IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

OUTSOURCING FACILITIES ASSOCIATION
1050 Connecticut Ave., NW
Suite 1100
Washington, D.C. 20036-5403,

Plaintiff,

v.

XAVIER BECERRA
in his official capacity as
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201,

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201,

ROBERT M. CALIFF
in his official capacity as
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993, and

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Civil Action No. 22-1702

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Outsourcing Facilities Association ("OFA") brings this complaint against Defendants Xavier Becerra, Robert Califf, U.S. Department of Health and Human Services ("HHS"), and U.S. Food and Drug Administration ("FDA") (collectively, "Defendants") for violating the Administrative Procedure Act ("APA"). In support thereof, OFA states the following:

NATURE OF ACTION

1. This action challenges as a violation of the Administrative Procedure Act Defendants' unreasonable delay in carrying out Congress's directive to list the bulk drug substances (*i.e.*, active pharmaceutical ingredients) "for which there is a clinical need." 21 U.S.C. § 353b(a)(2)(A)(i). Congress assigned this task to the HHS Secretary nearly a decade ago. Yet, Defendants still have not listed a single bulk drug substance for compounding sterile drugs.

2. In November 2013, Congress quickly reacted to an urgent crisis in the nation's supply of safely compounded sterile drugs by creating a new type of FDA-regulated entity called "the drug compounding outsourcing facility." These facilities are also known as "503B facilities" because they were created by Section 503B of the Food, Drug, and Cosmetic Act ("FD&C Act") to safely compound sterile drugs. Plaintiff Outsourcing Facilities Association ("OFA") is a trade association whose members responded to Congress's urgent call by making substantial investments to establish 503B facilities and register them with the U.S. Food and Drug Administration ("FDA").

3. Congress intended 503B facilities to supply safely compounded sterile drugs to the nation's healthcare providers using bulk drug substances for which there is a clinical need and directed the HHS Secretary to list those substances in the Federal Register using 60-day

notice and comment procedures. 21 U.S.C. § 353b(a)(2)(A)(i). The Secretary delegated that responsibility to FDA, which refers to the list as the "503B Bulks List."

4. In more than eight years, however, FDA has added only four substances to the 503B Bulks List, all of which are for compounding topical dosage forms, not sterile drugs. Defendants' unreasonable delay in identifying the bulk drug substances for which there is a clinical need is thwarting Congress' purpose in creating 503B facilities and hurting public health by denying healthcare providers' access to the safely compounded sterile drugs their patients need.

5. In 2018, FDA established a process to publicly categorize nominations for adding a bulk drug substance to the 503B Bulks List. The categorization of nominations is how FDA indicates whether the nominator provided sufficient information for FDA to act on the nomination or if the nominator must supply more information. FDA stated at the time that it would categorize nominated substances monthly. Yet, FDA has not categorized many of the nominations it has received, including more than 30 of the OFA-nominated substances. More than half of those OFA-nominated substances were submitted to FDA more than three years ago.

6. Defendants should comply with Congress's directive to list the bulk drug substances for which there is a clinical need so the facilities Congress created to compound sterile drugs for the nation's healthcare providers can serve public health as Congress intended. At a minimum, FDA should follow its own policy by promptly categorizing the nominations that have languished in regulatory limbo for years and categorize any new nominations monthly as it said it would.

PARTIES

7. Plaintiff Outsourcing Facilities Association is the trade association representing FDA-registered outsourcing facilities ("503B facilities") operating pursuant to Section 503B of the FD&C Act. OFA's members provide compounding services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications. OFA has been actively following FDA's implementation of the Compounding Quality Act ("CQA") and has brought together members of industry to advocate for a safe, reasonable and practical rollout of the CQA. OFA's offices are located at 1050 Connecticut Ave., NW Suite 1100, Washington, D.C. 20036-5403.

8. Defendant Xavier Becerra ("Secretary") is Secretary of U.S. Health and Human Services ("HHS"). He maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In his capacity as Secretary, he is responsible for the conduct and policies of HHS. Defendant Becerra, by and through his designees at HHS, has delayed and withheld the agency action Congress required. His governmental activities occur in this District and nationwide. Defendant Becerra is sued solely in his official capacity.

9. Defendant Robert Califf ("Commissioner") is Commissioner of the U.S. Food and Drug Administration ("FDA"). FDA is the agency that administers the programs under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Defendant Califf, by and through his designees at FDA, has delayed and withheld the agency action Congress required. His governmental activities occur in this District and nationwide. Defendant Califf is sued solely in his official capacity.

10. Defendant HHS is a cabinet-level department of the United States government. Its headquarters and principal place of business are at 200 Independence Avenue, SW, Washington, D.C. 20201. Its governmental activities occur in this District and nationwide.

11. Defendant FDA is an agency of the United States and a division of HHS. FDA's headquarters and principal place of business are at 10903 New Hampshire Avenue, Silver Spring, MD 20993. Its governmental activities occur in this District and nationwide. FDA is the federal agency in charge of administering the FD&C Act, including implementation of the Drug Quality and Security Act of 2013 ("DQSA").

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action presents a case and controversy under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FD&C Act") and the Administrative Procedure Act, 5 U.S.C. § 551 et seq. ("APA").

13. Plaintiff's claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, 5 U.S.C. § 706, 28 U.S.C. § 1361, 28 U.S.C. § 1651(a), Rules 57 and 65 of the Federal Rules of Civil Procedure, and the general legal and equitable powers of this Court (which exist even absent a finding of unreasonable delay).

14. OFA has standing because it, and at least one of its members, have been and continue to be harmed by Defendants' delay in identifying the bulk drug substances "for which there is a clinical need," as required under 21 U.S.C. § 353b(a)(2)(A)(i). These injuries would be redressed by requiring Defendants to fulfil their obligation to identify those bulk drug substances. Through this lawsuit, OFA seeks to vindicate interests that are germane to its purposes. Litigation will not be adversely affected by the absence of the individual members of

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