UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 950 F Street NW, Suite 300, Washington, DC 20004; PARTNERSHIP FOR SAFE MEDICINES, 315 Montgomery St, Suite 900, San Francisco, CA 94104; and THE COUNCIL FOR AFFORDABLE HEALTH COVERAGE, 440 First Street NW, Suite 430, Washington, DC 20001,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., 200 Independence Avenue SW, Washington, DC 20201; ALEX M. AZAR II, Secretary of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, in his official capacity only; U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue, Silver Spring, MD 20993; and STEPHEN M. HAHN, Commissioner of Food and Drugs, 10903 New Hampshire Avenue, Silver Spring, MD 20993, in his official capacity only,

Defendants.

Case No._____

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 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* 85 Fed. Reg. 62,094 (Oct. 1, 2020) (the "Final Rule"); Alex M. Azar, II, Sec'y, HHS, Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020) (the "Certification").[1]

To ensure the safety of the U.S. drug supply, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), prohibits entities other than a drug's manufacturer and entities authorized by that manufacturer from importing into the United States a drug that is labeled for and exported to another country, with narrow exceptions. Section 804 of the FDCA, 21 U.S.C. § 384, 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 would yield little to no savings for American consumers, HHS

[1] *Available at* https://www.safemedicines.org/2020/09/hhs-secretary-sent-congress-the-certification-to-allow-canadian-drug-importation.html.

Secretaries of both political parties have consistently declined for nearly two decades to certify importation. As recently as May 2018, current 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 an election, the Secretary has written 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. And HHS and FDA (together, the "Agencies") have 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. For the reasons that follow, the HHS Secretary's Certification is contrary to Section 804 and unsupported by the record, and the Final Rule disregards key protections of the FDCA that are designed to ensure patient safety. In addition, there is no indication that the Final Rule will reduce costs to actual American patients. Furthermore, aspects of the Final Rule are contrary to the FDCA, 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

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

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 account for approximately 70 percent of 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. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives. As explained further below, the Certification and Final Rule directly and adversely affect PhRMA's members in multiple ways.

3. 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.

4. 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.

5. Plaintiff 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.

6. Defendant the U.S. Department of Health and Human Services ("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.

7. Defendant Alex M. Azar II is the Secretary of HHS and is ultimately responsible for HHS's operations, including the development and implementation of the Final Rule. Furthermore, under the FDCA, Secretary Azar is principally responsible for, among other things, (a) the Certification at issue in this suit, 21 U.S.C. § 384(*l*)(1); and, if a Certification is made, (b) issuing regulations governing the commercial importation of prescription drugs from Canada, *id.* § 384(b); and (c) waiving prohibitions against personal importation of certain drugs, *id.* § 384(j). Secretary Azar maintains an office in HHS's Washington, D.C., headquarters, and is sued in his official capacity only.

8. Defendant the U.S. Food and Drug Administration ("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.

9. Defendant Dr. Stephen M. Hahn is the Commissioner of Food and Drugs and is principally responsible for FDA's operations, including its development and implementation of the Final Rule and approval of SIPs. Dr. Hahn maintains an office in FDA's headquarters at White Oak in Silver Spring, Maryland, and is sued in his official capacity only.

JURISDICTION AND VENUE

10. This action arises under the FDCA, the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* ("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.

11. 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.

12. Venue in this Court is proper under 28 U.S.C. § 1391(e)(1) because Defendants Secretary Azar 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.

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").[3]

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").[4] 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

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

[4] 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). 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. *See*

FDA, Div. of Import Ops. & Pol'y, Information on Importation of Drugs (last accessed Oct. 19, 2020).[5]

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 also prohibits the importation of foreign-manufactured drugs and the reimportation of drugs that are manufactured in the United States and exported abroad unless the drug is authorized for importation by the drug's manufacturer or reimported by that manufacturer,

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

with limited 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, discussed further below. 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 (certain drugs imported 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); *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. Further, as the Task Force Report recognized, Health Canada is unlikely to prioritize 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, that sets maximum permissible drug prices using a complex formula that includes the prices charged for comparable drugs in other countries.[6]

21. 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.[7] However, use of generic drugs is much more widespread in the United States than in Canada. 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).

22. 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

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[6] 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.

[7] 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.

10 or 20 percent of U.S. prescriptions in Canada would exhaust the Canadian prescription drug 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).

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

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.

24. 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

[§ 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).

25. 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."

26. 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.

27. 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").[8]

28. As with the MEDS Act, these provisions do not take effect automatically. Instead, Congress retained the balance it struck in the MEDS Act: The Executive Branch could 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 found that it could be

[8] 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).

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

29. 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).[9]

30. 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).

31. 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 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).

[9] 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).

32. 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).

33. 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 importation of prescription drugs by individuals. 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.

34. 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 expressly stated that it left existing provisions relating to the importation untouched: "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.

35. 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.

36. 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).

37. 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.").

38. 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.*

39. 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.*

40. 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, 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, and in part because importation would raise serious questions under the U.S. Constitution's Takings Clause and under U.S. and international intellectual property law. *Id.* at 91–97.

3. HHS Secretaries Repeatedly Refused to Certify Section 804.

41. 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).[10] Indeed, prior to proposing the scheme at issue here, 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 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.*

42. The Agencies consistently and successfully maintained the position that importation could not be implemented in a way that would result in significant consumer savings and would not increase public health risks in the face of efforts by state and local governments to force them to authorize importation.

43. 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

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

> 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).

44. 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

45. 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).

46. 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[11] (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.[12] If the testing were successful, the Importer would 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.

47. 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

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[11] 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").

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

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."

48. 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 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.

49. 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, because 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);[13]; *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).[14]

50. 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:

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

[14] *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 2019	7 3	10 10	
Annualized Quantified	.....	.....	.....	2019 2019	7 3	10 10	
Qualitative	Potential cost savings to consumers and third-party payers or entities			.....	.....	10	
Costs:							
Annualized Monetized $millions/year	.....	.....	.....	2019 2019	7 3	10 10	
Annualized Quantified	.....	.....	.....	2019 2019	7 3	10 10	
Qualitative	Potential costs to Federal Government, SIP sponsors, importers, and manufacturers of imported drugs			.....	.....	10	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	2019 2019	7 3	10 10	
From/To	.....	From:			To:		
Other Annualized Monetized $millions/year	.....	.....	.....	2019 2019	7 3	10 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:							

51. 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.

52. 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).[15] 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).[16]

53. 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.* Whatever bearing these considerations may have on the Secretary's decision not to certify personal importation, the

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

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

Secretary's decision to make a conditional certification as to commercial importation alone is contrary to both the text of the statute and the Agencies' successful litigation positions in *Vermont* and *Montgomery County*.

54. 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.

55. 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

56. 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."

57. 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).

58. 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

59. The Final Rule was publicly released on September 24, 2020, and published in the Federal Register on October 1, 2020. 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 "Section 804 Importation Programs" or "SIPs" to facilitate the importation of certain prescription drugs from Canada.[17] Such a SIP Sponsor 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 Canadian wholesaler that will purchase the drugs directly from the drugs' manufacturers (the "Foreign Seller") and a U.S. pharmacy or wholesaler that will receive delivery of the drugs from the Foreign Seller (the "Importer"). 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

[17] 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')").

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. This SIP scheme poses additional risk to the public's health and safety in multiple ways.

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.

61. 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).

62. 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 does not have 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.

63. *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, would differ from drugs approved in the respective applications: For example, the parties responsible for relabeling and repackaging a drug imported under a SIP and the relabeling and repackaging processes would not be identified in the 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.

64. *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 would 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.

65. *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 product.

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

66. 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.

67. *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; do not have the systems in place to inspect drug supply chain participants; play no role in implementing the DSCSA; lack expertise with pharmacovigilance; and 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).[18] 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).

[18] *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).

68. *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, will inevitably increase safety risks (as well as requiring substantial investments, the recoupment of which would greatly reduce, if not eliminate, any purported cost savings from importation).

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

69. 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 Final Rule adopts purported substitutes for the DSCSA that are inadequate. 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).

70. 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 would be obligated to affix/imprint product identifiers to drugs imported under Section 804 but not drugs that comply with the DSCSA. An Importer also would have to attempt to 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 may not even be possible—is unnecessary under the DSCSA, which requires transaction information to be exchanged at each step of the supply chain. Such gaps may mask lapses in supply chain security that would otherwise be apparent and 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>

71. 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' TRADE-SECRETS AND SPEECH RIGHTS.

72. The Final Rule also requires manufacturers to take a variety of harmful steps to facilitate importation.

73. A drug's manufacturer would be required to facilitate importation by assisting Importers with the testing required by Section 804, and would face the Hobson's choice of either conducting the testing itself for free or turning over all information necessary to authenticate the drug and 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").

74. The information a manufacturer would be required to turn over to facilitate testing 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.").

75. 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.

76. Moreover—and despite the absence of any provision in Section 804 authorizing such a requirement—the manufacturer would be 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 new drug application or abbreviated new drug application 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 importation scheme under the final rule, would include:

- "[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)."

77. 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. 21 C.F.R. § 251.5(d). Elsewhere, however, the Final Rule states that knowing failure to comply with the requirement that the manufacturer "supply the information needed to authenticate the drug being tested and to confirm that the labeling is in compliance with the [FDCA]" is a criminal offense subject to up to 10 years' imprisonment. 85 Fed. Reg. at 62,103.

78. The manufacturer would also be required 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), or such approval would be deemed to have been given if the manufacturer did not give it within 30 days of a request, 21 C.F.R. § 251.13(a). Drug labeling for NDA products will typically include trademarked information, such as drugs' brand names and logos.

79. Drugs imported under the Final Rule would be required to bear the following statement: "[This drug was/These drugs were] imported from Canada without the authorization of

[Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program." 21 C.F.R. § 251.13(b)(4)(iv)

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, 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. The Final Rule's Regulatory Impact Analysis notes, however, 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).[19]

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

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:

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					7%		
	Annualized Monetized $millions/year					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. HHS has also claimed in the Final Rule that the 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.

85. 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 SIPS

86. States stand ready to begin importing drugs under the Final Rule. As of November 23, 2020, at least six States have moved to develop programs for the importation of Canadian drugs under Section 804.

87. For example, 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 also requires the State to move with haste to implement the program: The State has until December 15, 2020, to submit a formal request for HHS to approve its proposed program, *id.* § 26-4-6, and must begin implementing and operating the program within six months of receiving that approval, *id.* § 26-4-7. On October 27, 2020, the New Mexico Department of Health released its draft SIP proposal for public comment.[20] That proposal is notably short on detail about how the State will ensure that importation does not increase public health and safety risks, and offers only the roughest back-of-the-envelope math (based largely on spending by *insurance plans*, not individual consumers) to support its claims that importation would reduce the cost of covered products to New Mexico consumers. N.M. Dep't of Health, Draft Prescription Drug Importation Plan at 9–14 (Oct. 27, 2020) (purported savings to consumers); *id.* at 15–32 (plan for purported compliance with federal law).

88. At least five other States—Colorado, Florida, Maine, New Hampshire, and Vermont—have also taken steps to sponsor programs for the importation of Canadian drugs. All five have enacted legislation to that effect. *See* Colo. Rev. Stat. Ann. § 25.5-2.5-201 *et seq.*; Fla. Stat. § 381.02035; 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). This legislation requires each State to move expeditiously to secure federal approval for these programs, as shown in the following table:

State	**Deadline to Seek HHS Approval**	**Deadline to Begin Operating SIP**	**Citation(s)**
Colorado	Sept. 1, 2020	Six months of federal approval	Colo. Rev. Stat. § 25.5-2.5-205(1)

[20] *Available at* https://www.nmhealth.org/publication/view/policy/6418/.

Florida	July 1, 2020	Six months of federal approval	Fla. Stat. § 381.02035(9)
Maine	May 1, 2020 or as soon as applicable after the finalization of the Final Rule	Six months of federal approval	Me. Rev. Stat. title 5, § 2042(2)–(3)
New Hampshire	February 1, 2021		N.H. Rev. Stat. § 126-CC:2
Vermont	July 1, 2020	Six months of federal approval and funding from state legislature	18 Vt. Stat. § 4653 *et seq.*

89. At least five 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);[21] State of Florida, Florida's Canadian Prescription Drug Importation Concept Paper (Aug. 20, 2019);[22] Maine Dep't of Health & Human Servs., Application to Operate a Section 804 Prescription Drug Importation Program (submitted May 1, 2020);[23] N.M. Dep't of Health, Section 804 Drug Importation Program Application (Oct. 27, 2020);[24] Vermont's Canadian Wholesale Importation Program for Prescription Drugs (submitted July 1, 2020).[25] Notably, Florida anticipated that it would seek approval based on purported savings to the State itself (which purchases drugs for use in, for example, state prisons) and that it would outsource responsibility for running the SIP on a day-to-day basis and ensuring

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

[22] *Available at* https://www.safemedicines.org/wp-content/uploads/2019/08/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf. The Florida proposal is

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

[24] *Available at* https://www.nmhealth.org/publication/view/policy/6418/.

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

that Importers comply with state and federal law. *See* Fla. Can. Prescription Drug Importation Concept Paper at 5, 7, 16.

INJURIES RESULTING FROM THE CERTIFICATION AND FINAL RULE

90. The Certification and Final Rule inflict, or are substantially likely to inflict, serious harm on Plaintiffs' members.

91. 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.

92. 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 they authorize the importation. The Final Rule will accordingly reduce the goodwill associated with PhRMA members' products and expose those members to reputational harm and litigation risks stemming from the increased likelihood that drugs imported under the Final Rule and bearing members' trademarks will be counterfeit, of substandard quality, or otherwise adulterated.

93. Implementation of the Final Rule would require manufacturers to make substantial investments in pharmacovigilance to address increased adverse events and medication errors

associated with Section 804-imported products. It also would require significant investments in education to consumers 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. Furthermore, implementation of the Final Rule increases the likelihood that Plaintiffs' members will be forced to defend themselves in products-liability litigation when American consumers are injured by 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.

94. Moreover, the Final Rule will intrude on (and may be held to 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 DMF holders—either to conduct the required testing of imported drugs at the border (which will cost these entities time and money to implement), 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 will 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, drugs themselves, and drug 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 patents or exclusivities would upend the Hatch-Waxman Act's successful balance between promoting innovation and fostering drug competition.

95. 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.

96. 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. Instead, 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. As the Final Rule explains, "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—yet still not 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 any difference between the cost of comparable U.S. and Canadian drugs.

97. The Certification and Final Rule will cause additional harms to PSM members. In particular, member organizations with a shared interest in ensuring the safety of the U.S. drug supply will be harmed.

a. *Patient advocacy organizations*, such as Oncology Managers of Florida, Rx Outreach, and Rx Partnership, will be exposed to increased risk that U.S. consumers will receive unapproved, misbranded, and adulterated drugs;

b. *Organizations combatting the misuse of prescription drugs*, such as the National Association of Drug Diversion Investigators, will be forced to expend additional resources to curtail the circulation of unapproved, misbranded, and adulterated drugs; and

c. *Distributor and pharmacy associations*, 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, 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, among other injuries.

98. The Certification and Final Rule will cause additional harms to 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.

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, among other injuries.

b. *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.

c. *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.

d. *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

CLAIMS FOR RELIEF

I. CERTIFICATION VIOLATES THE APA AND FDCA.

Count I (Against Defendants HHS and Azar): APA—Contrary to Law (Certification)

99. Plaintiffs incorporate the foregoing allegations by reference.

100. 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).

101. 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).

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

103. *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.

104. *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). Secretary Azar did not certify "implementation of this section" but only commercial importation under subsections (b) through (h).

105. *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.

106. *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.

107. Accordingly, Secretary Azar's certification under Section 804(*l*)(1) was both contrary to law and in excess of statutory right.

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

108. Plaintiffs incorporate the foregoing allegations by reference here.

109. 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).

110. Secretary Azar's decision to certify importation under Section 804(*l*)(2) was arbitrary and capricious in light of the record before him, for several reasons including the following.

111. *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).

112. *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.

113. *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).

114. *Fourth*, the Secretary's rationale for 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.

115. *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.

116. Accordingly, Secretary Azar's certification under Section 804(*l*)(1) was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

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

117. Plaintiffs incorporate the foregoing allegations by reference.

118. 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).

119. Here, the process by which HHS issued the Section 804(*l*)(1) certification was legally flawed in ways that violated both the FDCA and the APA.

120. *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 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.

121. *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).

Instead, the Secretary deferred consideration of such facts until such time as FDA approves one or more SIP Proposals. But the Final Rule does not provide for public notice and comment on SIP Proposals, which will necessarily include confidential information that cannot be disclosed to the public. As a result, the Secretary's conditional certification will deprive regulated parties and the public at large of *any* opportunity to comment on the factual basis for the Secretary's safety and cost findings.

122. This issuance of the Final Rule without prior issuance of a valid NPRM thus violated the notice-and-comment rulemaking requirements of the APA.

II. THE FINAL RULE VIOLATES THE APA, FDCA, AND CONSTITUTION.

Count IV (Against All Defendants): APA—Contrary to Law (Final Rule)

123. Plaintiffs incorporate the foregoing allegations by reference.

124. The Final Rule conflicts with the FDCA in several respects.

125. *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 necessarily 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.

126. *Second*, 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.

127. *Third*, 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.

128. *Fourth*, 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). 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 would discloses these trade secrets and confidential information without the statutory authority to do so.

129. *Fifth*, 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);[26] *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.[27] 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 manufacturer) may lack access. Section 804 nowhere authorizes the Agencies to require such information from anyone other than a drug's manufacturer.

130. 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. These provisions 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

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

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

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.

131. 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)

132. Plaintiffs incorporate the foregoing allegations by reference here.

133. The Final Rule itself would also be arbitrary and capricious in at least three respects.

134. *First*, the Final Rule itself would represent 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.

135. *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 112. 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.

136. *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 provisions 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.

Count VI (Against All Defendants): First Amendment

137. Plaintiffs incorporate the foregoing allegations by reference.

138. 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).

139. 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).

140. 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.

141. *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.

142. *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.").

143. *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.

144. *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. The Final Rule insists, however, that knowing violation of the Rule is a crime punishable by up to 10 years' imprisonment. Faced with such harsh sanctions, manufacturers may feel compelled to make attestations with which they disagree, in violation of the First Amendment. *See, e.g., CTIA v. City of Berkeley*, 928 F.3d 832, 853 (9th Cir. 2019) (Friedland, J., dissenting) (First Amendment prohibits "requiring businesses to make false or misleading statements about their own products").

145. 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: November 23, 2020

Respectfully submitted,

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