UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANTONEI B. CSOKA, Ph.D., 5725 North Capitol Street NW Washington, DC 20011, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	)	Civil Action No. 24-1486

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Antonei B. Csoka, Ph.D., brings this action pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706, to compel the United States Food and Drug Administration (FDA) to act on a citizen petition submitted on May 10, 2018. The petition requests that the FDA require the revision of all selective serotonin reuptake inhibitor (SSRI) and serotonin-norepinephrine reuptake inhibitor (SNRI) product labeling to warn of the risk that sexual side effects may persist, worsen, or begin after stopping SSRI or SNRI treatment. The petition also requests that the FDA require the issuance of a "Dear Health Care Provider Letter" that would inform those who prescribe SSRIs and SNRIs of the serious adverse reactions associated with their use, and the development of a medication guide and communication plan to make patients aware that the drugs have serious side effects that could persist post-treatment. Although the petition was filed six years ago, the FDA has neither granted nor denied it. Plaintiff seeks a declaration that the FDA has acted unlawfully by withholding action on the petition and an order requiring the FDA to act.

PARTIES

2. Plaintiff Antonei B. Csoka, Ph.D., is an Associate Professor in the Department of Anatomy at Howard University College of Medicine in Washington, DC, where he directs the Epigenetics Laboratory. Dr. Csoka has been researching Post-SSRI Sexual Dysfunction (PSSD) since 2004. He is a scientific advisor to the PSSD Network, a non-profit advocacy organization that seeks to increase awareness of PSSD, encourage research into potential treatments and cures, and offer support to patients. Dr. Csoka is one of the scientists who submitted the citizen petition at issue.

3. Defendant FDA is a component of the Department of Health and Human Services, an agency of the federal government. The FDA is responsible for deciding whether to approve new drug applications, for withdrawing approval of unsafe indications previously approved, and for regulating the content and format of prescription drug labeling.

JURISDICTION

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

FACTS

5. SSRIs and SNRIs are prescription drugs approved by the FDA to treat clinical depression and certain other conditions. SSRIs include citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), paroxetine (Paxil), sertraline (Zoloft), and vortioxetine (Trintellix). SNRIs include desvenlafaxine (Pristiq), duloxetine (Cymbalta), and venlafaxine (Effexor). SSRIs and SNRIs are known to cause adverse sexual effects, and current product labeling in the United States warns of disturbances to sexual functioning during treatment with SSRIs and SNRIs. The labeling does not currently convey the risk of persistent, worsening, or new symptoms of sexual dysfunction after stopping use of those drugs.

6. On May 10, 2018, a group of twenty-two physicians and scientists, including plaintiff Dr. Csoka, submitted to the FDA a citizen petition requesting that the product labeling be updated to state the risk of sexual dysfunction after stopping SSRI or SNRI treatment. The FDA's docket management division acknowledged receipt of the petition and assigned it docket number FDA-2018-P-1846.

7. The petition summarizes the scientific literature suggesting that the adverse sexual effects associated with the use of SSRIs and SNRIs can sometimes persist for years or indefinitely after discontinuation of the drugs, may emerge or worsen when the drugs are withdrawn, and may occur after only a brief exposure to the drugs. The petition explains that current labeling in the United States does not adequately convey the risk of broad, severe, and potentially permanent post-treatment changes to sexual function.

8. The petition requests that the FDA require the revision of SSRI and SNRI product labeling to warn of the risk of sexual side effects that may persist after discontinuation of the drug. The petition requests that the FDA require the issuance of a "Dear Health Care Provider Letter" that would inform those who prescribe SSRIs and SNRIs of such risks, and the development of a medication guide and communication plan to make patients aware of the risk. The petition explains that, without adequate warnings about the risk of potentially permanent damage to sexual functioning, patients and health care professionals cannot weigh the benefits of the drugs' use against the potential harms.

9. After receipt of the petition, the FDA posted it for public comment. The docket reflects receipt of 35 comments. The docket status is stated as "open." *See* https://www.regulations.gov/docket/FDA-2018-P-1846.

10. FDA regulations provide that, "[e]xcept as provided in paragraphs (e)(4) and (5) of this section," which provide for a shorter response time, the FDA "shall furnish a response to each petitioner within 180 days of receipt of the petition." 21 C.F.R. § 10.30(e)(2). On November 6, 2018, the FDA sent an "interim response" stating that it had not yet reached a decision because the petition "raises complex issues requiring extensive review and analysis."

11. To date, the FDA has not issued a decision on the May 2018 citizen petition and has not taken any of the actions requested in it.

12. After receipt of similar petitions in 2018, the drug regulatory agencies in Europe and Canada acted to warn patients and health care professionals of the risk that sexual side effects may persist after stopping SSRI or SNRI treatment. In 2019, the European Medicines Agency adopted product information updates to warn that SSRIs and SNRIs may cause long-lasting sexual dysfunction that may continue despite discontinuation of treatment. In 2021, Health Canada completed a safety review and announced updates to the labeling and product safety information for SSRIs and SNRIs to reflect the risk.

13. The FDA has unreasonably delayed issuing a decision in light of the nature and extent of the public health interests addressed in the petition.

CLAIM FOR RELIEF

14. The FDA's failure to act on the citizen petition constitutes agency action unlawfully withheld or unreasonably delayed. 5 U.S.C. § 706(1).

WHEREFORE, Plaintiff requests that this Court:

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

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

C. Award plaintiff his costs and attorney's fees under 28 U.S.C. § 2412; and

D. Grant all other appropriate relief.

Respectfully submitted,

/s/ *Michael T. Kirkpatrick*
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