IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, 1600 20th Street NW Washington, DC 20009, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	)	Civil Action No. 19-1229

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Public Citizen brings this action pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 706, to compel the United States Food and Drug Administration (FDA) to act on a petition Public Citizen filed on June 29, 2016, seeking revised warnings about impulse-control problems and compulsive behavior on the labeling of dopamine agonist drugs. In that petition, Public Citizen requested that the FDA take two actions: (1) require a boxed warning about the risk of developing certain impulse-control problems and compulsive behaviors on the product labeling for all dopamine agonist drugs approved in the United States; and (2) establish a risk evaluation and mitigation strategy (REMS) for dopamine agonist drugs that includes the requirement that a "Dear Health Care Provider" (DHCP) letter be distributed to health care providers and a Medication Guide be distributed to patients, both warning about the risk of certain impulse-control problems and compulsive behaviors and providing instruction on appropriate measures to reduce

the risk of developing such behaviors and of recognizing and mitigating the harms from such adverse reactions when they occur.

2. Although more than two and a half years have passed since Public Citizen filed its petition, the FDA has neither granted nor denied the petition. In this action, Public Citizen seeks a declaration that the FDA has acted unlawfully by withholding action on Public Citizen's petition and an order requiring the FDA to act thereon.

PARTIES

3. Plaintiff Public Citizen is a non-profit, public-interest research, litigation, and advocacy organization based in Washington, D.C. Since its founding in 1971, Public Citizen has advocated before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide range of consumer-protection issues, including issues related to drugs, medical devices, and health care policy. Public Citizen submitted the petition at issue in this case, and it and its members have been, and continue to be, injured by the FDA's failure to act on the petition.

4. Defendant FDA is a component of the Department of Health and Human Services, an agency of the federal government. The FDA is responsible for administration of the FDCA. In particular, the FDA regulates the content and format of prescription drug labeling. *See* 21 C.F.R. § 201.

JURISDICTION

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

6. Six drugs in the dopamine agonist class are currently available in the United States: apomorphine, bromocriptine, cabergoline, pramipexole, ropinirole, and rotigotine. Dopamine agonist drugs are approved for a wide variety of indications, including treatment of Parkinson's

disease (apomorphine, bromocriptine, pramipexole, ropinirole, rotigotine), restless legs syndrome (pramipexole, ropinirole, rotigotine), hyperprolactinemic disorders (bromocriptine, cabergoline), acromegaly (bromocriptine), and type 2 diabetes mellitus (bromocriptine).

7. Dopamine agonist drugs are drugs within the meaning of the FDCA, 21 U.S.C. § 321(g)(1).

8. The FDCA, 21 U.S.C. § 331(a), prohibits the introduction into interstate commerce of any drug that is misbranded. A drug is misbranded unless its labeling bears adequate warnings. *Id*. § 352(f).

9. Evidence shows a classwide, causal relationship between dopamine agonist drugs and impulse-control behaviors, many of which can be classified as impulse-control disorders. Impulse-control problems and compulsive behaviors associated with dopamine agonist drugs include pathological gambling, hypersexuality, compulsive shopping/spending/buying, and compulsive eating.

10. Peer-reviewed studies have identified dopamine agonist drugs as increasing the risk for developing such impulse-control problems and compulsive behaviors two- to twenty-fold. This effect has been demonstrated with different dopamine agonists and across different patient populations.

11. Impulse-control problems and compulsive behaviors caused by dopamine agonist drugs can be extremely serious, having devastating, life-altering effects on patients and their families. Losses of hundreds of thousands of dollars, divorces, criminal charges, and suicide attempts have been reported.

12. None of the dopamine agonist drugs includes a boxed warning about impulse-control problems and compulsive behaviors. Moreover, none describes which patients may be at the highest risk of such adverse events.

13. On June 29, 2016, pursuant to 21 C.F.R. § 10.30, Public Citizen sent a petition to the FDA urging the FDA to require on the product labeling for all dopamine agonist drugs currently approved in the United States a boxed warning describing the risk of developing certain impulse-control problems and compulsive behaviors, including pathological gambling, hypersexuality, compulsive shopping/spending/buying, and compulsive eating. Public Citizen also urged the FDA to establish a REMS for dopamine agonist drugs that includes the requirements that a DHCP letter be distributed to doctors and healthcare providers and that a Medication Guide be distributed to patients with all new and refill prescriptions for such drugs. Public Citizen explained that the DHCP and Medication Guide should warn doctors and patients about the risk of certain impulse-control problems and compulsive behaviors and instruct them in appropriate measures to reduce the risk of developing such behaviors and to recognize and mitigate the harms from these adverse reactions when they occur.

14. In its petition, Public Citizen examined the results of more than 80 studies regarding the link between impulse-control problems and compulsive behaviors and the use of dopamine agonist drugs. It summarized findings from industry-sponsored randomized, controlled trials, discussed published analyses of the FDA Adverse Event Reporting System (FAERS), and explained that the development of abnormal behavior is consistent with the pharmacology of the drugs. It also described the real-world impact of impulse-control problems and compulsive behaviors on patients and their families and set forth possible strategies for prevention and mitigation. It explained that a boxed warning is needed to strengthen the current warnings found

in the labeling of dopamine agonist drugs, and that a REMS is also necessary to ensure that the benefits of dopamine agonist drugs outweigh their risks. It suggested wording both for the boxed warning and for the top of the Medication Guide.

15. Public Citizen's petition provided sufficient grounds for the FDA to require the addition of a boxed warning to the labeling of dopamine agonist drugs, as well as for the FDA to require a REMS that includes distribution of a DHCP letter and Medication Guide with all such drugs.

16. On June 30, 2016, the FDA docket management division acknowledged its receipt of the petition and assigned it docket number FDA-2016-P-1874.

17. On December 20, 2016, the FDA sent a letter to Public Citizen, indicating that the FDA had not yet reached a decision on the petition because the petition "raises complex issues requiring extensive review and analysis by Agency officials."

18. To date, the FDA has not issued a decision on Public Citizen's petition or taken either of the actions requested in the petition. The FDA has failed to act despite the seriousness of the adverse effects about which Public Citizen petitioned the agency.

19. The FDA's decisional process is lagging unreasonably in light of the nature and extent of the public health interests addressed in the petition.

CLAIMS FOR RELIEF

20. The FDA's failure to act on Public Citizen's petition constitutes agency action unlawfully withheld or unreasonably delayed and violates the Administrative Procedure Act, 5 U.S.C. § 706(1).

21. The FDA's failure to act on Public Citizen's petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, Plaintiff requests that this Court

A. Declare unlawful the FDA's failure to act on Public Citizen's petition;

B. Order the FDA to issue a decision on Public Citizen's petition within 30 days of the Court's order;

C. Award Public Citizen its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

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