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.

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