UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR INQUIRY, INC., **Plaintiff,** **v.** **DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,** **Defendants.**	**Civil Action No. 21-3118 (JEB)**

MEMORANDUM OPINION

Plaintiff Center for Inquiry, Inc. styles itself a non-profit "dedicated to fostering a secular society in which evidence, science, and compassion — rather than superstition, pseudoscience, or prejudice — guide public policy." ECF No. 1 (Compl.), ¶ 4. Training its sights on homeopathic drugs, CFI sought to obtain from Defendant Department of Health and Human Services certain information on those remedies. To that end, it submitted a Freedom of Information Act request in 2021 and filed this FOIA action soon after against HHS and the Food & Drug Administration. After two years of litigation, CFI has received much but not all of what it seeks. Contending that the Agency adequately searched for records and relied on the appropriate exemption in redacting some of the documents it produced, Defendants now move for summary judgment. Disagreeing on both fronts, Plaintiff cross-moves for summary judgment. In the end, the Court delivers a split decision: it will grant both Motions in part and deny them in part.

I. Background

The following facts are undisputed. On August 19, 2021, CFI submitted a FOIA request to HHS seeking two categories of documents. See ECF Nos. 37 (Def. Stmt. of Material Facts), ¶¶ 1–2; 29 (Pl. Stmt. of Material Facts), ¶¶ 1, 22. These were:

> 1) [T]he complete, current, Homeopathic Pharmacopoeia of the United States; and
> 2) All communications between [HHS] and [the Homeopathic Convention of the United States ("HPCUS")] for the time period beginning 1/1/2015. This include[d], without limitation, electronic mail, attachments, publications, schedule of meetings between agency personnel and HPCUS employees, agents and affiliates and any record generated as a result of such a meeting.

ECF No. 37–1 (Decl. of Sarah Kotler), ¶ 13.

The Homeopathic Pharmacopoeia is a collection of monographs and other materials meant to set standards for the production and composition of homeopathic drugs. See ECF No. 23-3 (First Decl. of William Shevin), ¶¶ 2–6. The task of drafting, revising, and publishing this collection is the *raison d'être* of the HPCUS, a non-profit organization staffed primarily by "volunteer pharmacists, physicians, and lay people with relevant technical or scientific experience." ECF No. 37-3 (Revised Decl. of William Shevin), ¶¶ 2, 9. HPCUS occasionally invites FDA employees to sit in on its committee meetings as guest observers. Id., ¶ 9. To support its work, HPCUS charges a subscription fee for access to the final version of the Homeopathic Pharmacopoeia; this, in turn, is "the main source of revenue for the Convention and its work." Id., ¶ 8.

A day after receiving CFI's request, HHS determined that the requested records were kept by the FDA, so it referred the request there. See Pl. SMF, ¶ 22; ECF No. 29-1 (Pl. Exhibits) at 9 (HHS Referral to FDA). The FDA accepted this referral that same day and sent Plaintiff a letter on September 2, 2021, acknowledging receipt of its FOIA request. See ECF Nos. 40-2

(Decl. of Arianne M. Perkins & Exhibits) at 4 (FDA Acceptance of Referral); 24-2 (Kotler Exhibits) at 10 (September 2, 2021, FDA Letter).

Not keen to wait and give the Agency additional time to respond to its request, CFI filed this suit on November 26, 2021. See Compl. In the ensuing months, FDA determined that the personnel in three specific offices within its Center for Drug Evaluation and Research (CDER) — the center tasked with regulating, *inter alia*, homeopathic drugs, see ECF No. 37-2 (Decl. of Howard R. Philips), ¶ 8 — were "most likely to possess records responsive to the request," and it accordingly instructed employees in those offices to search for any emails within the relevant time period (January 1, 2015, to March 15, 2022) "to or from the HPCUS." Id., ¶¶ 17–18.

More specifically, CDER staff were instructed to manually search for emails "accessible in electronic form on their computer workstation," which included emails stored in employee hard drives, calendar invites, and network files. See ECF No. 40-3 (Supp. Decl. of Howard R. Philips), ¶ 8. They were further told to search their inboxes for emails sent to and from an hpus.com domain, as well as emails including the terms specified in Plaintiff's request: Homeopathic Pharmacopoeia, HPUS, Homeopathic Pharmacopoeia Convention of the United States, and HPCUS. Id. Further still, the Agency tasked these employees with searching for emails containing the names of "certain" HPCUS members that FDA had frequently interacted with in the past. Id., ¶ 9.

The Agency limited its search in two ways that will become relevant later. First, it did not instruct the employees in the three selected offices to search for emails sent to or from the business addresses of HPCUS members. Id.; Pl. SMF, ¶ 25. As volunteers who otherwise work for "well-known pharmaceutical companies," many of these HPCUS members did not have or use a Convention-specific email address, instead opting to use their own business email even

when corresponding about HPCUS business. See Philips Supp. Decl., ¶ 9. The Agency nevertheless declined to include these addresses in its search terms because the employers of HPCUS members frequently interacted with FDA on non-homeopathic matters, so a search that included such addresses would presumably have produced records "outside the scope" of CFI's request. Id.

Second, FDA did not search the archived emails of Immo Zadezensky, a former FDA employee who served as a guest observer at HPCUS from January to March 2016. Id., ¶ 7; Philips Decl., ¶ 24. Although Defendants asked their eDiscovery staff to recover the email attachments sent from HPCUS to Zadezensky that are (now) the crux of this suit, they did not "conduct a complete eDiscovery search" of his inbox. See Philips Supp. Decl., ¶ 7.

After concluding this initial search, FDA sent a response letter to Plaintiff on April 26, 2022. The letter noted that, as to CFI's first category of records, Defendants had nothing to produce. See Pl. Exhs. at 4 (FDA Apr. 26, 2022, Letter) (noting that FDA "does not maintain or control the HPUS in paper or electronic format"). As to the second, it informed Plaintiff that it would produce 514 pages of records with redactions. Id.; Philips Decl., ¶ 20. To justify its redactions, the Agency invoked Exemptions 4 and 6 of FOIA, which protect confidential commercial or financial information and the personal privacy of individuals, respectively. See Philips Decl., ¶ 20. This letter concluded by stating that this was the "final response" to Plaintiff's request. See FDA Apr. 26, 2022, Letter.

End of story, right? Not quite. In June 2022, Plaintiff told FDA that it believed that some records responsive to the second part of its request had been "inadvertently omitted." Philips Decl., ¶ 23. In particular, CFI thought that the Agency had left out or excessively redacted attachments to two emails that were part of the 514 pages produced: one email between

then-Chairman of HPCUS's Standards & Control Committee and Zadezensky welcoming him as a guest observer, and another sent to former CDER employee Richard Lostritto discussing presentation materials for an upcoming HPCUS event. Id., ¶¶ 21–23; Pl. Exhs. at 15–17 (Lostritto Emails). Defendants responded six weeks later, informing Plaintiff that these attachments had not been produced both because Zadezensky was no longer an FDA employee and because the attachments to the Lostritto email had been appropriately redacted — at least by the Agency's lights — under Exemption 4. See ECF No. 24-4 (Philips Exhibits) at 8 (August 11, 2022, Response). With these clarifications, Defendants hoped, the parties would finally be ready to "close[] everything up." Id.

They were not. Unhappy with the Agency's explanations, Plaintiff emailed Defendants on September 12, 2022, asking them to reconsider their Exemption 4 redactions and insisting that they search elsewhere for the Zadezensky email attachments. See Pl. Exhs. at 12 (September 12, 2022, Pl. Email); Philips Decl., ¶ 26. Some back and forth ensued over the next three months, culminating in two more productions. See Def. SMF, ¶¶ 19–20; Philips Decl., ¶¶ 27, 30. The November 2022 production — some 200 pages total — comprised the attachments to the Zadezensky email, which the Agency retrieved through its eDiscovery staff and which it heavily redacted pursuant to Exemptions 4 and 5, the latter of which protects pre-decisional and deliberative agency information. See Philips Decl., ¶ 27; Philips Supp. Decl., ¶ 7. The December 2022 one consisted of 96 pages of the previously, but no longer, redacted attachments to the Lostritto emails. See Philips Decl., ¶ 30. All in all, the FDA produced a total of 714 pages of records deemed responsive to category number two, many of which were redacted in whole or in part pursuant to various FOIA exemptions. See Def. SMF, ¶ 21.

Careful readers might be wondering what ultimately became of the first part of CFI's request, which asked for a complete, current version of the Homeopathic Pharmacopoeia of the United States. See Kotler Decl., ¶ 13. The answer: at some point during the aforementioned negotiations that took place between the parties in 2022, Plaintiff decided to withdraw this part of its FOIA request and accordingly so informed the FDA on December 1, 2022. See Pl. SMF, ¶ 20; Philips Decl., ¶¶ 28.

This long and winding road finally brings us to the Motions at hand. Having narrowed their disputes to two issues — the overall adequacy of FDA's search and the redactions it made to the Zadezenksy email attachments pursuant to Exemption 4 — the parties now cross-move for summary judgment. See ECF Nos. 23 (Def. MSJ), 29 (Pl. MSJ). Having also revised and re-revised their briefs a number of times in the preceding months, see ECF Nos. 37, 39, 40, 44, the parties' dueling Motions are now ready for resolution.

II. Legal Standard

Summary judgment must be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986); Holcomb v. Powell, 433 F.3d 889, 895 (D.C. Cir. 2006). A fact is "material" if it can affect the substantive outcome of the litigation. See Liberty Lobby, 477 U.S. at 248; Holcomb, 433 F.3d at 895. A dispute is "genuine" "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Liberty Lobby, 477 U.S. at 248; see also Scott v. Harris, 550 U.S. 372, 380 (2007); Holcomb, 433 F.3d at 895. "A party asserting that a fact cannot be or is genuinely disputed must support the assertion" by "citing to particular parts of materials in the record" or "showing that the materials cited do not establish the absence or presence of a genuine

dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

"FOIA cases typically and appropriately are decided on motions for summary judgment." Defenders of Wildlife v. U.S. Border Patrol, 623 F. Supp. 2d 83, 87 (D.D.C. 2009); Brayton v. Office of U.S. Trade Rep., 641 F.3d 521, 527 (D.C. Cir. 2011). In a FOIA case, a court may grant summary judgment based solely on information provided in an agency's affidavits or declarations when they "describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith." Larson v. Dep't of State, 565 F.3d 857, 862 (D.C. Cir. 2009) (citation omitted). Such affidavits or declarations "are accorded a presumption of good faith, which cannot be rebutted by purely speculative claims about the existence and discoverability of other documents." SafeCard Servs., Inc. v. SEC, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (citation and internal quotation marks omitted). "Unlike the review of other agency action that must be upheld if supported by substantial evidence and not arbitrary or capricious, the FOIA expressly places the burden 'on the agency to sustain its action' and directs the district courts to 'determine the matter de novo.'" Dep't of Just. v. Reps. Comm. for Freedom of the Press, 489 U.S. 749, 755 (1989) (quoting 5 U.S.C. § 552(a)(4)(B)). Summary judgment is only proper when the court is assured that the record justifies the result. See Ctr. For Investigative Reporting v. Customs & Border Prot., 436 F. Supp. 3d 90, 100 (D.D.C. 2019).

III. Analysis

Under FOIA, "each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules[,] . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A). If the records fall into one of nine statutorily created exemptions, however, the Government need not turn over the requested information. Id. § 552(b)(1)–(9). To show that an exemption applies and justifies the withholding of records, the Government "must provide a 'relatively detailed justification'" for its withholding, "specifically identifying the reasons why a particular exemption is relevant." Morley v. CIA, 508 F.3d 1108, 1122 (D.C. Cir. 2007) (quoting King v. Dep't of Just., 830 F.2d 210, 219 (D.C. Cir. 1987)). It must also show that "foreseeable harm would result from the material's release." Reps. Comm. for Freedom of the Press v. Fed. Bureau of Investigation, 3 F.4th 350, 369 n.2 (D.C. Cir. 2021). This Court can compel the release of any records that do not satisfy the requirements of at least one exemption. See Reps. Comm. For Freedom of Press, 489 U.S. at 755.

As explained above, only two issues remain at this stage. The first is whether Defendants' search was adequate. See Def. MSJ at 7–8; Pl. MSJ at 5–6. The second is whether the information that FDA redacted from the Zadezensky email attachments pursuant to Exemption 4 is actually covered by that exemption. See Def. MSJ at 8–14; Pl. MSJ at 6–9. The Court considers each in turn.

A. Adequacy of Search

An agency "fulfills its [search] obligations . . . if it can demonstrate beyond material doubt that its search was 'reasonably calculated to uncover all relevant documents.'" Valencia-Lucena v. Coast Guard, 180 F.3d 321, 325 (D.C. Cir. 1999) (quoting Truitt v. Dep't of State, 897

F.2d 540, 542 (D.C. Cir. 1990)). Thus, "[i]n a FOIA case, a district court is not tasked with uncovering 'whether there might exist any other documents possibly responsive to the request,' but instead, asks only whether 'the search for [the requested] documents was adequate.'" In re Clinton, 970 F.3d 357, 367 (D.C. Cir. 2020) (quoting Weisberg v. Dep't of Just., 745 F.2d 1476, 1485 (D.C. Cir. 1984)). A FOIA defendant's affidavits or declarations must "set[ ] forth the search terms and the type of search performed, and aver[ ] that all files likely to contain responsive materials (if such records exist) were searched." Oglesby v. Dep't of Army, 920 F.2d 57, 68 (D.C. Cir. 1990); see also Bartko v. Dep't of Just., 167 F. Supp. 3d 55, 64 (D.D.C. 2016) (agency must invoke "the 'magic words' concerning the adequacy of the search — namely, the assertion that [the Department] searched all locations likely to contain responsive documents"). Unless there is evidence to the contrary, affidavits or declarations meeting these requirements are generally enough to show that an agency complied with FOIA. See Perry v. Block, 684 F.2d 121, 127 (D.C. Cir. 1982). "If, however, the record leaves substantial doubt as to the sufficiency of the search, summary judgment for the agency is not proper." Truitt, 897 F.2d at 542.

Plaintiff offers three objections to the Agency's search here. First, it says, FDA started off on the wrong foot by searching for records only in certain offices within the Agency. See Pl. MSJ at 5; see also ECF No. 47 (Pl. Reply) at 7–8. Second, it contends that Defendants' search was incomplete because FDA did not actually search the inbox of former CDER employee Zadezensky. See Pl. MSJ at 5 (citing Philips Decl., ¶ 24). Finally, CFI posits that FDA improperly narrowed its FOIA request by searching for the names, but not the business email addresses, of individuals known to be HPCUS members. Id.

1. *Narrowing to Three Offices*

To begin, the Court agrees that the record "leaves substantial doubt" as to whether certain CDER offices were the only places likely to contain responsive records. Truitt, 897 F.2d at 542. Indeed, the declaration on which the Government relies admits that the Agency searched for records only in the three CDER offices "most likely to possess records responsive to" CFI's request. See Philips Decl., ¶ 17 (emphasis added). Although the statements in this declaration have proven to be something of a moving target, this characteristic of the Agency's search has remained constant across revisions. Compare id. with Philips Supp. Decl., ¶¶ 5–6. Notably, FDA's decision to narrow its search to three CDER offices followed an initial decision by the Agency to search only in CDER, as opposed to in other centers within FDA. See Def. SMF, ¶ 12. And while Defendants have offered a credible reason for this initial focus on CDER alone — they explain that this center is the one in FDA responsible for regulating "homeopathic drug products," see id., ¶ 8; Philips Decl., ¶ 8 — they never adequately explain their decision to cabin search locations even further to three offices within that center. They never, for example, describe why other offices within CDER were not likely to contain responsive records. See Oglesby, 920 F.2d at 68 ("At the very least, [the Agency is] required to explain in its affidavit that no other [location] was likely to produce responsive documents."); see also Hart v. Dep't of Justice, 648 F. Supp. 2d 113, 117 (D.D.C. 2009) (granting summary judgment where agency declaration averred that "the most likely, and only, place where [responsive] records" could be located was searched) (emphasis partially omitted).

Lest this seem like a dispute over mere "magic words," the Court also notes that the record in fact indicates that there was at least one more office within CDER where responsive records could have been found. See Pl. SMF, ¶ 24; cf. Shapiro v. Dep't of Justice, 40 F.4th 609,

613 (D.C. Cir. 2022) (one way to raise substantial doubt as to adequacy of search is through "positive indications of overlooked materials"). In its response to the April 2022 production, CFI informed FDA that one of the emails produced was sent from Francis Godwin, a CDER employee who worked in an office other than the three specified here. See September 12, 2022, Pl. Email. Understandably, Plaintiff followed up with the Agency to let it know that this office was "also likely to have records." Id. Instead of responding by expanding its search to this CDER office or explaining why this office was not likely to contain responsive documents, Defendants simply assert that the Agency conducted an adequate search and insist that its saying so entitles it to a "presumption of good faith." See ECF No. 40 (Def. Reply) at 10. That will not cut it. See Oglesby, 920 F.2d at 68 (reversing grant of summary judgment to agency in part because its affidavit stated that agency only searched in system "most likely to contain the information which had been requested"). The Court will therefore require the Government to conduct a further search.

2. *Zadezensky Emails*

To assist the Government in the next iteration of such a search, the Court will also consider Plaintiff's remaining grounds for finding FDA's efforts inadequate. CFI contends that the Agency was also deficient because it "did not actually conduct" a search of Zadezensky's inbox at all. See Pl. MSJ at 5. Zadezensky was a CDER employee until April 2016 and was the Agency's guest observer to HPCUS from January to March in 2016. See Philips. Supp. Decl., ¶ 7. Defendants acknowledge that, as a guest observer to the Convention, his inbox was likely to contain documents responsive to CFI's request; indeed, the Agency conducted a very, very limited search to recover attachments to an email sent from the then-Chairman of HPCUS's Standards & Control Committee to Zadezensky (more on that below). Id. Defendants try a

different approach to justify this decision, retorting that the Agency was simply following its "standard practice" of having each employee manually search her own records, a task that a person no longer employed at FDA would not be able to complete. See Def. Reply at 9.

Plaintiff, again, has the better of this dispute. For one, the Agency's declaration intimates that FDA has the capacity to "conduct a[n] . . . eDiscovery search of Mr. Zadezensky's archived emails." Philips Supp. Decl., ¶ 7. To its credit, the declaration does explain that when the Agency conducted its initial search — presumably back in April 2022 — the collection of electronic files archived on FDA servers was "limited" and "did not include full searches of former employees' archived emails." Id. But the Agency does not say whether this technical limitation also hampered its later, "expanded" search in September 2022. See Philips Decl., ¶ 26; Philips Supp. Decl., ¶ 7 (noting that collections were "limited at that time" — *i.e.*, when first search was conducted) (emphasis added). In any event, this description of the Agency's eDiscovery capacities would adequately explain a decision to search only the portion of Zadezensky's emails that was archived on its servers, but it does not explain what the Agency actually opted for here: to not search any of its former employee's actual emails. This is especially true because none of the Agency's declarations avers that such a search would have been "unreasonably burdensome." Am. Immigr. Council v. United States Dep't of Homeland Sec., 21 F. Supp. 3d 60, 73 (D.D.C. 2014) (citation omitted).

Defendants rejoin that FDA met its obligations by conducting a search limited to the attachments mentioned above, and that there is "nothing wrong with performing different sets of searches for current and former employees." Def. Reply at 10. Yet the case the Government cites, Byrnes v. Dep't of Justice, 2021 WL 5422281 (D.D.C. Sept. 29, 2021), only drives home the conclusion that the Agency's search here was inadequate. There, the agency responded to

the plaintiff's FOIA request by asking current employees to manually search their records while simultaneously running an automated search of former-employee records. Id. at *3, *7. The court had no trouble finding that this decision to employ different search methods for current and former employees was reasonable, since it led to the agency's actually searching both sources for records. Id. at *7.

Here, by contrast, FDA did not just employ different methods for searching the records of current and former CDER employees. It instead chose to barely search the records of the latter, even though it knew that this location was likely to house records responsive to CFI's request. See Valencia-Lucena, 180 F.3d at 327 ("It is well-settled that if an agency has reason to know that certain places may contain responsive documents, it is obligated under FOIA to search barring an undue burden."). FDA's search of attachments limited to a single email, moreover, can hardly be called a search of Zadezensky's inbox itself; it thus falls far short of the kind of search method the Byrnes court found adequate.

In a final effort to justify the Agency's omission, Defendants trot out the good-faith presumption to which their declarations are ordinarily entitled, see Def. Reply at 9–10, but that dog won't hunt. Simply put, FDA's failure to search Zadezensky's emails "makes clear that summary judgment" for Defendants is inappropriate. Valencia-Lucena, 180 F.3d at 327.

3. *Business Email Addresses*

Rounding out this section is Plaintiff's submission that FDA's search was inadequate because it did not include the business email addresses of known HPCUS members. See Pl. MSJ at 5–6. Because the Government was aware that HPCUS members frequently communicated with FDA "using their business email addresses," ECF No. 40-5 (Supp. Decl. of William Shevin), ¶ 8, Plaintiff argues that the only reasonable search here would have been one that

included these email addresses. Because the search terms only included HPCUS-member names and hpus.com addresses, Plaintiffs continue, FDA's search was "patently insufficient." Pl. MSJ at 5. In response, Defendants note that agencies are generally entitled to "'discretion in crafting a list of search terms' as long as they 'are reasonably tailored to uncover'" responsive records, and member names and hpus.com email addresses are so tailored. See Def. Reply at 7 (quoting Liberation Newspaper v. Dep't of State, 80 F. Supp. 3d 137, 146 (D.D.C. 2015)).

The Court this time agrees with Defendants. As the Agency's declaration explains, its interactions with the Convention "are limited to a small number of active HPCUS members." Philips Supp. Decl., ¶ 9. Because many of these members are also employed by "well-known pharmaceutical companies and other organizations" that frequently come before FDA, though, the Agency chose to search for member names instead of their business email addresses, believing that this was necessary to avoid search results that included the members' work on non-homeopathic matters. Id. (noting that such results "would fall outside the scope of Plaintiff's FOIA request"). These search terms were thus "reasonably tailored to uncover documents responsive to" CFI's ask. Liberation Newspaper, 80 F. Supp. 3d at 146 (cleaned up).

Plaintiff vigorously resists this conclusion, but offers no concrete reason for so doing. It is true that "an agency cannot ignore what it cannot help but know," Naumes v. Dep't of the Army, 588 F. Supp. 3d 23, 36 (D.D.C. 2022) (cleaned up), but CFI merely supposes that FDA's chosen search terms missed at least some emails sent by HPCUS members. See, e.g., Pl. Reply at 7–8 (speculating that the fact that FDA's search produced some records with "non-Convention email addresses" in addition to those "using Convention email addresses" simply "demonstrates why [it] was unreasonable and inadequate"); see also Shapiro, 40 F.4th at 613 (presumption given to agency declaration "cannot be rebutted by purely speculative claims") (quoting Bartko

v. Dep't of Justice, 898 F.3d 51, 74 (D.C. Cir. 2018)). Simply put, CFI faults Defendants for not including a search term that would, at best, result in finding the very emails that the Agency already found and produced and could, at worst, have turned up a number of non-responsive records. Cf. Shapiro, 40 F.4th at 614 (FOIA "does not require what the government represents would be a redundant search"). Unlike the previous two objections, then, the Court finds that this one has no merit.

* * *

Because the Government's declaration has neither averred that FDA searched all locations likely to contain responsive records nor justified its decision to exclude Zadezensky's emails, the Court cannot conclude that Defendants have satisfied their obligations under FOIA.

B. Exemption 4

The only remaining issue is whether Exemption 4 protects the redaction of the attachments to the email sent by the then-HPCUS chair to Zadezensky. These attachments include "[m]inutes" from previous Standards and Controls Committee meetings and Committee notes on "common repetitive test procedures that appear in the [HPUS] monographs." ECF No. 46-2 (Feb. 25, 2016, Email Welcoming Zadezensky) at 3. Exemption 4 shields from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). To justify withholdings or redactions made pursuant to this exemption, an agency must establish that the information is "(1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential." Pub. Citizen Health Rsch. Grp. v. Food & Drug Admin., 704 F.2d 1280, 1290 (D.C. Cir. 1983). Only the first and third prongs are in dispute, so the Court will focus its analysis on those.

1. *Commercial or Financial Information*

Invoking the shield of Exemption 4, Defendants must first establish that the redacted material is "commercial or financial information." 5 U.S.C. § 552(b)(4). Here, they rely only on the "commercial" prong. Information is only commercial if it is "commercial in and of itself, meaning it serves a commercial function or is of a commercial nature." CREW v. Dep't of Just., 58 F.4th 1255, 1263 (D.C. Cir. 2023) (cleaned up). Paradigmatic commercial information includes "sales statistics, profits and losses, and inventories," Pub. Citizen Health Rsch. Grp., 704 F.2d at 1290, but the exemption also covers any information in which the "provider of the information has a commercial interest." Baker & Hostetler LLP v. U.S. Dep't of Com., 473 F.3d 312, 319 (D.C. Cir. 2006). The term "commercial" is not infinitely malleable, however, and "not every bit of information submitted to the government by a commercial entity qualifies for protection under" this exemption. CREW, 58 F.4th at 1264 (cleaned up).

At the outset, the Court's task is unfortunately not made any easier by Defendants' rather cursory Vaughn Index, which states that most of the redacted material comprises "recommendations, opinions, and proposals of" the HPCU committee tasked with "establish[ing] . . . standards and quality control tests for HPUS" monographs. See ECF No. 20-1 (Vaughn Index); see also Watkins L. & Advoc., PLLC v. U.S. Dep't of Just., 78 F.4th 436, 452 (D.C. Cir. 2023) ("Specificity is the defining requirement of the Vaughn index[,] . . . yet [this] Vaughn index in this case is threadbare.") (cleaned up). Neither this nor anything else in the record, however, describes these categories in greater detail, so the Court has no way of knowing what exactly lies behind the Agency's redactions. See, e.g., Shevin Supp. Decl., ¶ 4 (stating, without further explanation, that redacted materials "pertain to the development, revision and implementation of monographs"). In the absence of a description of the redacted information,

the Court has a hard time determining which material (if any) qualifies as commercial for these purposes.

Despite these shortcomings, Defendants push ahead with their contention that all of the redacted information is commercial because it contains discussions of HPUS monographs, while the redacted material "literally constitutes the contents of the Homeopathic Pharmacopoeia." Def. Reply at 11. The Government's theory for why this material is commercial is as follows: the only way for the public to access HPUS monographs is by purchasing a subscription to the HPUS, and these subscription fees make up "65 percent of the annual income of the HPCUS." Shevin Supp. Decl., ¶ 4; Def. MSJ at 11–12. Release of the redacted materials would undermine this revenue source because it would reveal, for free, the content of these monographs. See Def. MSJ at 11. HPCUS thus has a clear commercial interest in the information the Agency kept from CFI.

The Court agrees that, to the extent the redacted material contains portions or entire copies of draft monographs, this plainly qualifies as commercial because it is directly related to HPCUS's "making of a profit." CREW, 58 F.4th at 1265. Plaintiff surmises that this information would merely "give a hint about the contents" of the HPUS, see Pl. MSJ at 7, but this ignores the fact that FDA withheld entire "draft monographs, with proposed revisions." Vaughn Index; see also Shevin Supp. Decl., ¶ 4 ("The redacted documents . . . reveal close-to-final monograph components."). In other words, the redacted material would not just hint at the contents of these monographs, but would directly reveal them if released. Nor is Defendants' argument — as to this kind of redacted material, at least — based on economic consequences alone, as CFI contends. See Pl. MSJ at 7; CREW, 58 F.4th at 1267 ("commercial consequences . . . . are not on their own sufficient" to make information commercial). The Government's

argument, rather, is that these monographs are the very product from which HPCU derives most of its income. Compare Nat'l Ass'n of Home Builders v. Norton, 309 F.3d 26, 38–39 (D.C. Cir. 2002) (finding that Exemption 4 did not apply because "there [was] no evidence that the parties who supplied the . . . information ha[d] a commercial interest at stake"). That Defendants also point to the financial consequences that would follow from disclosure of materials that ordinarily cannot be accessed without a subscription fee only evidences its commercial function.

To agree with Defendants as to that specific category of materials, though, is not to agree with them wholesale. As CFI rightly notes, the Agency has a duty to show "how each withheld record" fits within Exemption 4's definition of "commercial." See Pl. Reply at 9. This it has not done. As already explained, the remaining categories of withheld information are described in such general terms that the Court cannot determine whether or not anything in them qualifies as commercial under this FOIA exemption. Some of the redacted materials, for instance, are described as "minutes from recently held" committee meetings. See Def. SMF, ¶ 17. This label provides no insight into whether specific monograph contents were discussed at these meetings, whether that discussion in fact disclosed the content of the monographs — as opposed to, say, the formatting of that draft — or whether such a discussion made up the entirety of those meetings and the resultant minutes. Indeed, as Plaintiff explains, to accept this description as currently written would be to find that "any information that passes through the HPCUS" is commercial and thus protected by Exemption 4. See Pl. Reply at 9.

Defendants' Vaughn Index gets them no further, since it simply states that the redacted material "contains recommendations, opinions, and proposals" for revising HPUS monographs. What is the content of these "recommendations, opinions, and proposals"? Do they threaten to reveal the contents of the draft monographs? Cf. Flyers Rts. Educ. Fund, Inc. v. Fed. Aviation

Admin., 71 F.4th 1051, 1056 (D.C. Cir. 2023) (agency may withhold even agency-authored materials when their disclosure would reveal "data supplied to the government from a person outside the government" or "proprietary information originally provided to [the agency] by [an outside entity]"). Or do they sometimes touch on non-substantive aspects of the monographs, or other topics unrelated? It is impossible to answer any of these questions with what the parties have presented thus far. Based on the record before it, therefore, the Court can only conclude that "some portion of" the redacted material "likely contain[s] commercial information" — *i.e.*, the material that contains portions or entire drafts of HPUS monographs. Shteynlyuger v. Ctrs. for Medicare and Medicaid Servs., 2023 WL 6389139, at *21 (D.D.C. Sept. 30, 2023).

2. *Privileged and Confidential*

It is not enough for the redacted material to be commercial, however. It must also be "privileged or confidential," with the latter meaning that it was "both customarily and actually treated as private by its owner." WP Company LLC v. SBA, 502 F. Supp. 3d 1, 12 (D.D.C. 2020) (quoting Food Marketing Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2366 (2019)). The critical question here is "how the particular party customarily treats the information, not how the industry as a whole treats the information." Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 244 F.3d 144, 148 (D.C. Cir. 2001) (citing Critical Mass Energy Project v. Nuclear Regulatory Comm'n, 975 F.2d 871, 872, 878–80 (D.C. Cir. 1992)).

An agency arguing that information is customarily treated in a certain way may "proceed solely on its sworn affidavits." Judicial Watch, Inc. v. U.S. Dep't of Comm., 337 F. Supp. 2d 146, 171 (D.D.C. 2004). Those affidavits must be "made on personal knowledge," Animal Legal Defense Fund, Inc. v. Dep't of the Air Force, 44 F. Supp. 2d 295, 303 (D.D.C. 1999) (quoting Fed. R. Civ. P. 56(e)), which can be demonstrated in a variety of ways. For instance, an agency may "relay[] that the submitters themselves told the agency that the information is confidential, .

. . indicat[e] that the agency reached an understanding with the submitters that the information w[ould] be held in confidence by the U.S. and not publicly divulged, . . . point[] to confidential markings on the documents themselves or to the existence of a non-disclosure agreement, . . . [or] provid[e] descriptions of the documents that demonstrate their confidential nature." Ctr. for Investigative Reporting, 436 F. Supp. 3d at 110–11 (internal quotation marks and citations omitted). An agency cannot, however, simply rely on "[c]onclusory statements by an agency official about what the agency official may believe about how a submitter customarily treats the information at issue." Id. at 111.

The parties, perhaps unsurprisingly, start at diametrically opposite ends. Defendants contend that all of the redacted information is confidential because it is "customarily kept private by HPCUS." Def. MSJ at 12. To support this, they point to the fact that the email transmitting the disputed materials to Zadezensky noted that the attachments were for the committee's eyes only and were subject to the Convention's "Document Security and Retention Policy." Shevin Revised Decl., ¶ 9. That policy (which the parties have not provided in full) apparently states that "[n]o personal notes, nor any interim documents, calculations, reports or analyses" may be distributed unless "approved by the committee members and the HPCUS Board." Id. Since neither the relevant committee nor the Board has approved the release of these materials, they remain confidential and should not be made public here. Id.; Def. SMF, ¶ 17.

For its part, Plaintiff retorts that HPCUS "regularly discloses" the redacted information and did so at a public webinar hosted by HPCUS and the American Association of Homeopathic Pharmacists. See Pl. MSJ at 7. It further contends that HPCUS regularly circulates this information "amongst private corporations and other entities" and does nothing to ensure that the information it shares with its member-volunteers stays private. Id.; see also Pl. Reply at 12–13.

And if that were not enough, says CFI, the record also shows that HPCUS only considers "[s]ome [committee] and HPCUS data" confidential — namely, that which the Convention specifically designates as such. See Pl. Reply at 13–14; ECF No. 46-7 (HPCUS Email for June 10, 2016, Meeting) at 8.

The Court ultimately finds that there is a material dispute as to whether HPCUS customarily treated the redacted materials as private, such that summary judgment for neither party is appropriate. Starting with the biggest problem, the Government's only source on this point, HPCUS President William Shevin, has shown remarkable inconsistency in his various declarations. In his first, he informed the Court that proposed changes to HPUS monographs were "announced" at some point in the revision process so the public could comment on these proposals. See Shevin First Decl., ¶ 15; see also ECF No. 46-1 (HPCUS Manuals) at 2–15 (suggesting that public comment period existed in past). His third declaration, however, walks this statement back. Shevin now says that "[d]raft monographs have never been the subject of a public comment period." ECF No. 37-4 (Second Decl. of William Shevin), ¶ 7; but see HPCUS Manuals at 2–15 (depicting public-comment period as part of monograph-evaluation process as late as 2019).

Similar problems surround the public webinar mentioned above. In his first discussion of the webinar, Shevin stated that "two monographs were shown in their entirety, while portions of three more were shown," and he admitted that "material that [he] considered confidential was released to the public." Shevin Second Decl., ¶ 4. In his fourth and final declaration, though, Shevin changes his tune and now states that the webinar "did not reveal substantive information contained within the HPUS." Shevin Supp. Decl., ¶ 6. And only in this declaration does Shevin say, without explanation, that the release of the webinar to the public was "accidental." Id.; but

see ECF No. 46-6 (HPCUS Webinar Announcement) at 2–3. Those conflicting statements, "made by the same person," suffice to deny Defendants' Motion. Cook v. Babbit, 819 F. Supp. 1, 21 (D.D.C. 1993).

All this being said, the Court cannot fully side with Plaintiff either because much in the record supports the Government's contention that HPCUS "actually and customarily keeps the withheld information confidential." Def. Reply at 13. For one, the email transmitting these particular materials to Zadezensky signaled that the Convention considered them "For [committee members'] Eyes Only" and directed the former CDER employee to its Document Security and Retention policy. See Philips Exhs. at 4–5 (Email Welcoming Zadezensky); see also ECF No. 40-4 (HPCUS Letters Inviting FDA Employees as Guest Observers) at 17, 20 (noting that FDA guest observers are subject to "HPCUS Document Security and Retention Policy"). So even if Plaintiff is right that HPCUS "will not consider information confidential unless it is explicitly designated so," Pl. Reply at 14, the record establishes that HPCUS did so with regard to the redacted materials.

What is more, there is little to support Plaintiff's belief that HPCUS "routinely" discloses this information to anyone other than their volunteer members. All of the evidence CFI points to — *e.g.*, the emails sent to Zadezensky from non-HPUS email addresses and a roster for a committee agenda — shows only that HPCUS is, as Shevin attests, an institution "staffed by volunteer pharmacists, physicians, and lay people with relevant technical or scientific experience." Shevin Revised Decl., ¶ 9; see also Pl. Exhs. at 30–31 (Agenda Roster) (noting professional affiliations of HPCUS members). The fact that HPCUS is staffed by individuals who work for private companies does not in itself prove that HPCUS freely disclosed the redacted materials to these corporate employers either. See Shevin Supp. Decl., ¶ 7 (noting that,

pursuant to HPCUS's "Policy on Safeguarding Confidential Information," all monograph-related information submitted by private companies is considered "confidential").

CFI tries on one final argument, raised for the first time in its Reply, for why the withheld information is not confidential: FDA has already released "myriad pages of notes" that "reveal information" of the kind at issue here. See Pl. Reply at 14. This position is certainly not without merit, see ECF No. 46-7 (Agenda for Council on Pharmacy Meeting) at 9–19, but the Court will follow the well-established practice of not considering arguments raised for the first time in reply briefs. See United States v. Sitzmann, 893 F.3d 811, 833 (D.C. Cir. 2018) ("It is generally understood that arguments first raised in a reply brief are untimely.") (cleaned up). "One of the reasons for this rule is to avoid unfair surprise to the other party," and such unfairness would likely result here because CFI's previous briefs had not even hinted at the possibility that the Agency had already disclosed the redacted materials in their initial productions. Jackson v. Dist. of Columbia, 327 F. Supp. 3d 52, 71 (D.D.C. 2018); see Pl. MSJ at 7 (arguing only that information was not confidential because "HPCUS regularly discloses it" to private corporations). This argument is thus untimely.

In sum, the Court finds that at least some of the material withheld by the Agency — *viz.*, the material that contains portions or entire copies of draft HPUS monographs — is commercial for purposes of Exemption 4. Since there is a material dispute as to whether this or any of the withheld information is confidential, however, it will deny the Motions as to the applicability of this exemption. In any subsequent round of briefing, therefore, the Government will need to offer considerable further detail to prevail on this issue. It should also expect the Court to more fully examine whether its alleged harms stemming from disclosure are "reasonably foresee[able]." 5 U.S.C. § 552(a)(8)(A)(i)(I).

IV. Conclusion

For the foregoing reasons, the Court will deny in part and grant in part Defendants' Motion for Summary Judgment and Plaintiff's Cross-Motion for Summary Judgment. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
Chief Judge

Date: March 14, 2024