specific associations such as the Maine, New Hampshire, and New Mexico Pharmacists Associations are also impacted by the harmful effects of the Rule, including the increased risk that unapproved, misbranded, and adulterated drugs will enter the U.S. drug supply chain and then be dispensed to patients, causing member distributors and pharmacies financial and reputational harm, among other injuries.

123. Pharmacists take an oath to advocate for patient care, and to assure optimal outcomes for their patients. *See* AACP, Oath Of A Pharmacist, *available at* https://www.aacp.org/sites/default/files/2017-11/OATHOFAPHARMACIST2008-09.pdf.

124. By circumventing fundamental supply chain protections, the Final Rule and any approved SIP make it impossible for pharmacists—the final gatekeepers between the supply chain and the patients—to rely on the integrity of the supply chain from which they receive the drugs dispensed to patients, thereby imposing a burden on PSM's members to implement new processes and systems—at their own expense—to vet the safety of imported medications. Failure to do so puts pharmacists and their pharmacies at risk.

125. Neither the Final Rule, nor any of the SIPs proposed to date, purport to absolve pharmacists of liability for dispensing adulterated and/or substandard drugs—even though it is the Rule's opening of the closed supply chain that undermines the assurances of safety created by the DSCSA.

126. Insofar as the Certification and Final Rule harm manufacturers, *see supra* ¶¶ 113–119, they will also harm PSM. PSM's members include PhRMA and the Association for Accessible Medicines (AAM). AAM represents generics and biosimilars manufacturers, and its members are manufacturers of nine out of every ten prescriptions dispensed in the United States.

127. PSM and its members are also harmed by the lack of notice and an opportunity to comment or otherwise participate in SIP proceedings. PSM and its members, including the American Pharmacists Association, would comment on SIP proposals and/or intervene in proceedings regarding those proposals if afforded the opportunity. They have frequently submitted comments to regulatory agencies in the past, including on the NPRM at issue here.

IV. INJURIES TO CAHC MEMBERS

128. The Certification and Final Rule also harm CAHC's members, who represent a diversity of industries and interests. In particular, member organizations with a shared interest in ensuring the safety of the U.S. drug supply, delivering effective and safe patient care, and producing cost savings for U.S. consumers will be harmed. CAHC and its members are also harmed by the lack of notice and an opportunity to comment or otherwise participate in SIP proceedings. CAHC and its members would comment on SIP proposals and/or intervene in proceedings regarding those proposals if afforded the opportunity. They have frequently submitted comments to regulatory agencies in the past, including on the NPRM at issue here.

a. *Pharmacy associations and retail pharmacies* face increased risk that unapproved, misbranded, and adulterated drugs will enter the U.S. drug supply chain and then be dispensed to patients, causing member pharmacies financial and reputational harms, and forcing pharmacies to take additional steps to protect the integrity of drug supply chains, among other injuries. *See supra* ¶¶ 122–125.

a. *Professional medical societies* face increased risk that unapproved, misbranded, and adulterated drugs will enter the U.S. drug supply chain and then be dispensed to patients, causing patients under their care serious injury, and delivering financial and reputational harms to doctors, among other injuries.

b. *Patient and consumer organizations* represent millions of patients and consumers who will be exposed to increased risk of unsafe drugs, who will incur additional costs of treatments resulting from adverse medical events, and who ultimately shoulder the added regulatory and liability costs created by the Agencies' implementation of Section 804.

c. *Employer associations and companies* face increased risk that they or their member companies will be liable for the increased costs and the health claims of their employees who become sick from counterfeit or adulterated drugs that enter the United States through loopholes in the closed drug-supply chain created by the Agencies' implementation of Section 804.

d. *Pharmaceutical manufacturers*, as enumerated above, will suffer the injuries alleged at paragraphs ¶ 113–119, *supra*, including being required to incur costs to perform testing or provide their intellectual property to third-parties on 30 days' notice, under threat of criminal penalties.

CLAIMS FOR RELIEF

Count I (Against Defendants HHS and Becerra): APA—Contrary to Law / In Excess of Statutory Authority (Certification)

129. Plaintiffs incorporate the foregoing allegations by reference.

130. The APA authorizes courts to hold unlawful and set aside agency action, findings, and conclusions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

131. Section 804 takes effect only if the HHS Secretary certifies to Congress "that the implementation of this section will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(*l*)(1).

132. Former HHS Secretary Azar's purported Certification is contrary to Section 804(*l*)(1) in several respects, including the following:

133. *First*, Section 804(*l*)(1) does not permit the Secretary to make a certification that is conditioned on future events or information. Under this provision, the Secretary must certify "that the implementation of [Section 804] *will*" produce significant savings for American consumers at no additional risk to public health and safety. (emphasis added). This definitive language leaves no room for the Secretary to defer a finding of actual savings until sometime in the future, or to make a certification that, as here, is conditioned on assumptions that States will be able to demonstrate savings or safety in the future. Indeed, the statute allows the Secretary to rely on "evidence obtained after the effective date" of implementing regulations as a basis for issuing a certification that *terminates* the program, *see* § 804(*l*)(2)(A), but includes no permission to rely on post-effective-date information as a basis for the certification that renders importation effective.

134. *Second*, Section 804(*l*)(1) precludes the Secretary from certifying only commercial importation, but not personal importation. By its terms, Section 804(*l*)(1) requires the Secretary to certify that "implementation of this section" will satisfy the safety and cost criteria in subparagraphs (A) and (B). Then-Secretary Azar did not certify "implementation of this section" but only commercial importation under subsections (b) through (h).

135. *Third*, Section 804(*l*)(1) certification is an "all-or-nothing" proposition; the Secretary may not certify importation on a state-by-state or tribe-by-tribe basis. This provision requires the Secretary to certify that implementation of 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 drugs to *the American consumer*." (emphasis added). Those requirements cannot be met by implementation of Section 804 through discrete SIPs sponsored by individual States or Tribes. In addition, because the statute elsewhere permits the Secretary to grant "case-by-case" waivers from the prohibition on importation by individuals, *see* § 804(j)(2), the absence of any provision

allowing commercial importation on a "case-by-case" basis confirms that Congress granted the Secretary no such authority.

136. *Fourth*, the Secretary's methodology for assessing the potential consumer savings from importation conflicts with Section 804. The Certification states that implementation of commercial importation will lead to significant savings in the cost of covered products for American consumers because HHS and FDA will approve only those SIP proposals that demonstrate that they will result in such savings. Certification at 1. As the Final Rule explains, however, the Agencies will allow SIP Sponsors to satisfy this requirement with evidence of "cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program." 85 Fed. Reg. at 62,101. But any such savings that accrue to state-sponsored programs and may have collateral benefits for state residents do not constitute "significant reduction[s] *in the cost of covered products* to the American consumer" and thus cannot be a basis for making the Certification.

137. Accordingly, the Certification was both contrary to law and in excess of statutory right.

Count II (Against Defendants HHS and Becerra): APA—Arbitrary and Capricious (Certification)

138. Plaintiffs incorporate the foregoing allegations by reference here.

139. The APA authorizes courts to hold unlawful and set aside agency action, findings, and conclusions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To satisfy this standard, an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*

v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). An agency acts arbitrarily and capriciously if it "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency[] or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43. An agency also acts arbitrarily and capriciously when it changes policy without acknowledging the change or explaining why the agency was disregarding factual findings that underlay the previous policy and undermine the new one. *FCC v. Fox Television Stations Inc.*, 556 U.S. 502, 515–16 (2009).

140. The Certification was arbitrary and capricious in light of the record before then-Secretary Azar for several reasons including the following.

141. *First*, the Secretary inadequately considered both the potential health risks and the consumer savings from importation. As the record makes clear, the Secretary failed to consider importation's patient safety or cost implications prior to certification, but instead deferred that consideration—and effectively subdelegated it to FDA (which, in turn, further subdelegated it to SIP Sponsors)—by incorporating patient safety and cost as criteria to be considered in approving and monitoring SIPs. Accordingly, the Certification is inadequately supported by facts in the record compiled by the agency. "It is difficult to define an agency's grant of conditional approval as an informed and reasoned administrative decision when that agency has yet to receive the minimum required information for its consideration." *Charette v. Bergland*, 84 F.R.D. 98, 102–03 (D.R.I. 1979).

142. *Second*, the Secretary entirely failed to consider, or failed to adequately consider, important aspects of the problem before him, which will impair or prevent the scheme

contemplated by the Agencies from delivering significant decreases in consumer prices without even marginally increasing public health and safety risks, including the following:

a. Canadian law enforcement resources are limited, and it is unlikely that drugs intended for importation to the United States will be an enforcement priority;

b. Whatever differences exist between the retail prices of U.S. and Canadian drugs are likely to be absorbed in substantial part by importers and offset by the costs of testing and relabeling those drugs for the U.S. market, leaving little (if any) savings for consumers;

c. FDA has little to no ability to regulate and inspect foreign sellers, which by definition are located in Canada and subject to Canadian jurisdiction;

d. FDA's ability to inspect drug imports is severely overstretched even by existing importation, and there is no indication that FDA will be able to increase its enforcement resources commensurate with large-scale importation;

e. The drug supply chain security measures contemplated by the Final Rule fall short of those required by the DSCSA, especially with respect to the ability to trace products back to their manufacturers, increasing the risk that counterfeit drugs will enter the Section 804 supply chain;

f. Drugs will be stored and relabeled in facilities that FDA has not inspected and will not commit to inspecting;

g. There is little to no ability to establish through testing that drugs have been transported and stored in accordance with CGMP;

h. No single entity is responsible for an imported drug, and the responsibilities that a drug's manufacturer would normally bear are instead scattered among multiple

actors with little to no expertise in carrying out that manufacturer's responsibilities; and

i. States have limited pharmacovigilance experience, limited jurisdiction, and limited enforcement resources, which will prevent them from adequately performing their SIP responsibilities and enforcing compliance with the FDCA, Final Rule, and SIP-specific requirements against out-of-state and foreign entities.

143. *Third*, and relatedly, the Secretary failed to acknowledge the change in the Agencies' two-decades-long, consistently held position on these and many other issues and explain why the Agencies were parting from the Agencies' prior positions and factual findings, including those embodied in the Task Force Report, on subjects that include: whether Section 505 would prohibit the importation and sale of drugs that do not have approved NDAs or ANDAs (*compare* Task Force Report at 26, *with* 85 Fed. Reg. at 62,114); whether FDA's enforcement capabilities are capable of maintaining consumer safety if importation expands (*compare* Task Force Report at 52–57, *with* 85 Fed. Reg. at 62,106); and whether the economic benefits of importation are likely to prove more than a "gimmick" (*compare* Task Force Report at 67–68, *with* Certification at 1). These "unexplained inconsistenc[ies] in agency policy [are] a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2126 (2016) (internal quotation marks omitted and alteration adopted).

144. *Fourth*, the Secretary's rationale for the Certification is also internally inconsistent and fails to support the Secretary's decision in various respects, including the following:

a. The Secretary certified commercial importation under Section 804(*l*)(b)–(h) but declined to certify personal importation under Section 804(j) based on concerns, according to the NPRM, that "sophisticated criminal networks" could use

"sophisticated technologies" to introduce unapproved, misbranded, and adulterated drugs—including counterfeit drugs—into the United States. 84 Fed. Reg. 70,800. The Final Rule does not explain, however, why the security measures proposed by the Rule would be sufficient to eliminate wholly the risk that unapproved, misbranded, and/or adulterated drugs could be commercially imported into the United States by "sophisticated" bad actors. Indeed, the Final Rule repeatedly acknowledges that importation could lead to additional public health and safety risks insofar as it contemplates that FDA may need to revoke a SIP's authorization, 21 C.F.R. § 251.6(c), and that parties may attempt to smuggle counterfeit drugs into the United States through SIPs, 85 Fed. Reg. at 62,108. These inconsistencies in the Agencies' rationale renders arbitrary and capricious the Certification that implementation of Section 804 will pose *no* added public health and safety risk. *See Bus. Roundtable v. SEC*, 647 F.3d 1144, 1153 (D.C. Cir. 2011).

b. Although the Secretary certified that implementation of Section 804(b)–(h) "will result in a significant reduction in the cost of covered products to the American consumer," the Final Rule explains that the Agencies "are unable to estimate the cost savings from this final rule, because [they] lack information about the likely size and scope of SIPs, the specific eligible prescription drugs that may be imported, the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States, and which eligible prescription drugs are produced by U.S.-based drug manufacturers." *E.g.*, 85 Fed. Reg. at 62,095. Without such information, there is no way the Secretary could have rationally

certified that implementation of Section 804 "*will* result in a *significant* reduction in the cost of covered products to the American consumer." (emphasis added).

c. The NPRM proffered several reasons why commercial importation under Section 804(b)–(h) did not pose the same public health and safety risks that the Agencies had previously identified. *See* 84 Fed. Reg. at 70,800–801. According to the NPRM, (i) Canada has improved its oversight of pharmaceutical manufacturing practices and supply chain participants; (ii) Canada and the United States have increased bilateral regulatory cooperation; (iii) "pharmaceutical supply chains have continued to mature and consolidate," including as a result of the enactment of the DSCSA, which "outlines steps to build an electronic, interoperable system to identify, trace, and verify certain prescription drugs as they are distributed among pharmaceutical supply chain trading partners"; (iv) manufacturers have developed new means of identifying counterfeit drugs, including "overt and covert security technology to enable identification of their authentic drug"; and (v) Section 804 would be implemented through SIPs, the sponsors of which would need to demonstrate that importation would pose no additional public health and safety risks. None of these reasons holds water. First, even if Canada has improved oversight of its *domestic* supply chain, there remains no system for ensuring the pedigree of products that are originally intended for Canada but are redirected to the United States. Indeed, Canada does not prohibit or track the transshipment of drugs from any country into Canada and into the United States. Second, even if Canada has increased cooperation with U.S. drug regulators in other respects, it has made abundantly clear that it opposes importation. Government of Canada,

Comment Letter on NPRM at pp.1, 3. Third, the DSCSA cannot justify certification because the Final Rule exempts Section 804-imported drugs from many of the DSCSA's key requirements, imposing instead meager substitutes that will be unable to safeguard drug supply chains. *See* 21 C.F.R. § 251.14(c)(7). Fourth, it is unclear what new security technologies the Agencies referred to, and to the extent any such technologies were tied to the DSCSA, they would be inapplicable because Section 804-imported drugs would not bear DSCSA-compliant product identifiers and would instead bear only SSIs affixed with stamps or adhesive stickers. Finally, as discussed above, Section 804(*l*) does not allow HHS to shift to SIP Sponsors the burden of showing that importation will result in *no* additional public health and safety risks, which *HHS* must certify *before* Section 804 is implemented.

145. *Fifth*, the Secretary also failed to explain adequately his reversal of HHS's longstanding position that Section 804(*l*)(1) certification is an "all-or-nothing" proposition that requires certification to be on a nationwide basis or not at all. *See* Mem. in Supp. of Fed. Defs.' Mot. to Dismiss at 10, *Vermont*, 405 F. Supp. 2d 466.

146. Accordingly, the Certification was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count III (Against Defendants HHS and Becerra): APA—Procedural Violations (Certification)

147. Plaintiffs incorporate the foregoing allegations by reference.

148. The APA authorizes a reviewing court to set aside final agency action taken "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;" and "without observance of procedure required by law." 5 U.S.C. § 706(2)(C)–(D).

149. Here, the process by which HHS issued the Certification violated both the FDCA and the APA.

150. *First*, HHS failed to issue a certification before promulgating the NPRM. Section 804(*l*) states that Section 804 "shall become effective only if" the Secretary makes the certification required by Section 804(*l*)(1). HHS (including FDA) therefore lacks authority to begin implementing Section 804 before the Secretary makes the certification required under Section 804(*l*)(1). But then-Secretary Azar made no such certification prior to initiating the rulemaking that culminated in the Final Rule, and consequently lacked authority to initiate that rulemaking. As a result, the Secretary *never* issued a valid notice of proposed rulemaking, as Section 553 of the APA requires.

151. *Second*, the Secretary also deprived regulated parties of any opportunity to comment on the actual supporting facts and analysis required to substantiate the Certification itself. The Certification is a rule subject to APA Section 553 notice-and-comment requirements. At no point—either in the NPRM or in the Final Rule—however, did the Secretary provide any data or analysis regarding the factual basis for that Certification (*i.e.*, the impact of implementation of Section 804 on public health and safety or the cost of covered products to American consumers).

152. Accordingly, the process by which the HHS Secretary issued the Certification was both inconsistent with the limits placed on his authority by Section 804 and with the APA's rulemaking requirements.

Count IV (Against All Defendants): APA—Contrary to Law / In Excess of Statutory Authority (Final Rule)

153. Plaintiffs incorporate the foregoing allegations by reference.

154. The Final Rule conflicts with the FDCA, and is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C), in several respects.

155. *First*, the drugs imported under the Final Rule would necessarily be unapproved new drugs or misbranded drugs which, under other provisions of the FDCA that the MMA left untouched, cannot be imported into the United States. As noted, the FDCA requires FDA to refuse admission into the United States of any drug that is misbranded or an unapproved new drug. 21 U.S.C. § 381(a). And Section 804 itself requires that regulations implementing any commercial importation program "shall . . . require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with" various provisions of the FDCA, including prohibitions against unapproved new drugs and misbranding. § 384(c).

a. *Unapproved*: A drug may be introduced into interstate commerce only under an FDA-approved NDA or ANDA, which application encompasses not only the formulation of the drug, but also (*inter alia*) how the drug is produced, packaged, and labeled. *See* § 355. A drug that differs in any respect from the drug approved in an NDA or ANDA is an unapproved new drug that may not be imported into the United States. Drugs imported under the scheme described by the Final Rule would be tested, relabeled, and transported in ways not described by existing NDAs or ANDAs, and would thus be unapproved new drugs. Furthermore, the Section 804-imported drug's labeling would not conform to that approved in the drugs' NDAs or ANDAs, making the drugs unapproved on that ground as well. *See* Task Force Report 26 (noting that "whether this was intended or not, section 355 strictly limits the universe of drugs that are eligible to be imported from Canada" to "a small subset of drugs that have approved NDAs and ANDAs"). Indeed, the Agencies *have admitted* that drugs imported under a SIP will be unapproved: "[F]or drugs imported under section 804 there will not be an 'approval of an application' under

section 505(a) of the [FDCA]," and these "drugs will not themselves be the subject of an approved NDA or ANDA." 85 Fed. Reg. at 62,114. The Agencies assert that these drugs "compl[y] with" Section 505—which, again, prohibits the importation of unapproved drugs—because these drugs *would be* approved but for the fact that they bear Canadian labeling. *Id.* But plain statutory text leaves no room for the Government's theory. "[U]nless an approval of an [NDA or ANDA] is effective with respect to [a] drug," the drug is unapproved and cannot be imported into the United States. 21 U.S.C. § 355(a).

b. *Misbranded*: For similar reasons, drugs imported under the Final Rule would also necessarily be misbranded. A drug is misbranded if its labeling is false or misleading. § 352(a). Attaching FDA-approved labeling to a drug imported under the Final Rule would be both false and misleading, insofar as it would (a) use FDA-approved labeling on an unapproved new drug; (b) mislead consumers into believing that the drug was identical to the FDA-approved drug; and (c) fail to provide consumers with important information about how the drug was transported and stored when being exported to, and imported or reimported from, Canada.

Accordingly—absent further amendments to the FDCA or approval of NDAs or ANDAs specifically covering drugs imported under Section 804—the Final Rule violates the FDCA by authorizing importation of drugs that are unapproved and/or misbranded.

156. *Second*, the Final Rule misapprehends the statutory standard that must be satisfied for importation to be certified under Section 804(*l*). As noted, for Section 804 to be implemented, the Secretary must certify that importation will result in a significant reduction in the cost of covered products—*i.e.*, prescription drugs—to the American consumer. And the Secretary has

certified that this standard is met because the Agencies would approve only those SIP applications that adequately demonstrated how they would satisfy this criterion. The Final Rule nevertheless authorizes SIP sponsors to satisfy this criteria with an explanation, for example, of savings to state programs that result in those programs covering more drugs or individuals. Such explanation does not demonstrate the savings to the costs of covered products to the American consumer, as the statute requires.

157. *Third*, FDA lacks statutory authority to deem manufacturers to have provided their labeling for use by importers. The Final Rule states that if the manufacturer does not provide authorization to use the labeling "within 30 calendar days of receiving the Importer's request, FDA may deem this authorization to have been given." 21 C.F.R. § 251.13(a). But Section 804(h) provides only 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" and says nothing about when a manufacturer will be *deemed* to have given authorization. Absent statutory authorization, FDA cannot simply pretend that manufacturers have been given authorization that they never gave.

158. *Fourth*, the requirement that manufacturers allow importers to use their trademarks without their consent and without compensation is inconsistent with trademark law, including international trade agreements to which the United States is a party—namely the U.S.-Mexico-Canada Agreement ("USMCA") and the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). Domestic law, the USMCA, and TRIPS all reflect the bedrock principle that the owner of a trademark has the right to control the use of that mark. *See* USMCA art. 20.19; TRIPS arts. 16(1), 21. The Final Rule upsets that bedrock principle. By requiring imported drugs to be distributed using essentially the same labeling as FDA-approved

drugs, despite material differences between the products, the Final Rule greenlights importers to infringe manufacturers' trademarks and risks significant consumer confusion.

159. *Fifth*, FDA lacks statutory authority to require a manufacturer to attest that a drug meets the conditions in an approved NDA or ANDA but for the fact that the drug bears Canadian labeling, or to notify FDA and explain with specificity why it cannot provide that attestation. Section 804(d) directs that the importer must submit to the Secretary certain information, including "[c]ertification from the *importer or* the manufacturer . . . that the prescription drug—(i) is approved for marketing in the United States and is not adulterated or misbranded; and (ii) meets all labeling requirements under this chapter." § 384(d)(1)(K) (emphasis added). This provision, which expressly imposes requirements on the importer that the importer itself may satisfy, does not authorize FDA to require the manufacturer to make specific representations about an imported drug—especially when that drug will have been purchased, stored, and transported by third parties, leaving the manufacturer without a sound basis for making that attestation.

160. *Sixth*, FDA lacks the authority to disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same. The FDCA and federal statutes prohibit FDA from disclosing trade secrets and confidential commercial information. *See* 18 U.S.C. § 1905 (criminalizing disclosure of trade secrets acquired during the course of governmental duties by a federal employee); 21 U.S.C § 301(j) (prohibiting the disclosure of trade secrets and confidential commercial information without express written consent of the person who submitted the information); *see also* 5 U.S.C. § 552(b)(4) (exempting trade secrets and confidential information from public disclosure under the Freedom of Information Act). Moreover, the USMCA and TRIPS both require the United States to protect proprietary data submitted to secure marketing approval of an innovative pharmaceutical against

disclosure and to ensure that this data is not relied upon by third parties to secure marketing approval of a generic or biosimilar version of the innovative product, *see* USMCA art. 20.48; TRIPS art. 39.3, and by requiring the United States to ensure that persons have means to protect against the disclosure, acquisition, or use of their trade secrets, *see* USMCA art. 20.69; TRIPS art. 39.2. Disclosing whether an FDA-approved product is the same as an HPFB-approved product reveals trade secrets and confidential information about the manufacturer's manufacturing process, including the sameness of the release specifications and manufacturing sites for the two products. By authorizing imports of drugs from Canada under the Final Rule, FDA discloses these trade secrets and confidential information without the statutory authority to do so.

161. *Seventh*, without statutory authority to do so, the Final Rule requires manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and the FDA-approved drug to importers for free.

a. The Final Rule requires a manufacturer to provide the importer executed batch records, including the certificate of analysis, and an attestation and information statement with confirmations about the sameness of the FDA-approved drug and HPFB-approved drug. It further requires a manufacturer to either conduct statutory testing itself or turn over to the importer "all information needed to conduct the Statutory Testing, including any testing protocols, Certificate of Analysis, and samples of analytical reference standards that the manufacturer has developed," along with formulation information about the Canadian drug, and stability-indicating assay, and the FDA-approved drug. 21 C.F.R. § 251.16(b). These requirements involve testing, the disclosure of trade secrets and confidential information, and the provision of physical products. The preamble to the Final Rule

indicates that the manufacturers must perform these services and provide this information for free. Although Section 804 requires a manufacturer to provide an importer with "written authorization for the importer to use, at no cost, the approved labeling for the prescription drug," the statute has no parallel provision requiring manufacturers that conduct the statutory testing to do so for free, nor does it have a parallel provision requiring manufacturers to supply trade secrets and CCI, analytical reference standards, and the FDA-approved drug to importers conducting the statutory testing for free.

b. The Final Rule defines "manufacturer" to include not only the applicant of an NDA or ANDA, or physical manufacturers, but also DMF holders. 21 C.F.R. § 251.2. DMFs are "submissions to FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products." FDA, Drug Master File (DMFs) (Mar. 31, 2020);[38] *see also* 21 C.F.R. § 314.420 (explaining that DMFs may contain information about any material used in the preparation of the drug product). DMFs can be held by a variety of entities that do not manufacture the prescription drug, including a testing laboratory, a research institute, a packaging supplier, or an ingredient supplier. *See* FDA, List of Drug Master Files, 3Q2020-All-Excel.[39] The Final Rule would allow an importer to demand access to this information, to which even a drug's manufacturer (*i.e.*, the NDA- or ANDA-holder or the physical

[38] *Available at* https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.

[39] *Available at* https://www.fda.gov/drugs/drug-master-files-dmfs/list-drug-master-files-dmfs.

manufacturer) may lack access. Section 804 nowhere authorizes the Agencies to require such information from anyone other than a drug's manufacturer.

162. *Eighth*, apart from the absence of statutory authority, these provisions of the Final Rule raise serious constitutional questions. The Fifth Amendment to the U.S. Constitution prohibits the Government from taking property without providing just compensation. The Final Rule would work an uncompensated taking by expropriating applicant holders', physical manufacturers', and drug master file holders' intellectual property in their drug labeling, testing protocols (or testing services), and in the similarity (or lack thereof) of U.S. and Canadian drugs, and giving it to importers without providing any compensation. These entities have reasonable investment-backed expectations in their intellectual property. Alternatively, if manufacturers decide to conduct the testing themselves to avoid compromising their intellectual property, the Final Rule will require them to incur the cost of conducting the testing, which the Agencies have stated cannot be recouped from importers. Although Plaintiffs cannot maintain a standalone Takings Clause claim before this Court (a claim for just compensation would need to be heard by the Court of Federal Claims), the extent to which the Final Rule will work a taking of Plaintiffs' members' intellectual and other property is relevant to the proper interpretation of various provisions located in Section 804.

163. Accordingly, the Final Rule is both contrary to law and in excess of statutory right.

Count V (Against All Defendants): APA—Arbitrary & Capricious (Final Rule)

164. Plaintiffs incorporate the foregoing allegations by reference here.

165. The Final Rule is arbitrary and capricious in at least four respects.

166. *First*, the Final Rule represents an inadequately explained shift in HHS's policy with respect to the status of imported drugs and the scope of its legal authority to permit their importation. As noted, the Task Force Report observed that, because Section 804 retained existing

law prohibiting the importation of unapproved new drugs, "whether this was intended or not, section [804] strictly limits the universe of drugs that are eligible to be imported from Canada" and that, as a result, "very few drugs would be eligible for importation, specifically, a small subset of drugs that have approved NDAs and ANDAs." Task Force Report at 26. In other words, "Canadian versions" of FDA-approved drugs would be unapproved new drugs that are *not* eligible for importation. *Id.* Likewise, the Task Force Report noted that even if Congress were to permit or require labeling or relabeling of an unapproved Canadian version of an FDA-approved drug with the labeling of its FDA-approved counterpart, "it would do violence to the reasons for which the misbranding provisions of the [FDCA] exist." By authorizing importation of certain drugs that could be sold in the United States but for the fact that they bear Canadian rather than U.S. labeling, the Final Rule implicitly rejects these prior positions, but does not meaningfully address this change of position. Rather than grapple with this issue, FDA simply asserts that changes have been made in the "intervening years," but fails to address that many of those enhanced safeguards would be disregarded by the Final Rule. 85 Fed. Reg. at 62,106.

167. *Second*, the Final Rule is arbitrary and capricious insofar as it fails to adequately consider various reasons why the contemplated importation scheme will necessarily increase the likelihood that FDA will admit adulterated drugs to the United States and otherwise compromise U.S. public health and safety, for reasons given above in paragraph 142. Instead, the Final Rule asserts that States will be able to protect public health and safety because FDA will approve a SIP proposal only if the SIP Sponsor demonstrates that it will be able to protect public health and safety—but that is a tautology, not the reasoned explanation required by the APA.

168. *Third*, the Final Rule is arbitrary and capricious insofar as it fails to offer a reasoned explanation for the Agencies' decision that manufacturers cannot charge importers reasonable,

market-based prices for the costs of conducting the statutory testing or provision of trade secrets and CCI, analytical reference standards, and FDA-approved drugs. As noted above, Section 804(h) requires manufacturers to provide importers with drug labeling, to use at no cost, but imposes no comparable requirement for testing services and provision of trade secrets and CCI, reference standards, and FDA-approved drugs. Additionally, requiring manufacturers to provide these services, trade secrets and CCI, reference standards, and FDA-approved drugs to importers for free raises serious First Amendment and Takings Clause concerns. The Agencies summarily rejected these concerns when raised in the comments, stating without additional explanation that (a) Section 804(h) "does not mean that manufacturers can charge for information or services that they are required to provide; (b) "[i]f manufacturers were permitted to charge it would directly undermine section 804's cost-reducing goal; and (c) Section 804 and the Final Rule do not effect a Fifth Amendment taking. This explanation falls well short of the "reasoned decision-making" required by the APA. Among other things, the Agencies offered no explanation for why allowing manufacturers to charge importers a reasonable price to conduct the testing themselves "would directly undermine section 804's cost-reducing goal," given that the alternative—having importers conduct the testing themselves with information provided by manufacturers—would mean that the testing is being conducted by entities that may lack the experience and scale to do that testing in a cost-effective manner. In addition, because the Agencies entirely failed to evaluate what cost savings the rule might generate, they also necessarily failed to evaluate the extent to which a reasonable fee might reduce any savings.

169. *Fourth*, the Final Rule is also arbitrary and capricious insofar as Defendants failed to adequately explain why the Rule's approach to manufacturers' trademarks was reasonable, lawful, and consistent with HHS's prior positions. As described above, the Final Rule's

requirement that manufacturers allow importers to use their labeling—which includes manufacturers' trademarks, including brand names and logos—at no cost deprives manufacturers of the ability to control the use of their marks and will lead to significant consumer confusion. In adopting this approach, Defendants did not explain their reversal of position from HHS's previous recognition that importation would raise serious intellectual-property problems.

170. Accordingly, the Final Rule is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count VI (Against All Defendants): APA—Procedural (Final Rule)

171. Plaintiffs incorporate the foregoing allegations by reference.

172. The APA authorizes the reviewing court to hold unlawful and set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(C)–(D).

173. The procedures adopted by the Final Rule for the promulgation of SIPs fail to meet minimum procedural requirements under the APA.

174. A SIP authorization constitutes a rule subject to the APA's notice-and-comment requirements because it has "future effect"; is an "agency statement of general or particular applicability," determining a drug importation program for the entirety of a State (or Indian Tribe); and is not subject to any notice-and-comment exemption. *See* 5 U.S.C. §§ 551(4), 553. Further, as described above, the Secretary deferred consideration of the critical determinations required by the MMA, including the impact of importation programs on public health and safety and the costs to American consumers, into the proceedings on the SIPs. The MMA directs that these determinations be made through rulemaking. 21 U.S.C. § 384(b)-(c). Thus, the APA notice-and-comment rulemaking requirements apply to the SIP proceedings.

175. The procedures set out by Final Rule, and currently being used by FDA in considering at least two SIP proposals, give neither advance notice nor the opportunity to comment on the proposed agency action by interested parties. By design, SIP proposals are confidential and not shared with the public. Plaintiffs have access only to information that the SIP Sponsor chooses to make public, including the existence of the SIP, details of the proposal and amendments thereto, and its status with the agency. And the Final Rule explicitly denies parties affected by a SIP the opportunity to comment on it. Because the Final Rule determines that the statutorily required safety and cost findings will be made in SIP proceedings, and then denies any opportunity for public notice and comment on SIP proposals, the Final Rule deprives regulated parties and the public at large of *any* opportunity to comment on the factual basis for the Secretary's safety and cost findings.

176. The Final Rule states that it is not necessary for regulated parties to have an opportunity to comment or otherwise participate in SIP proceedings because it considers SIP proceedings to be an "order" rather than a "rule," and because interested persons "may petition the Commissioner" under FDA's Citizen Petition regulations "with regard to, or to seek a stay of, the authorization of a SIP." 85 Fed. Reg. at 62121. But the ability to file a Citizen Petition is not a substitute for the APA's notice-and-comment rulemaking requirements. *See, e.g., Safari Club Int'l v. Zinke*, 878 F.3d 316, 331–32 (D.C. Cir. 2017) (agencies are "required to adhere to the notice-and-comment procedures under 5 U.S.C. § 553"); *Batterton v. Marshall*, 648 F.2d 694, 710 (D.C. Cir. 1980) ("[W]here, as here, the agency action satisfies the APA's definition of a rule and eludes exemptions to § 553, it is procedurally defective unless promulgated with the procedures required by law."). Further, FDA does not explain how interested persons can file a Citizen Petition when they are not even provided notice of pending SIP proposals.

177. Alternatively, even if the SIP proceedings were properly considered an informal adjudication, the Final Rule violates the APA by depriving all "interested persons"—including manufacturers who will be subject to statutory obligations under SIPs, as well as doctors, pharmacists, patients, and others who will be directly affected by the importation of Canadian drugs—from participating in the process. *See* 5 U.S.C. § 555(b).

178. Moreover, the process by which the Final Rule was promulgated violated the requirement, imposed by Section 804(b), that the HHS Secretary consult with the U.S. Trade Representative and Commissioner of Customs and Border Protection before issuing the final rule.

179. Section 804 provides that the Secretary may promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada, but only "after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection." 21 U.S.C. § 384(b).

180. Yet neither the Final Rule nor, to Plaintiffs' knowledge, any material subsequently disclosed by Defendants, suggest that the HHS Secretary engaged in the consultation with the U.S. Trade Representative or the Commissioner of Customs and Border Protection required by Section 804(b) before issuing the Final Rule. Although PhRMA has sought more information about any consultation between the Secretary and the Trade Representative and Commissioner, HHS has not provided any such documentation.

181. The Final Rule's procedures for SIPs thus violate the FDCA's and APA's minimum procedural requirements.

Count VII (Against All Defendants): First Amendment

182. Plaintiffs incorporate the foregoing allegations by reference.

183. The APA authorizes the reviewing court to hold unlawful and set aside agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

184. The Free Speech Clause of the First Amendment to the U.S. Constitution prohibits the Federal Government from making any law "abridging the freedom of speech." The First Amendment's protections encompass not only the freedom to speak, but the freedom to refrain from speaking or subsidizing others' speech. *E.g.*, *Wooley v. Maynard*, 430 U.S. 705, 714 (1977).

185. The Final Rule violates PhRMA members' speech rights in multiple respects, warranting vacatur of the Rule and counseling in favor of construing Section 804 to avoid these serious constitutional issues.

186. *First*, the Final Rule would compel manufacturers to allow importers to use, at no cost, the manufacturers' FDA-approved labeling, which includes the manufacturers' speech. The Final Rule specifically requires the importer to label the imported drug with the FDA-approved label, along with (1) a statement that "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program"; (2) the name and place of business of the importer; and (3) a National Drug Code specific to the imported drug. 21 C.F.R. § 251.13(b)(4). The labeling statement also may include the SIP website. *Id.* This compelled use of manufacturers' labels, which often include the manufacturer's name and other trademarks, would imply that the manufacturers vouch for the quality of the imported drugs and the accuracy of their labeling and are associated with the importer and the SIP, notwithstanding the statement that drugs were being imported without manufacturers' authorization. The First Amendment prohibits the government from requiring manufacturers to make these misrepresentations about products they make and affiliations that do not exist. The

statement that the drugs are imported "without authorization" of the manufacturer is not sufficient to cure this defect.

187. *Second*, the attestation, compelled use of manufacturers' labeling, and requirement that manufacturers conduct the statutory testing for free or provide importers with the information, standards, and drugs necessary to conduct the testing themselves amount to a compelled subsidy of importers. The First Amendment prohibits the government from requiring manufacturers to support other private parties unless the subsidy "serve[s] a compelling state interest that cannot be achieved through means significantly less restrictive of associational freedoms." *Janus v. AFSCME Council 31*, 138 S.Ct. 2448, 2465 (2018) (citation omitted). But the compelled attestation, use-of-labeling, and testing provisions would require just such a subsidy, by allowing importers to appropriate the goodwill associated with name-brand drugs; free-ride on manufacturers' substantial investments in developing, testing, manufacturing, and securing FDA approval for those drugs; and save the costs associated with testing drugs or acquiring the information, standards, and drugs necessary to conduct that testing, all under the guise of "simply call[ing] upon [manufacturers] to help with the process of product authentication, quality control, and product identification." 85 Fed. Reg. at 62,115; *see* 21 U.S.C. § 384(h) ("The 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."). The Final Rule states that a manufacturer's violation of its obligations under the Final Rule is a prohibited act under 21 U.S.C. § 331(aa), *see* 85 Fed. Reg. at 62,103, which is punishable under the strict-liability misdemeanor provision of the FDCA by up to one year's imprisonment, 21 U.S.C. § 333(a)(1), and under the felony provision of the FDCA by up to three year's imprisonment, 21 U.S.C. § 333(a)(2). Moreover, the FDCA

specifies that a knowing violation of Section 804(e), which relates to the statutory testing requirements for imported drugs, is punishable by up to 10 years' imprisonment. § 333(b)(6).

188. *Third*, the Final Rule would also restrict manufacturers' speech rights by depriving them of the opportunity to add to the labels of imported drugs any disclaimers or other language by which they could note that, for example, they disagree with claims that imported drugs are equivalent to approved drugs, or do not stand behind such products. The Rule would thus exacerbate manufacturers' injury from having to associate themselves with imported drugs by also restricting them from speaking their opinion about those drugs. Moreover, the blanket statement that the drugs were imported *without* authorization of the manufacturer also violates manufacturers' First Amendment rights, insofar as some manufacturers in some situations may approve of such importation.

189. *Fourth*, the Final Rule would compel manufacturers to make attestations with which they may disagree about drugs to be imported. The First Amendment prohibits the government from compelling speech where "the complaining speaker's own message [is] affected by the speech it [is] forced to accommodate." *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 63 (2006). As noted above, the Final Rule requires the manufacturer of a drug proposed to be imported under a SIP to attest that, *inter alia*, the imported drug meets certain conditions of an FDA-approved drug's NDA or ANDA (including that the imported drug was manufactured in accordance with the conditions described in the NDA or ANDA and in compliance with CGMPs), and to provide "[i]nformation needed to confirm that the labeling of the [imported] drug complies with labeling requirements" of the FDCA. 21 C.F.R. § 251.5(c)(4)(xii). The manufacturer must either provide that attestation within 30 days of receiving the importer's request or "articulate

with specificity the reason(s) why it cannot provide the attestation and information statement." *Id.* § 251.5(d). The Final Rule does not establish a process for resolving disputes over attestations, as when FDA disagrees with the manufacturer's belief that the manufacturer can truthfully make the required attestation. Faced with such uncertainty and the possibility of criminal prosecution under the strict-liability misdemeanor provision of the FDCA, manufacturers may feel compelled to make attestations with which they disagree, in violation of the First Amendment.

190. Accordingly, the Final Rule violates the First Amendment and thus APA § 706(2)(B).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks an order and judgment:

a. Holding unlawful, setting aside, and declaring invalid the Certification and Final Rule in their entirety;

b. Declaring, *inter alia*, that the Secretary has failed to properly certify that implementation of Section 804 will pose no additional risk to public health and safety and will result in a significant reduction in the cost of covered products to the American consumer;

c. Enjoining Defendants from implementing or enforcing any aspect of the Certification and Final Rule;

d. If necessary and appropriate, remanding this proceeding to HHS and FDA for reconsideration in light of the relief requested above;

e. Retaining jurisdiction to ensure compliance with this Court's order;

f. Awarding Plaintiffs the costs of their participation in this action, including attorneys' fees; and

g. Granting such other relief as the Court deems just and proper.

Dated: July 2, 2021

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