IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS, INC., *Plaintiff*, v. FOOD AND DRUG ADMINISTRATION, *Defendant*.	Case No. 1:22-cv-938 (CRC)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* SUPPORTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, WLF often appears as *amicus curiae* in federal court to ensure government transparency and accountability under the Freedom of Information Act, 5 U.S.C. § 552. *See, e.g.*, *Bloomberg, LP v. Bd. of Governors of the Fed. Res, Sys.*, 601 F.3d 143 (2d Cir. 2010); *Ctr. for Nat'l Sec. Studies v. U.S. Dep't of Justice*, 331 F.3d 918 (D.C. Cir. 2003).

INTRODUCTION & SUMMARY OF ARGUMENT

Congress enacted FOIA in 1966 to "pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny." *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976) (citation omitted). Generally, "upon any request for records," the agency "shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3). But FOIA contains several discrete exemptions. *Id.* § 552(b). Exemption 5, the deliberative-process privilege, applies to work product in draft form or to documents that contain agency deliberations before a decision. *Id.* § 552(b)(5). Having skyrocketed in use, the deliberative-process privilege has become the go-to exemption of choice for federal agencies. The privilege is so abused that, among government watchdogs, Exemption 5 has been nicknamed the "withhold-it-because-you-want-to" exemption.

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[*] No party's counsel authored any part of this brief. No one, apart from Washington Legal Foundation and its counsel, contributed money intended to fund the brief's preparation or submission

This rampant overuse of the deliberative-process privilege has harmed the public's right to know. Look no further than this case. The Food and Drug Administration insists that its medical and statistical reviews of Vanda's Supplemental New Drug Application (sNDA) for Hetlioz® should remain hidden forever behind FOIA's deliberative-process privilege. But as Vanda has established, the reviews are not covered by the privilege because they are neither "pre-decisional" nor "deliberative." WLF fears that allowing FDA to withhold critical parts of the agency's final decision will thwart government accountability at a time when public confidence in FDA's decision-making is more important than ever.

As it must, FDA insists that disclosing the reviews will chill candid deliberation inside the agency. But that argument makes little sense. FDA routinely discloses medical and statistical reviews when applications are ultimately approved, and the reviews become part of the administrative record when a sponsor appeals an application's denial to federal court. So agency staff cannot reasonably expect that these documents will be kept from the public. Here, FDA concedes that the reviews "were prepared by staff who did not know what the ultimate decisions on the application would be." (Dkt. 8 at 11) But if FDA staff must assume the risk that Vanda's application ultimately may be approved—or denied and then appealed—then disclosing the reviews could not possibly chill frank discussion within FDA.

FDA's hiding behind its Complete Response Letter (CRL) places drug companies like Vanda in a serious bind. The CRL cannot condense in a few pages

the substantive insights of hundreds of pages of scientific analysis and statistical modeling. And because the CRL is neither an approval nor a denial, the drug sponsor cannot challenge FDA's action in court under the Administrative Procedure Act (APA). Unable to fully evaluate the supposed shortcomings of its application, a sponsor cannot know whether FDA's position results from its own error. Nor can it benefit from FDA's expert analysis, which would otherwise help the sponsor to address any shortcomings in its application. Ultimately, it is doctors and patients who will suffer because of FDA's lack of transparency, as many otherwise beneficial drugs will not be brought to market.

ARGUMENT

I. FDA HAS NOT SHOWN THAT DISCLOSING THE REVIEWS WILL CHILL CANDID DISCUSSION INSIDE THE AGENCY.

To "encourage candor" and promote sound agency decisions, FOIA's deliberative-process privilege "blunts the chilling effect that accompanies the prospect of disclosure." *U.S. Fish & Wildlife Serv. v. Sierra Club, Inc.*, 141 S. Ct. 777, 785 (2021). The privilege reflects "the obvious realization" that agency officials will not speak candidly "if each remark is a potential item of discovery and front page news." *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8–9 (2001). An agency's invocation of the deliberative-process privilege does "not obscure the basic policy that disclosure, not secrecy," is FOIA's "dominant objective." *Rose*, 425 U.S. at 361.

The burden of proving that the privilege applies falls on the agency asserting it. *Petroleum Info. Corp. v. Dep't of the Interior*, 976 F.2d 1429, 1433 (D.C. Cir.

1992). Responding to concerns about government secrecy in 2016, Congress amended FOIA to "increase the availability of government records to the public." *Reporters Comm. for Freedom of the Press v. Fed. Bureau of Investigation*, 3 F.4th 350, 357 (D.C. Cir. 2021) (citations omitted). An agency may withhold documents under a FOIA exemption only if (1) the agency "reasonably foresees that disclosure would harm an interest protected by an exemption" or (2) "disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A)(i).

The Supreme Court has explained that Congress's use of "would" in FOIA provides a "stricter standard" than, say, "could," and reflects a deliberate word choice that should be given effect by the courts. *Dep't of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 756 n.9 (1989). To succeed on its claim of deliberate-process privilege, therefore, FDA must prove not that disclosure "*could* chill speech," but that "it is reasonably foreseeable that it *will* chill speech." *Jud. Watch, Inc. v. Dep't of Commerce*, 375 F. Supp. 3d 93, 101 (D.D.C. 2019) (emphasis added).

Nor is it enough for the agency to merely incant generic rationales that undergird the deliberative-process privilege. Rather, the agency must prove, with admissible evidence, that the privilege is necessary to "prevent injury to the quality of agency decisions." *Reporters Comm.*, 3 F.4th at 357 (cleaned up). To meet this burden, it must establish "the link between the harm and the specific information contained in the material withheld." *Id.* Here, FDA simply cannot show that disclosing the requested reviews will harm the agency by chilling "the candor of

present and future agency decision-making." *Nat'l Sec. Archive v. CIA*, 752 F.3d 460, 464 (D.C. Cir. 2014).

Disclosing the reviews will not chill frank discussion within FDA because agency staff have no reason to expect that these documents will be withheld in the first place. Indeed, FDA has a long history of disclosing these materials. When a drug application is approved, for example, FDA publishes the medical and statistical reviews of that application on its website as part of a "Drug Approval Package." *See* FDA, *Drug Approval Package: Compath* (June 23, 2000) <perma.cc/MQ48-6HTV>; FDA, *Drug Approval Package: BEOVU* (Oct. 7, 2019) <perma.cc/P85Q-PV3W>. When doing so, FDA redacts from the published reviews neither the reviewers' scientific reasoning nor the staff's recommendations. *Id.*

What's more, medical and statistical reviews become part of the administrative record whenever a drug sponsor appeals FDA's decision to federal court under the APA. Before the court can assess the applicant's "probability of success on the merits," the FDA must "file the administrative record" and already "have determined the grounds" for its decision. *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001). This is because the only grounds an agency may rely on to defend an action "are those upon which the record discloses that [the] action was based." *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943). The medical and statistical reviews are thus integral to that record. By contrast, "pre-decisional and deliberative documents . . . are not part of an administrative record as a matter of

law." *Oceana, Inc. v. Locke*, 634 F. Supp. 2d 49, 51 (D.D.C. 2009), *rev'd on other grounds*, 670 F.3d 1238 (D.C. Cir. 2011).

In its memorandum of law supporting summary judgment, FDA contends that FDA staff "would not anticipate" that the reviews would be made public because "FDA does not publish review documents associated with unapproved or pending drug applications to its website." (Dkt. 8 at 13) Yet only two pages earlier, FDA assures the Court that the reviews "were prepared by staff who did not know what the ultimate decisions on the application would be." (*Id.* at 11) A staff member who cannot know whether a drug sponsor's application ultimately will be approved or denied should assume that, under a host of scenarios, the reviews may be disclosed—automatically if the application is approved or the decision is later overturned by the agency, and as part of the administrative record if the application is denied and that denial is challenged in court.

This routine practice of publicly disclosing medical and statistical reviews—both after approval and in response to litigation—undermines FDA's claim that secrecy is needed to ensure the candor of agency staff. Because they are quite accustomed to routine public disclosure of medical and statistical reviews, FDA staff have no reasonable expectation that the reviews and the scientific evidence they contain will be kept confidential. As a result, the release of those materials under FOIA would not alter FDA reviewers' incentives to be candid in their deliberations.

The "mere possibility that disclosure discourages a frank and open dialogue" is not enough. *Jud. Watch*, 375 F. Supp. 3d at 101. Otherwise, government

documents would be exempt "whenever the deliberative process privilege was invoked regardless of whether disclosure of the information would harm an interest protected by the exemption." *Id.* At all events, there is little evidence for the supposed chilling effect that underlies the deliberative-process privilege. The rationale for the privilege "rests on the conclusory and unverified assertions of interested parties and has never been supported by anything that might fairly be called evidence." Gerald Wetlaufer, *Justifying Secrecy: An Objection to the General Deliberative Privilege*, 65 Ind. L.J. 845, 897-98 (1990).

No surprise, then, that unlike other FOIA exemptions, Congress has never defined the deliberative-process privilege. Even the Department of Justice characterizes Exemption 5's text as "opaque language." *Department of Justice Guide to the Freedom of Information Act, Exemption 5*, at 1 (Aug. 6, 2019) < https://bit.ly/3InCqrZ>. According to a leading treatise, the notion "that government bureaucrats will not feel free to express their opinions fully and candidly when they fear that their views will be made public" is a "dubious empirical assumption." 26A Kenneth W. Graham, Jr. & Ann Murphy, *Federal Practice and Procedure: Evidence* § 5680 (April 2020 update). Because it "rests on such a puny instrumental rationale," the privilege "should seldom be upheld in a case where there is any need for the evidence." *Id.* This is just such a case; Vanda's need to understand the scientific bases for FDA's view of Hetlioz® as a jet-lag therapy is critical to drug development.

II. THE GOVERNMENT'S REFLEXIVE USE OF THE DELIBERATIVE-PROCESS PRIVILEGE ABUSES THE EXEMPTION AND UNDERMINES FOIA'S PURPOSE.

The promise of FOIA "build[s] on what our Founding Fathers recognized hundreds of years ago: that a truly democratic system depends on an informed citizenry to hold their leaders accountable." 114 Cong. Rec. S1496 (Mar. 15, 2016) (statement of Sen. John Cornyn). But that promise cannot be realized if federal agencies like FDA can hide behind statutory exemptions without justification.

The deliberative-process privilege "is widely considered to be one of the most abused bases for denying access to information." Ryley Graham, Reporters Comm. for Freedom of the Press, *What is the 'deliberative process' privilege? And why is it used so often to deny FOIA requests?* (Apr. 30, 2020) <https://bit.ly/3Itwttg>. Overreliance on the privilege to withhold documents "has proven extraordinarily frustrating for reporters who rely on FOIA for newsgathering and increasingly find themselves disillusioned by improper use of exemptions." *Id.*

After finding that "agencies [we]re overusing FOIA exemptions that allow, but do not require, information to be withheld from disclosure," S. Rep. No. 114-4, at 2 (2015), Congress codified the foreseeable-harm standard in FOIA's 2016 amendments. *See* FOIA Improvement Act of 2016, Pub. L. No. 114-185, 130 Stat. 538. Congress was "especially concerned" about "agencies' reliance on Exemption 5 and the deliberative process privilege." *Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 104 (D.D.C. 2019). The House Report flagged "[e]xemption five . . . as a particularly problematic exemption." H.R. Rep.

No. 114-391, at 10 (2016). Indeed, the deliberative-process privilege was "the most used privilege and the source of the most concern regarding overuse." *Id.*

As this litigation shows, the problem of agencies' reflexively using the deliberative-process privilege to deny FOIA requests has not been eradicated. Agencies still withhold massive quantities of documents each year under Exemption 5. In fiscal year 2019, federal agencies invoked the exemption more than 74,000 times. *See* FOIA.gov. That number was the highest since 2013, when agencies invoked the exemption 81,000 times. *Id.* So pronounced is the problem that, among government-watchdog groups, Exemption 5 has come to be known as the "withhold-it-because-you-want-to" exemption. JPat Brown, *Nine Days of FOIA Exemptions: b(5)*, Muckrock (Mar. 5, 2018) <https://bit.ly/3AEMriy>.

Given its rampant overuse, the privilege suffers from inconsistent and arbitrary use. A 2020 analysis by the Project on Government Oversight (POGO), for example, compared redactions made to records it obtained from the Department of Homeland Security to identical records obtained by National Public Radio. Nick Schwellenbach & Sean Moulton, *The "Most Abused" Freedom of Information Act Exemption Still Needs to Be Reined In*, POGO (Feb. 6, 2020) <https://bit.ly/3NT4mFf>. Invoking Exemption 5, DHS redacted "vast swaths of text" from the records provided to POGO, yet "did not claim the exemption for any of the same records provided to NPR." *Id.* After comparing the two FOIA responses, POGO concluded "that many, if not all, of the department's Exemption 5 redactions in POGO's records were not supported by the law." *Id.*

Many assertions of the privilege are frivolous or made solely to avoid political embarrassment. In 2018, the Federal Communications Commission relied on the privilege to withhold drafts of the script for a skit presented at the Federal Communications Bar Association's annual dinner. Dell Cameron, *FCC Says Releasing 'Jokes' It Wrote About Ajit Pai Colluding with Verizon Would 'Harm' Agency*, Gizmodo (Feb. 6, 2018) <https://bit.ly/3bXtopt>. According to the agency, releasing the drafts would "harm the [FCC's] deliberative process." FCC, FOIA response letter from Elizabeth Lyle, Assistant General Counsel, to Dell Cameron, Gizmodo Media Group (Feb. 2, 2018) <https://bit.ly/3NQeP44>.

In 2011, the State Department relied on the privilege to redact an employee's handwritten annotation—"What a bunch of crap!!"—scribbled on a nonbinding House Resolution calling for Pakistan to be designated as a state sponsor of terrorism. Nate Jones, *Document Friday: Someone from the Department of State thought that punishing Pakistan for "providing refuge and assistance" to Osama Bin Laden was "a bunch of crap!!,"* Unredacted (May 13, 2011) <https://bit.ly/3PcJgmg>. The redacted material was disclosed two years later, but only after a long and costly appeal by the requesting party. *Id.*

Still other claims of the deliberative-process privilege arise from agency incompetence. In 2014, a nonprofit requested "training documents, manuals, and guidance" on applying Exemption 5 from several departments and agencies. Invoking Exemption 5, the Federal Election Commission rejected the request. Shawn Musgrave, *Federal Election Commission argues it can't tell you why it can't*

tell you what it can't tell you, Muckrock (Feb. 26, 2014) <https://bit.ly/3yZJqYT>. On appeal, the FEC reversed course because "the documents the FEC originally withheld had already been posted on the agency's own website." *Id.* The agency had asserted the privilege for publicly available documents.

In sum, the government's abuse of the deliberative-process privilege has generated "widespread concern among journalists, academics, lawyers, and the general public that FOIA's 'workable balance' has been tilted so far in favor of government secrecy that . . . [FOIA] is failing to service its core purpose." Katie Townsend & Adam A. Marshall, "Striking the Right Balance: Weighing the Public Interest in Access to Agency Records under the Freedom of Information Act" in *Troubling Transparency* 227 (David E. Pozen & Michael Schudson, eds., 2018). The FDA's conduct here only exasperates this disturbing trend.

III. FDA'S SECRECY HARMS PUBLIC HEALTH BY IMPEDING THE ADVANCEMENT OF NEW BENEFICIAL THERAPIES.

A drug company confronted with a CRL for its sNDA needs to fully understand every deficiency that FDA has found with its application. Such an understanding is critical not only to addressing the agency's need for more data or new analyses, but also to appealing FDA's findings through the agency's formal dispute-resolution (FDR) process.

But a CRL is merely a summary document identifying deficiencies that must be resolved to FDA's satisfaction before the application can be approved. 21 C.F.R. § 314.3. It condenses many months of medical and scientific analyses into a few pages, while excluding the hundreds of pages of detailed work performed by FDA

reviewers. As a result, a CRL cannot provide a drug sponsor with a nuanced grasp of FDA's scientific view or the reasons behind the agency's decision not to approve the application. Nor may a drug sponsor sue FDA under the APA to obtain the reviews. That is because federal courts lack jurisdiction to hear appeals from a CRL, which is not an "order of the Secretary" that "refus[es] . . . approval of an application" under 21 U.S.C. § 355(h). *Nostrum Pharm., LLC v. FDA*, 35 F.4th 820, 825 (D.C. Cir. 2022).

True, FDA regulations allow for an informal End-of-Review (EOR) meeting—a prerequisite for appeal under the FDR process. 21 C.F.R. § 314.102(d). But these meetings are often unable to satisfactorily explore the many complex scientific issues at stake. It is simply impossible to condense hundreds of pages of scientific reviews, including the methods and results of nuanced statistical modeling, into an hour-long meeting. Unlike citing a publicly available study, relying on an FDA-conducted analysis known only to the agency is both inadequate and improper. *Nat'l Classification Comm. v. United States*, 779 F.2d 687, 695 (D.C. Cir. 1985) ("The agency cannot, however rely on data known only to the agency.").

In practice, this "lack of clarity can result in deep frustration and misunderstanding as applicants address what they have understood to be the basis of FDA's concern, only to learn that there are one or more additional bases." Deborah L. Livornese, et al., *Putting the "Complete" Back into Complete Response Letters*, FDA Law Blog (Oct. 25, 2018) <https://bit.ly/3uN0oar>. Having spent enormous time and resources trying to address a deficiency, drug sponsors "can feel

as though FDA is constantly 'moving the goal posts.'" *Id.* "While not the FDA reviewers' intent, the applicant may find itself trapped in a game of regulatory whack-a-mole at a moment when resources are dwindling and investors are losing faith." *Id.*

Here, the medical and statistical reviews themselves are the only documents that can give Vanda a full understanding of how FDA interprets the data on Hetlioz® and why FDA scientists and staff arrived at their conclusions. FDA's failure to provide these reviews is not only highly inefficient, it is deeply unfair. Drug sponsors should be able to fully scrutinize the agency's analysis and uncover any methodological flaws that may exist. Indeed, "public evaluation" of an agency's "technical studies and data" can "allow for useful criticism," enabling regulated parties "to point out where that information is erroneous or where the agency may be drawing improper conclusions." *Am. Radio Relay League v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008).

FDA's secrecy not only frustrates FOIA's goal of agency transparency, but also undermines public health. FDA's mission is severely damaged by unfairly withholding detailed reviews that can help drug sponsors secure approval for new beneficial drugs or add indications to the labels of existing drugs. When no other therapy is available, patients would lose access to safe and effective drugs for a broad range of disorders.

CONCLUSION

The Court should grant Vanda's motion for summary judgment.

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