UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANTONEI B. CSOKA, Ph.D.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 24-1486 (ABJ)
	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S RESPONSE IN OPPOSITION
TO DEFENDANT'S MOTION TO DISMISS

Plaintiff Antonei B. Csoka brought this action against the Food and Drug Administration (FDA) to challenge the FDA's failure to issue a decision on a petition that he submitted more than six years ago, in May 2018. Dr. Csoka has a substantive legal right to a decision, and the FDA's failure to provide one constitutes agency action unlawfully withheld or unreasonably delayed in violation of the Administrative Procedure Act (APA).

The FDA has moved to dismiss, asserting that Dr. Csoka lacks Article III standing because he has not alleged a cognizable injury. According to the FDA, its failure to issue a response to Dr. Csoka's petition is a procedural violation that has caused Dr. Csoka no harm. The FDA's unlawful six-year delay, however, has caused Dr. Csoka two cognizable injuries, each of which independently satisfies Article III: The FDA has deprived him of a substantive response to which he has an individualized legal entitlement, and it has deprived him of valuable information that would benefit his academic research. The Court should deny the FDA's motion to dismiss.

BACKGROUND

The Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction into interstate commerce of any drug that is misbranded, 21 U.S.C. § 331(a), and a drug is misbranded unless its

label bears adequate warnings, *id.* § 352(f). As the agency responsible for administering the FDCA, the FDA regulates the content and format of prescription drug labeling, and FDA regulations set forth procedures for concerned individuals to petition the FDA to take administrative action. 21 C.F.R. § 10.30. The regulations state that, "[e]xcept as provided" in certain regulatory subsections that establish a shorter deadline for the agency, the FDA "shall furnish a response to each petitioner within 180 days of receipt of the petition." *Id.* § 10.30(e)(2). When the FDA responds to a petition, it provides substantive discussion of the points raised in the petition and gives detailed reasoning as to why it will or will not take the administrative action that the petitioner has urged.[1]

Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) are prescription drugs that the FDA has approved to treat clinical depression and certain other conditions. Compl., ECF No. 1, ¶ 5. SSRIs and SNRIs are known to cause adverse sexual effects, and current product labeling in the United States warns of potential disturbances to sexual functioning during treatment with these drugs. *Id.* The labeling in the United States does not warn that such side effects may endure or worsen after a patient stops taking the drugs. *Id.*

Dr. Csoka is an Associate Professor in the Department of Anatomy at Howard University College of Medicine, where he directs the Epigenetics Laboratory. *Id.* ¶ 2. Dr. Csoka has been researching Post-SSRI Sexual Dysfunction (PSSD) since 2004. *Id.* He is a scientific advisor to the PSSD Network, a non-profit advocacy organization that aims to increase awareness of PSSD, encourage research into potential treatments and cures, and offer support to patients. *Id.*

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[1] *See*, *e.g.*, Letter from FDA to John Santmann, Post-Finasteride Syndrome Foundation (June 8, 2022), https://www.regulations.gov/document/FDA-2017-P-5787-0242 (43-page response); Letter from FDA to Donna J. Harrison, Am. Ass'n of Pro-Life Obstetricians & Gynecologists, et al. (Dec. 16, 2021), https://www.regulations.gov/document/FDA-2019-P-1534-0016 (40-page response); Letter from FDA to Victoria Powell, Pub. Citizen, et al. (Oct. 21, 2019), https://www.regulations.gov/document/FDA-2016-P-1874-0007 (39-page response).

On May 10, 2018, Dr. Csoka and twenty-one other physicians and scientists petitioned the FDA to require the revision of SSRI and SNRI product labeling to warn of the risk of sexual side effects that may persist, worsen, or begin after stopping SSRI or SNRI treatment. *Id.* ¶¶ 6–8. The petition also requests that the FDA require manufacturers to inform healthcare providers who prescribe SSRIs and SNRIs of these risks and to develop a medication guide and communication plan to explain these risks to patients. *Id.* ¶ 8. The petition explains that, without adequate warnings about the risk of potentially permanent damage to sexual functioning, patients and healthcare professionals cannot weigh the benefits of the drugs' use against the potential harms. *Id.* The FDA's docket management division acknowledged receipt of the petition and posted it for comment on the regulations.gov website.[2] *Id.* ¶¶ 6, 9.

On November 6, 2018, the FDA sent an "interim response" to Dr. Csoka's petition, informing him that it had not yet reached a decision because the petition "raises complex issues requiring extensive review and analysis," but that the FDA would respond to the petition as soon as it reached a final decision. *Id.* ¶ 10. More than six years have now passed since Dr. Csoka submitted the petition, and the FDA still has not supplied him with a response. *Id.* ¶ 11. During this time, regulatory authorities in both the European Union and Canada—which were petitioned at the same time as the FDA—have taken action to warn patients and healthcare professionals of the risk that sexual side effects may persist after stopping SSRI or SNRI treatment. *Id.* ¶ 12.

Dr. Csoka filed this action on May 20, 2024, alleging that the FDA's delay in responding to the petition has been unreasonable in light of the nature and extent of the public-health interests at stake. *Id.* ¶ 13. Dr. Csoka seeks a declaration that the FDA's failure to issue a decision constitutes

[2] The petition, comments, and related materials are available at https://www.regulations.gov/docket/FDA-2018-P-1846.

agency action unlawfully withheld or unreasonably delayed in violation of the APA, 5 U.S.C. § 706(1), and an order requiring the FDA to issue a decision. *Id.* ¶ 14. The FDA has moved to dismiss, arguing that Dr. Csoka lacks standing. Def.'s Mot. to Dismiss, ECF No. 8.

ARGUMENT

To establish Article III standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). Here, the FDA argues that Dr. Csoka's allegations fail to establish the first requirement: injury in fact.

The FDA is wrong. Federal statutes and FDA regulations assure an interested party that, if he petitions the FDA in accordance with 21 C.F.R. § 10.30, the FDA will give him something concrete in response. Dr. Csoka has fulfilled his end of the bargain, expending time and resources to petition the FDA in the manner provided by law. The FDA, however, has not fulfilled its end of the bargain, withholding from Dr. Csoka the response to which he is legally entitled, as well as the valuable information that the response would provide. The government's refusal to furnish an individual with a substantive benefit to which he claims a legal entitlement is a concrete, particularized injury. The FDA's theory that such an individual can establish standing only by alleging an additional, downstream harm that flows from the deprivation has no basis in law.

I. The deprivation of the substantive response to which Dr. Csoka is legally entitled is a cognizable injury.

FDA regulations, which have the force of law, provide that a petition filed in accordance with 21 C.F.R. § 10.30 will receive a substantive response. *See* 21 C.F.R. § 10.30(e). The APA, in turn, requires that the FDA provide such a response "within a reasonable time." 5 U.S.C. § 555(b).

Having filed a petition in accordance with the FDA's rules, Dr. Csoka has a right to an agency response—a concrete entitlement that is particular to him, that the FDA has withheld through its inaction, and that can be vindicated by an order requiring the FDA to issue a decision without further delay. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561–62 (1992) (observing that in a suit "challenging the legality of government … inaction," there is typically "little question that the … inaction has caused [the plaintiff] injury" as long as "the plaintiff is himself an object of the … forgone action[] at issue"). By failing to issue Dr. Csoka the response to which he is legally entitled, the FDA has injured him in a concrete and particularized way.

As the D.C. Circuit has explained, "a concrete and particular injury for standing purposes" need not cause "economic, physical, or psychological damage"; it "can also consist of the violation of an individual right conferred on a person by statute." *Zivotofsky ex rel. Ari Z. v. Sec'y of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) (holding that an alleged violation of the plaintiff's statutory entitlement to have "Israel" listed as his place of birth on his passport was a cognizable injury). Thus, for example, a plaintiff who has been denied access to government records to which he is entitled under the Freedom of Information Act, 5 U.S.C. § 552, has suffered a cognizable injury for standing purposes irrespective of "why he wants the information, what he plans to do with it, [or] what harm he suffered from the failure to disclose." *Id*. at 617. The injury arises from the fact that the requester "did not get what the statute entitled him to receive." *Id.* at 618.

In keeping with this principle, both this Court and the D.C. Circuit have for decades addressed challenges to the FDA's failure to provide a response to a plaintiff's petition, without noting any concern about the plaintiff's standing. *See*, *e.g.*, *In re NRDC*, 645 F.3d 400 (D.C. Cir. 2011); *Pub. Citizen Health Rsch. Grp. v. FDA*, 740 F.2d 21 (D.C. Cir. 1984); *Ctr. for Sci. in the Pub. Interest v. FDA*, 74 F. Supp. 3d 295 (D.D.C. 2014); *Hill Dermaceuticals, Inc. v. FDA*, 524 F.

Supp. 2d 5 (D.D.C. 2007); *Pub. Citizen Health Rsch. Grp. v. FDA*, 724 F. Supp. 1013 (D.D.C. 1989); *Pub. Citizen v. Dep't of Health & Human Servs.*, 632 F. Supp. 220 (D.D.C. 1986).

Mischaracterizing Dr. Csoka's legal claim, the FDA contends that Dr. Csoka alleges only the "deprivation of a *procedural* right without some concrete interest that is affected by the deprivation." Def.'s Mot. to Dismiss at 2 (emphasis added; quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)). The deprivation of a response to which he is entitled, however, is not a "bare procedural violation, divorced from any concrete harm." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016). The lack of a substantive response is "concrete": It "actually exist[s]" and affects Dr. Csoka in a way that is "'real,' and not 'abstract.'" *Id*. at 340 (citations omitted). As evidenced by the FDA's responses to other petitions, *see supra* p.2 n.1, a response from the FDA goes far beyond terminating a process; it provides substantive analysis and detailed explanation. Indeed, it is because the FDA offers such "concrete" responses that the agency told Dr. Csoka five-and-a-half years ago that his petition required "extensive review and analysis." Compl. ¶ 10.

For this reason, this case is not analogous to *Judicial Watch, Inc. v. FEC*, 293 F. Supp. 2d 41 (D.D.C. 2003), on which the FDA relies. There, the court rejected the plaintiff's argument that he suffered a concrete injury when the Federal Election Commission (FEC) failed to act on his administrative complaint within 120 days. *Id.* at 48. The court explained that the statute at issue did not confer a right to any particular FEC action within 120 days, but only a right to sue if the FEC did not act on the complaint within that time period. *Id.* And simply being "deprived … of the benefit of [the statutory] timetable for processing complaints," the court explained, was not a concrete injury. *Id*. In contrast, Dr. Csoka is not claiming here that the FDA's failure to meet its 180-day regulatory timetable for responding to a petition constitutes injury. The agency's unreasonable delay in acting on his petition creates his cause of action under the APA. But his

injury is the deprivation of a substantive response to which he, unlike the *Judicial Watch* plaintiff, is entitled. *See also infra* p.9 (further distinguishing *Judicial Watch*).

The FDA's reliance on *NRDC v. Bodine*, 471 F. Supp. 3d 524 (S.D.N.Y. 2020), is also misplaced. In *NRDC*, environmental organizations sought a court order requiring the Environmental Protection Agency (EPA) to respond to a petition for a rulemaking that they had submitted just weeks earlier. *Id.* at 527–28. The plaintiffs' claimed injury was that, absent their proposed rule, policies that the EPA had put in place to respond to the COVID-19 pandemic would compromise "the integrity of environmental monitoring data" that the organizations needed for their advocacy efforts. *Id.* at 535. The court reasoned that the asserted injury could be redressed only if the EPA *granted* the petition by promulgating the rule that the plaintiffs sought, but the only relief that the court could order (and the only relief that it was asked to order) was that the EPA give "some sort of response," whether a grant or a denial. *Id.* Because of the mismatch between the remedy sought and the injury claimed, the court held that the plaintiffs lacked standing. *Id.* Unlike in *NRDC*, Dr. Csoka's injury does not arise from the FDA's failure to grant his petition but from the FDA's failure to provide any form of substantive response.

The other two cases relied on by the FDA likewise cast no doubt on Dr. Csoka's standing. First, in *Brown v. FBI*, 793 F. Supp. 2d 368 (D.D.C. 2011), the court held that the plaintiff, a pro se prisoner serving a life sentence, lacked standing to challenge the Justice Department's failure to respond to his petition seeking rules clarifying whether a particular drug was covered by the Controlled Substances Act. *Id.* at 377–79. The plaintiff asserted that he was injured by the lack of a response because he had been prosecuted for distributing the drug in the past and was under "imminent threat" of being prosecuted again. *Id.* at 378. The court, though, explained that the plaintiff's claims of past prosecution for distributing this particular drug were "completely

unjustified in light of the total absence of evidence in the record," *id*., and that his "paranoid belief that he [was] being prosecuted" again, despite already serving a life sentence, was "baseless," *id*. at 379. Here, Dr. Csoka's standing rests on his unfulfilled legal right to a response to his petition, not on a "baseless" or "paranoid" belief that his petition—if granted—would reduce his risk of befalling some speculative future injury.

Finally, in *Singh v. Napolitano*, 710 F. Supp. 2d 123 (D.D.C. 2010), a noncitizen plaintiff sued the Federal Bureau of Investigation (FBI) for its delay in completing a background check associated with his application for an adjustment of immigration status. *Id.* at 128. The court held that the plaintiff lacked standing to pursue this claim because he had "not allege[d] any harm flowing from this delay," given "his position … that regardless of the delay, he [was] entitled to have his adjustment of status application granted under current [agency] policy." *Id*.; *see also id*. at 128 n.4 (noting that the FBI had provided the results of the background check years earlier). Here, Dr. Csoka has alleged "harm flowing from" the FDA's delay: the lack of a response.

II. Informational injury caused by the FDA's failure to provide a response creates an additional basis for standing.

In addition, the FDA's unlawful failure to issue a decision on Dr. Csoka's petition has deprived him of valuable information that would benefit him in his research activities. The FDA's responses to petitions like Dr. Csoka's are substantive and provide in-depth analysis of the medical and scientific issues presented by the petition. *See supra* p.2 n.1. Again, the FDA stated in 2018 that it needed more than 180 days to respond to Dr. Csoka's petition so that it could conduct "extensive review and analysis." Compl. ¶ 10. The results of that extensive review and analysis will be provided to Dr. Csoka when the FDA issues its decision on the petition, and the information is likely to be useful for his work, regardless of whether the petition is granted or denied. *See* Decl. of Antonei B. Csoka (Csoka Decl.) ¶ 5.

It is well established that the loss of access to information can constitute an injury in fact sufficient to support standing. *See*, *e.g.*, *FEC v. Akins*, 524 U.S. 11, 21 (1998) (holding that individuals suffered an injury in fact where a challenged agency action interfered with their ability to obtain information); *Pub. Citizen v. Dep't of Justice*, 491 U.S. 440, 449–50 (1989) (holding that plaintiffs suffered an injury in fact when they were denied access to records that plaintiffs contended were subject to disclosure requirements); *Waterkeeper All. v. EPA*, 853 F.3d 527, 533 (D.C. Cir. 2017) (holding that an organization suffered an injury in fact where a challenged agency action reduced the organization's access to information); *PETA v. USDA*, 797 F.3d 1087, 1095 (D.C. Cir. 2015) (holding that an organization suffered injury where the challenged agency action deprived it of information); *Action All. of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 937–38 (D.C. Cir. 1986) (holding that organizations had standing where the challenged agency action denied them access to information). Again, *Judicial Watch*, on which the FDA relies, is not to the contrary. *See* 293 F. Supp. 2d at 47 (finding no informational injury where the agency investigation that the plaintiff alleged was required would not have informed the plaintiff of new facts that he "was not already aware of when he filed [his] administrative complaint").

Here, the FDA's response to Dr. Csoka's petition would provide substantive information, including the FDA's expert analysis of the issues raised in the petition. That information would be valuable to Dr. Csoka, a scientist who has been researching PSSD for two decades, and who serves as a scientific advisor to the PSSD Network, a non-profit advocacy organization that disseminates information on PSSD. *See* Csoka Decl. ¶¶ 1–2, 5–6; *see also Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002) ("[A] denial of access to information can work an 'injury in fact' for standing purposes, at least where a statute (on the claimants' reading) requires that the information 'be publicly disclosed' and there 'is no reason to doubt their claim that the information would help

them.'" (quoting *Akins*, 524 U.S. at 21)). By withholding this valuable information from Dr. Csoka, the FDA has inflicted a distinct injury that establishes an additional basis for standing.

CONCLUSION

Defendant's motion to dismiss should be denied.

Respectfully submitted,

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Dated: August 5, 2024