UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC., Plaintiff, v. **FOOD AND DRUG ADMINISTRATION**, Defendant.	Case No. 22-cv-938 (CRC)

MEMORANDUM OPINION

In this Freedom of Information Act ("FOIA") case, Plaintiff Vanda Pharmaceuticals seeks records created by the Food and Drug Administration ("FDA") during its review of Vanda's application to add a new approved use for its sleep-disorder drug, Hetlioz. Specifically, Vanda requested two reviews created by the interdisciplinary team of FDA experts that evaluated the application. The FDA withheld both reviews under FOIA Exemption 5 to protect its deliberative process.

Both parties seek summary judgment as to whether the FDA properly invoked Exemption 5. For the reasons explained below, the Court will grant summary judgment for Vanda and deny summary judgment for the FDA.

I. Background

The Food, Drug, and Cosmetic Act requires that the FDA approve a new drug before it can be introduced on the market. 21 U.S.C. § 355(a). To receive approval, a pharmaceutical company submits a New Drug Application ("NDA")—including scientific data to support that the drug is safe and effective—to the FDA's Center for Drug Evaluation and Research ("CDER"). 21 U.S.C. § 355(a)–(b); Def.'s Mot. Summ. J., Ex. 3 ¶ 5 ("Farchione Decl.").

Similarly, a pharmaceutical company seeking to market an already-approved drug for another use must file a supplemental New Drug Application ("sNDA") to obtain CDER's pre-approval. 21 C.F.R. § 314.70(b); see Farchione Decl. ¶ 6. Upon receipt of an NDA or sNDA, CDER assembles an interdisciplinary review team of clinicians and scientists to review the submission and compile its opinions and recommendations, including reviews of the drug's clinical effectiveness and the statistical soundness of the manufacturer's studies. Farchione Decl. ¶¶ 5–8, 15–16. After consulting the reviews, CDER either approves the drug for its proposed use or sends the manufacturer a Complete Response Letter ("CRL") detailing the application's deficiencies. See id. ¶¶ 8-9. If a CRL is sent, the sponsor is faced with several options: it can withdraw its application, submit additional information to address the deficiencies, or appeal the decision through the FDA's formal dispute resolution process. Pl.'s Cross Mot. Summ. J., Ex. 2 ¶ 14 ("Jarow Decl.").

Vanda manufactures the prescription drug Hetlioz, a melatonin receptor agonist approved by the FDA to treat non-24-hour sleep-wake disorder, a circadian-rhythm disorder that disrupts normal sleep cycles. Pl.'s Mot. at 5. In 2018, Vanda filed an sNDA for approval to market Hetlioz as a treatment for jet lag. Id. at 6. Following the multi-disciplinary assessment, CDER issued a CRL and the application is still pending. Farchione Decl. ¶¶ 11–14.

A few months after receiving the CRL, Vanda submitted a FOIA request to the FDA for the "[Clinical] Review[1] and Statistical Review" generated during the multi-disciplinary assessment of the Hetlioz sNDA. Compl., Ex. A. The clinical review "covers the strength of the

[1] While Vanda's FOIA request asked for the "Medical Review," the parties refer to this document as a "clinical review" in their briefs. See Def.'s Mot. at 3 n.2; Pl.'s Mot. at 4 n.1. The Court will follow suit.

clinical evidence" in the application and the statistical review "covers the statistical validity of the findings of the clinical studies performed" by the drug's sponsor. Pl.'s Mot. at 4. The FDA withheld the reviews based on FOIA Exemption 5, asserting that they were protected from disclosure under the deliberative process privilege. Pl.'s Mot., Ex. 10. Vanda appealed the decision within the agency, and the FDA upheld the withholdings.[2] Pl.'s Mot., Ex. 13. Vanda then filed suit and both parties moved for summary judgment on whether Exemption 5 and the deliberative process privilege were properly applied to the reviews.[3]

II. Legal Standards

Summary judgment is the typical mechanism to determine whether an agency has met its FOIA obligations. See, e.g., Jud. Watch, Inc. v. CFPB, 60 F. Supp. 3d 1, 6 (D.D.C. 2014). In FOIA cases, an "agency is entitled to summary judgment if no material facts are genuinely in dispute and the agency demonstrates 'that its search for responsive records was adequate, that any exemptions claimed actually apply, and that any reasonably segregable non-exempt parts of records have been disclosed after redaction of exempt information.'" Prop. of the People, Inc. v. Office of Mgmt. & Budget, 330 F. Supp. 3d 373, 380 (D.D.C. 2018) (quoting Competitive Enter. Inst. v. EPA, 232 F. Supp. 3d 172, 181 (D.D.C. 2017)).

The agency may satisfy its burden to justify claimed exemptions through declarations that "describe[ ] the justifications for withholding the information with specific detail" and "demonstrate[ ] that the information withheld logically falls within the claimed exemption."

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[2] Initially, the FDA also invoked the attorney-client privilege and the attorney-work-product privilege to withhold the reviews. Pl.'s Mot., Ex. 10. On appeal, the FDA conceded that those justifications did not apply. Pl.'s Mot., Ex. 13

[3] After the FDA moved for summary judgment, Vanda moved for limited discovery, which the Court denied. See Order, ECF No. 14.

ACLU v. Dep't of Def., 628 F.3d 612, 619 (D.C. Cir. 2011). "Such declarations are entitled to a presumption of good faith, and the court can award the agency summary judgment based solely on the information so provided." Jud. Watch, Inc. v. CIA, 310 F. Supp. 3d 34, 41 (D.D.C. 2018). Agency declarations will not support summary judgment, however, if the plaintiff puts forth contrary evidence or demonstrates the agency's bad faith. ACLU, 628 F.3d at 619.

Exemption 5 protects "inter-agency or intra-agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). The exemption thus incorporates, "albeit in a less-than-straightforward way[,] . . . the privileges available to Government agencies in civil litigation," including the deliberative process privilege. U.S. Fish & Wildlife Serv. v. Sierra Club, Inc., 141 S. Ct. 777, 785 (2021). The deliberative process privilege exists "[t]o protect agencies from being forced to operate in a fishbowl." Id. (internal quotation marks omitted). To that end, it "shields from disclosure documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." Id. (internal quotation marks omitted). An agency may only invoke the deliberative process privilege "for documents that are both predecisional and deliberative." Reps. Comm. for Freedom of the Press v. FBI, 3 F.4th 350, 362 (D.C. Cir. 2021). "Documents are 'predecisional' if they were generated before the agency's final decision on the matter, and they are 'deliberative' if they were prepared to help the agency formulate its position." U.S. Fish & Wildlife Serv., 141 S. Ct. at 786.

The government must also demonstrate at summary judgment that it has satisfied the standards imposed by the FOIA Improvement Act of 2016, which allow an agency to withhold information only if it "reasonably foresees that disclosure would harm an interest protected by an

exemption" to FOIA or "disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i). The statute's "distinct foreseeable harm requirement . . . foreclose[s] the withholding of material unless the agency can articulate both the nature of the harm [from release] and the link between the specified harm and specific information contained in the material withheld." Reps. Comm., 3 F.4th at 369 (second alteration in original) (internal quotation marks omitted). As applied to the deliberative process privilege and Exemption 5, the requirement is only satisfied if the agency can "concretely explain how disclosure 'would'—not 'could'—adversely impair internal deliberations." Id. at 369–70 (quoting Machado Amadis v. Department of State, 971 F.3d 364, 371 (D.C. Cir. 2020).

III. Analysis

The FDA asserts that the clinical and statistical reviews at issue are both predecisional and deliberative, and therefore are protected by the deliberative process privilege in the first instance, and that their release would cause foreseeable harm by (1) chilling agency discourse regarding drug applications and (2) harming public health by causing consumer confusion or contributing to false advertising. Vanda disputes each of those claims

While the parties offer cogent arguments on multiple fronts, the Court will begin and end with Vanda's "principal argument" that disclosure will not harm the agency's deliberative process. Pl.'s Reply at 3. Finding that the agency has not satisfied its obligation to show a foreseeable harm from publication regardless of whether the reviews are predecisional or deliberative, the Court will grant summary judgment in Vanda's favor.

A. Chilling Effect

The FDA asserts that "[d]isclosing clinical and statistical reviews prepared for the evaluation of a drug application would have a chilling effect on staff communications."

Farchione Decl. ¶ 18. In its view, the agency scientists who review sNDAs do "not anticipate that their comments [will] be used for anything but internal deliberations" and publication of the reviews would thus deter the scientists from giving their honest assessments. Def.'s Mot. at 13. The FDA fears that such a chilling effect would harm agency decision-making because "a comprehensive record" of staff opinions is critical "given the complexity of interdisciplinary discussions." Farchione Decl. ¶ 18. The FDA considers the risk of chilling "particularly concerning here" because the agency may need to further deliberate on Vanda's sNDA. Id.

The Court is not convinced that disclosure of reviews related to pending sNDAs would lead to the chilling effect the agency fears. As Vanda points out, the FDA currently discloses clinical and scientific reviews to the public in a variety of circumstances. For starters, the agency is required by statute to publish underlying reviews whenever an *NDA* is approved. See 21 U.S.C. § 355(l)(2)(A), (C)(i), (C)(iv) (requiring, upon approval of an NDA, the release of "[d]ocuments generated by the [FDA] related to the review of the application" and "a summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved[.]"). Although the record does not contain definitive statistics on the approval rate of NDAs, at least one study cited by Vanda puts it at over 90%. See Biotechnology Innovation Organization et al., Clinical Development Success Rates and Contributing Factors 2011-2020 at 9 (Feb. 2021) ("[The] unlimited allowance of submission attempts pushes the overall success [of NDA submissions] above 90.6% across all diseases[.]"). And in at least one instance, the agency has also disclosed clinical reviews to defend its decision not to grant an evidentiary hearing for an NDA it declined to approve. Pl.'s Mot. at 15; Pl.'s Mot., Ex. 14; Pl.'s Mot., Ex. 15. In addition, while the FDA avers that it does not release reviews associated with approved *sNDAs*

as a matter of course, the agency acknowledges that it will release reviews from approved sNDAs in response to a FOIA request or "a request by one of FDA's Review divisions if deemed important for public health reasons." Def.'s Mot., Ex. 2 ¶¶ 13–14 ("Philips Decl.").

The FDA may be correct that it does not have a practice of releasing statistical and clinical reviews underlying *pending* sNDAs like Vanda's. As explained above, however, a pending sNDA may become an approved sNDA should the sponsor choose to adopt the recommendations offered by the review team in the CRL explaining the basis for the conditional denial of the application. As a result, reviews associated with pending sNDAs would be subject to release at least under the circumstances noted above, should the application ultimately be approved.

As the FDA acknowledges, the clinical reviewers do not know whether or not an application will be approved when the reviews are compiled. Def.'s Mot. at 11; see Jarow Decl. ¶ 17. They are, therefore, unaware during the review process whether their work will be made public under any of the circumstances described above. Given that uncertainly, the agency has not established that reviewers currently expect written descriptions of their views and deliberations to be shielded from public view. That is certainly the case for teams conducting reviews for NDAs, upwards of 90% of which, based on the evidence before the Court, are made public following approval of the application. And the agency offers no explanation for why it is not also the case for teams assigned to sNDAs. It does not suggest, for example, that sNDA applications are reviewed by different experts within the agency, or that sNDA reviews entail different types of analyses or deliberations. Absent any current expectation of confidentiality, in the context of NDAs and sNDAs alike, the Court struggles to see how requiring FOIA disclosure of statistical and clinical reviews associated with pending sNDAs would in any way chill the

reviewers' frank and honest deliberations. Disclosure cannot chill deliberations if those deliberating do not reasonably expect their deliberations to remain private.

To be clear, the Court does not hold that the FDA somehow waived its ability to invoke Exemption 5 by voluntarily releasing isolated NDA and sNDA reviews to the public. It finds, rather, that the agency has not established that the reviewers presently expect their deliberations to be kept private given the meaningful potential for release of both types of reviews. And if the reviewers don't expect confidentiality now, this ruling should not affect the tenor of their deliberations in the future.

The FDA's public disclosure of NDA and sNDA reviews distinguishes this case from Machado Amadis and others on which the FDA relies. 971 F.3d at 370-71. In Machado, for example, the D.C. Circuit found that releasing the recommendations of agency line attorneys would undermine candid debate within the agency. Id. at 371. But there was no indication that the attorney recommendations there were publicly disclosed by the agency in other circumstances. Id. Here, the experts reviewing NDAs and sNDAs know that their reviews could very well be published. Accordingly, the FDA has not met its burden to "concretely explain" how release would chill internal agency deliberations. See Reps. Comm., 3 F.4th at 369–70

B. Public Health

The FDA also asserts that "disclosure of clinical and statistical reviews in the context of an unapproved sNDA raises public health and safety concerns." Farchione Decl. ¶ 19. In particular, the FDA expresses concern that drug sponsors may misrepresent the opinions expressed in the reviews to mislead consumers and medical practitioners about the efficacy and safety of the drug under review. Def.'s Mot. 13–14. But this concern is insufficient to justify withholding the reviews. To start, the FDA speculates about harm that "could" happen if the

reviews were released but has not "concretely explain[ed]" what harm "would" occur. See Reps. Comm., 3 F.4th at 369–70. Such conjecture does not satisfy the agency's foreseeability requirement. Id. Moreover, as Vanda points out, there are a number of factors that lessen the FDA's stated concern. First, drug manufacturers are prohibited from promoting the unapproved use of an already-approved drug. See 21 U.S.C. §§ 331(a), 352(a); Jarow Decl. ¶¶ 22–23. Second, even if a consumer was confused by misinformation about Hetlioz, the consumer could not act on that misinformation alone because Hetlioz is only available by prescription. Jarow Decl. ¶ 27. Prescribing doctors serve as learned intermediaries who educate consumers about the uses and misuses of the drug. See id. Last, the agency's public-safety concerns are weaker here, where the FDA has already determined that Hetlioz is safe for consumption and has no known serious adverse effects. Pl.'s Mot., Ex. 1, ¶¶ 12–15 ("Comb Decl."). The FDA does not contest any of these points.

Accordingly, the FDA has failed to show any foreseeable harm that would arise if the requested reviews were released.

IV. Conclusion

For these reasons, the Court will grant Plaintiff's Cross Motion for Summary Judgment and deny the FDA's Motion for Summary Judgment.

A separate Order shall accompany this opinion.



CHRISTOPHER R. COOPER
United States District Judge

Date: March 27, 2023