UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JUUL LABS, INC., *Plaintiff*, v. FOOD & DRUG ADMINISTRATION, *Defendant.*	Civil Action No. 22-2853 (RDM)

MEMORANDUM OPINION AND ORDER

In July 2020, Plaintiff Juul Labs Inc. ("Juul") submitted several premarket tobacco applications ("PMTAs") to the U.S. Food and Drug Administration ("FDA") for certain e-cigarette products. Two years later, on June 23, 2022, the FDA issued a marketing denial order ("MDO") with respect to those PMTAs, finding that the applications had toxicological deficiencies that precluded their approval. After the MDO was issued, Juul submitted two Freedom of Information Act ("FOIA") requests to the FDA that sought the release of the agency's internal review documents relating to Juul's PMTAs. In response to Juul's FOIA requests, the FDA provided Juul with the toxicological reviews that it had directly relied upon when denying Juul's PMTAs, but the agency withheld the other materials it had created during the review process pursuant to FOIA Exemption 5. In particular, the FDA maintains that the withheld materials are protected by the deliberative process privilege and that foreseeable harm will result from their release.

The parties' cross-motions for summary judgment are now before the Court. Dkt. 16; Dkt. 19. For the reasons that follow, the Court will **GRANT** the FDA's motion for summary judgment in part and will **DENY** it in part, Dkt. 16, and will **GRANT** Juul's cross-motion for

summary judgment in part and will **DENY** it in part, Dkt. 19. The Court will also order the FDA to conduct further review of the withheld materials to identify any remaining segregable material and will order the parties to file a joint status report concerning that review in one months' time.

I. BACKGROUND

A. Statutory and Regulatory Background

For many years, the FDA played a minimal role in the regulation of tobacco products. *See Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, 202 F. Supp. 3d 31, 36 (D.D.C. 2016) (explaining that "[i]n 1996, the FDA attempted to bring the tobacco industry within its jurisdiction by asserting that nicotine was a 'drug' as defined under the Food, Drug, and Cosmetic Act" but that "endeavor failed . . . when the Supreme Court determined that the FDA had exceeded its statutory authority and struck down its attempts at regulation" (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000))). That changed in 2009, however, when Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA" or "the Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

The TCA made the FDA the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." *Id.* § 3(1). Under the Act, the FDA is authorized to impose "tobacco product standards" that govern the ingredients or properties of tobacco products, *see* 21 U.S.C. § 387g; to restrict the sale and distribution of tobacco products, *see id.* § 387f(d)(1); and to prescribe regulations governing the manufacturing of these products, *see id.* § 387f(e). *See Fontem US, LLC v. U.S. Food & Drug Admin.*, 82 F.4th 1207, 1212 (D.C. Cir. 2023). "The Act also provides that all new tobacco products—those not commercially marketed in the United States prior to February 2007—must be approved by the FDA before being marketed to the public." *Id.* (citing 21 U.S.C. § 387j).

There are two ways a manufacturer can secure such approval from the FDA. "First, a sponsor of a 'new tobacco product' can show that its new product is 'substantially equivalent' to an existing, 'predicate' product, which has been grandfathered under the Act." *Philip Morris*, 202 F. Supp. 3d at 35; *see also* 21 U.S.C. § 387j(a)(2)(A)(i)(I). Alternatively, a sponsor can submit a premarket tobacco product application (known as a premarket tobacco application or "PMTA") to the FDA, which contains information about the product's health risks, its ingredients, additives, and properties, its proposed labeling, any applicable tobacco product standard and whether the product meets that standard or a deviation is justified, and the proposed manufacturing methods, facilities, and controls. *See* 21 U.S.C. §§ 387j(b), (c)(1)(A)(i); *Philip Morris*, 202 F. Supp. 3d at 35. The FDA must deny a PMTA if:

> (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;
>
> (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of [Title 21];
>
> (C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or
>
> (D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of [Title 21], and there is a lack of adequate information to justify the deviation from such standard.

21 U.S.C. § 387j(c)(2). The TCA further specifies that the FDA, in determining whether the product is "appropriate for the protection of the public health," must "tak[e] into account" "the increased or decreased likelihood that existing users of tobacco products will stop using such products" and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4).

Initially, the TCA did not apply to "electronic nicotine delivery systems," more commonly known as vaping products or e-cigarettes. *Fontem*, 82 F.4th at 1212. "These devices utilize solutions containing nicotine," and "[w]hen activated, the device heats the solution, vaporizing it and allowing the user to inhale the aerosolized liquid." *Id.* But under the TCA, the FDA may subject "any product made or derived from tobacco . . . intended for human consumption" to the provisions of the TCA. 21 U.S.C. § 321(rr)(1).[1] "In 2016, the agency invoked this authority to deem vaping products subject to the Act." *Fontem*, 82 F.4th at 1212; *see also* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,975 (May 10, 2016). "As a result of this . . . [r]ule, manufacturers of vaping products were required to secure premarketing approval from the FDA unless the product in question had been marketed prior to 2007." *Fontem*, 82 F.4th at 1212.

When a tobacco company submits a PMTA to the FDA for approval, the application is sent to the FDA's Center for Tobacco Products ("CTP") for review. Within the CTP is the Office of Science ("OS"), which conducts all scientific premarket review of PMTAs. *See* Dkt. 16-2 at 1 (Mital Decl. ¶ 2). The review takes place in three stages.

First, "[d]uring OS's scientific review of PMTAs, reviewers in each applicable scientific discipline draft a review memo," known as a "Discipline Review Memo." *Id.* at 3 (Mital Decl. ¶ 10). Discipline Review Memos "discuss how the available data and information informs and

[1] The FDA may do so if the Secretary of the Department of Health and Human Services "determines that such regulation would be appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). "In making that determination, the Secretary must consider the likelihood that the regulation will increase or decrease the number of tobacco users in the overall population." *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 964 F.3d 56, 59 (D.C. Cir. 2020).

supports the reviewer's opinion regarding the limitations and strength[s] of the application." *Id.* Each Discipline Review Memo is placed in CTP's database (known as the "Image" database) under the PMTA's "Submission Tracking Number" ("STN"). *Id.* The Image database is used by CTP "to catalog and store submissions, such as PMTAs and Ingredient Listings, that are provided to the agency by external parties." Dkt. 16-3 at 3 (German Decl. ¶ 11 n.1). The "database also contains CTP work product made during the course of review of such submissions, and correspondence with submitters, including the decisions ultimately issued." *Id.*

Next, the Technical Project Lead ("TPL"), who is "an experienced staff member," "aggregates and assesses the contents of the Discipline Review Memos" and "evaluates the application under the statutory standard required for marketing authorization." *Id.* at 3–4 (Mital Decl. ¶ 11). Specifically, the TPL considers "whether permitting the marketing of the product would be 'appropriate for the protection of the public health.'" *Id.* at 3 (Mital Decl. ¶ 11) (quoting 21 U.S.C. § 387j(c)(2)(A)). The TPL then "makes [a] recommendation[] to the Director of OS regarding the action the TPL believes FDA should take on the application" in a "TPL Review Memo." *Id.* at 4 (Mital Decl. ¶ 11).

Finally, the Director of OS "often [although not always] makes the FDA decision as to whether to grant or deny marketing authorization." *Id.* at 4 (Mital Decl. ¶ 12). In making that decision, the Director of OS "considers the TPL's evaluations and recommendations" and receives "input" from the Office of the CTP Director ("OCD"). *Id.* The final decision by the FDA to approve a PMTA is known as a Marketing Granted Order ("MGO"), and a denial is known as a Marketing Denial Order ("MDO"). *Id.* OCD may decide to review some or all of the conclusions reached by OS before those conclusions are finalized. *Id.* at 5 (Mital Decl. ¶ 18).

B. Factual Background

In July 2020, Juul submitted to the FDA a bundle of PMTAs for approval of various e-cigarette products. Dkt. 16-2 at 4 (Mital Decl. ¶ 13). Those products included two devices and four types of pods (Virginia Tobacco and Menthol flavors, both in 5.0% and 3.0% concentrations). *See* Dkt. 19-1 at 11. The applications contained "over 125,000 pages of information, data, and analysis." *Id.* Over the next two years, the FDA reviewed Juul's PMTAs.

As is customary, in the first step of the review process, reviewers within OS produced Discipline Review Memos for Juul's PMTAs. Twenty-five such Discipline Review Memos were produced, including two toxicology reviews, two regulatory reviews, and two environmental science reviews. Dkt. 19-5 at 9; Dkt. 16-3 at 6 (German Decl. ¶¶ 20–22). The first of these documents, a "first cycle consultation response" that "describes a summary of adverse experience reports submitted to the FDA Safety Reporting Portal that potentially involved the PMTA products," was drafted on September 16, 2020. Dkt. 19-4 at 2. The last are "second cycle" Discipline Reviews, dated June 15, 2022, that concern behavioral and clinical pharmacology, engineering, microbiology, social science, and bioresearch monitoring. *Id.* at 6–8.

At some point in the process, according to Michele Mital, the acting Director of the CTP at the time, "OCD advised OS that it 'would review any conclusions reached by OS for [Juul's application] bundle before those conclusions [become] a final agency decision.'" Dkt. 16-2 at 4 (Mital Decl. ¶ 14). "As [OS] neared the end of its scientific review," Mital recalls that "OS proposed to OCD that a decision denying [Juul]'s application bundle should issue based solely on identified toxicological deficiencies." *Id.* (Mital Decl. ¶ 15). "Consistent with this approach," Mital explains, "the TPL prepared two separate TPL Review Memos." *Id.* The first

pertained to toxicology, and summarized the toxicology, regulatory, and environmental science Discipline Review Memos. *Id.* The second TPL Review Memo pertained to other disciplines. *Id.*

The Toxicology TPL Review Memo recommended that the FDA "[i]ssue marketing denial order letters for [Juul's PMTAs]." Dkt. 19-5 at 2. The memo explained that the TPL "found that the applicant did not provide sufficient information for [the TPL] to assess the toxicological risks posed by the new products, and the information that was provided raised concerns." *Id.* at 5. As a result of these deficiencies, the memo further explained that the TPL "[could] not determine that these products have met the statutory standard" and, as a result, "the applicant [had] not met its burden of 'showing' that permitting the marketing of the new products would be [appropriate for the protection of the public health] as required by Section 910(c)(2)(A)." *Id.* The Toxicology TPL Review Memo concluded by noting that "[e]ven assuming the rest of the applications otherwise fully supported authorization, that finding could not outweigh the toxicological concerns identified in the applications and thus could not support a finding that the marketing of these products would be appropriate for the protection of public health." *Id.* at 8. Accordingly, the "TPL Review [did] not reach other aspects of the application." *Id*.

The TLP also prepared an Additional Disciplines TPL Review Memo. That second TPL Review Memo "consider[ed] the contents of the identified discipline review memos . . . and [made] recommendations to the director of OS regarding the action the TPL believe[d] FDA should take on the application." Dkt. 19-4 at 8. "Under 'Scope of Review,' this memo contains a table listing 'Disciplines reviewed' and another listing 'Consultations.'" *Id.* Those tables identify the other nineteen Discipline Reviews (including an addendum to one of the reviews)

prepared during the OS's review of Juul's PMTAs as well as the Discipline Review Memos relied upon in the Toxicology Review Memo. *Id.*

"After OCD reviewed the Toxicology TPL Review Memo," it concurred with OS's proposal to deny Juul's "application bundle should rest on the toxicological deficiencies . . . alone." Dkt. 16-2 at 4–5 (Mital Decl. ¶¶ 15–16). The Toxicology TPL Review Memo was signed on June 23, 2022 by the TPL and by the Director of OS, who "[c]oncur[red] with TPL recommendation and basis of recommendation." Dkt. 19-5 at 2.

Also on June 23, 2022, Mital signed a memorandum that described the process by which Juul's PMTAs were reviewed and denied. Dkt. 16-2 at 29. In that memo, she first noted that OS "regularly consults with the Office of the Center Director . . . in making regulatory decisions under the [TCA], including when review raises novel and complex regulatory questions, such as application of the statute's unique public health standard to a new category of products." *Id*. She then explained that, as of June 23, 2022:

> The Technical Project Lead (TPL) has finished reviewing the pending Juul application bundle and has advised OCD that an MDO should be issued because of toxicological deficiencies, which are described in the TPL Review (Toxicology) and the relevant disciplinary reviews. The TPL has also advised OCD in a separate memo, TPL Review (Additional Disciplines), that OS has completed other (non-toxicology) discipline reviews.
>
> OCD initiated review of the conclusions reached by OS. OCD completed review of the TPL Review (Toxicology) and hereby concurs with its conclusions. Because OCD concurs that the toxicological issues are dispositive of the applications, it is not necessary for OCD to review and resolve (and thus CTP has not resolved) any other aspects of the applications.
>
> OS and OCD agree that CTP should issue an MDO for the application bundle on the basis of the toxicological deficiencies alone. Therefore, the discipline reviews and related conclusions in the separate memo, TPL Review (Additional Disciplines), have not been adopted by OCD and do not reflect complete agency consideration or a final agency decision. In addition, the MDO letter should indicate that the list of deficiencies supporting the denial is not necessarily exhaustive. Whether further deficiencies may be found would not change the

> current conclusion that the applicant has not demonstrated that marketing of these products is appropriate for the protection of the public health.

Id. at 29–30.

That same day, the OS Director issued an MDO letter denying Juul's PMTAs. *See* Dkt. 16-2 at 32. That letter informed Juul that the FDA's OS "had completed substantive scientific review of your PMTAs" and that, based on this review, the agency was "denying issuance of marketing granted order for the tobacco products identified." *Id.* The letter further explained that:

> Based on our review of your PMTAs, we determined that the applications for the new tobacco products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that permitting the marketing of the products subject to these applications is appropriate for the protection of the public health.

Id. The letter then identified four specific deficiencies and informed Juul that if it wished to resubmit its PMTAs, it would need to "include all information necessary to respond to all deficiencies identified in this letter." *Id.* at 43. The letter noted that "the list of deficiencies identified . . . is not necessarily exhaustive," *id.*; rather, OS had "found that the toxicological deficiencies identified . . . are dispositive of your applications because they preclude a finding that permitting the marketing of your new tobacco products is [appropriate for the protection of the public health]" and, "[a]ccordingly, FDA has not reached a final agency decision on other aspects of your application, including for example, the potential benefit to adults as compared to the risk to youth posed by your tobacco or menthol products." *Id.*

The same day the MDO was issued, Juul challenged the FDA's decision in the D.C. Circuit. *Juul Labs, Inc. v. FDA*, No. 22-1123, Petition for Review (D.C. Cir. June 23, 2022). On June 24, 2022, the D.C. Circuit entered an administrative stay and set a briefing schedule. *Juul Labs, Inc. v. FDA*, No. 22-1123, Per Curiam Order (D.C. Cir. June 24, 2022). Shortly thereafter,

Juul informed the FDA that it intended to request supervisory review of the MDO pursuant to 21 C.F.R. § 10.75. That regulation permits "[a]n interested person outside the agency [to] request internal agency review of a decision" under certain circumstances. 21 C.F.R. § 10.75(c). On July 5, 2022, the new director of the CTP, Brian King, informed Juul that the agency had decided that "it will review the marketing denial order it issued to Juul relating to certain products . . . because in the course of reviewing the briefing materials in [the petition before the D.C. Circuit], CTP determined that there are scientific issues unique to this application that warrant additional review." Dkt. 1 at 19. While that supervisory review occurred, CTP decided to stay the MDO "to help reduce potential confusion about the status of the marketing denial order during this review." *Id.*

In addition to challenging the substance of the MDO, Juul also submitted two FOIA requests the FDA on June 23, 2022. The first request sought "the technical project lead review (TPL) and any related documents for the mid-cycle review of" Juul's PMTAs. *Id.* at 26. And the second sought "the disciplinary review documents for the" PMTAs. *Id*. at 28.

Upon receiving Juul's FOIA requests, the CTP FOIA office conducted a search of its Image database. CTP searched the Image database because that is where CTP stores PMTAs, "work product made during the course of review of such submissions," and "the decisions ultimately issued." Dkt. 16-3 at 3 (German Decl. ¶ 11 n.1). Based on this search, CTP FOIA identified "25 scientific discipline review memos . . . and a Technical Project Lead (TPL) review memo limited to toxicological issues." *Id.* at 3–4 (German Decl. ¶ 12). Of these responsive records, CTP FOIA determined that seven were releasable and produced those records to Juul on July 8, 2022 and July 21, 2022. *Id.* at 4 (German Decl. ¶ 13). The released records are the Toxicology TPL Review Memo and the six Discipline Review Memos that were relied upon in

the Toxicology TPL Review Memo. Dkt. 16-1 at 11. The remaining 19 records were withheld pursuant to Exemption 5. Dkt. 16-3 at 4 (German Decl. ¶ 14).

It was not until Juul filed this suit, however, that CTP FOIA identified the Additional Disciplines TPL Review Memo. Dkt. 16-3 at 4 (German Decl. ¶ 15). That memo was initially overlooked because it was not stored in the Image database. *Id.*; Dkt. 16-2 at 5–6 (Mital Decl. ¶ 19). The second TPL Review Memo was also withheld pursuant to Exemption 5. Dkt. 16-3 at 4 (German Decl. ¶ 15).

C. Procedural Background

On September 20, 2022, Juul filed this suit challenging the FDA's application of Exemption 5 to the records it had withheld. Dkt. 1. The FDA answered the complaint on November 4, 2022. Dkt. 9. Roughly four months later, the parties moved for summary judgment: the FDA did so on March 2, 2023, Dkt. 16, and Juul cross-moved for summary judgment on April 12, 2023, Dkt. 19.

At that time, Juul also moved for expedited briefing on its summary judgment motion and for *in camera* review, citing its need to use the documents in its defense in a civil case then pending in Minnesota state court. Dkt. 18-1 at 10. The Court held a hearing on the motion for expedited briefing on April 17, 2023. On April 20, 2023, the Court denied that motion, explaining that Juul had "failed to identify any heightened need for expedition" because the pending case for which Juul claimed it needed the documents had been settled, and Juul had "failed to identify any similarly pressing matter." *See* Min. Order (April 20, 2023). After reviewing the parties' summary judgment briefs and the FDA's detailed declarations and *Vaughn* index, and after further discussion at oral argument, however, the Court concluded that *in camera* review of the withheld records would assist the Court in resolving the pending motions,

and, accordingly, the Court ordered the FDA to submit the records for *ex parte*, *in camera* review. Min. Order (Dec. 21, 2023). At the same time, the Court also directed the FDA to file a supplemental declaration further addressing the foreseeable harm requirement. *Id.* The FDA has now complied with both of those directions, Dkt. 31, and Juul has responded to the FDA's supplemental declaration on foreseeable harm, Dkt. 32.

II. LEGAL STANDARD

"The Freedom of Information Act supports a fundamental pillar of free societies: transparency in government." *Protect Democracy Project, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 569 F. Supp. 3d 25, 34 (D.D.C. 2021). Consistent with this purpose, "FOIA . . . mandates that an agency disclose records on request, unless they fall within one of nine exemptions." *Milner v. Dep't of Navy*, 562 U.S. 562, 565 (2011). "These exemptions are 'explicitly made exclusive' and must be 'narrowly construed.'" *Id.* (first quoting *EPA v. Mink*, 410 U.S. 73, 79 (1973), then *FBI v. Abramson*, 456 U.S. 615, 630 (1982)).

Ordinarily, FOIA cases are resolved on motions for summary judgment under Federal Rule of Civil Procedure 56. *See Beltranena v. U.S. Dep't of State*, 821 F. Supp. 2d 167, 175 (D.D.C. 2011). Under that rule, a court may grant summary judgment if there is no "genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." In a FOIA case, "[t]he burden is on the agency to justify withholding the requested documents." *Elec. Priv. Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 777 F.3d 518, 522 (D.C. Cir. 2015). Agencies may satisfy that burden by providing affidavits or declarations that "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) (quoting *Miller v. Casey*, 730 F.2d 773, 776 (D.C. Cir. 1984)). Pursuant to the FOIA Improvement Act, an agency also bears the burden on demonstrating that it is "reasonably foresees that disclosure would harm an interest protected by [the] exemption . . . or [that] disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A). The Court, in turn, must review the agency's affidavits and declarations *de novo*. *See Ctr. for Nat'l Sec. Studies v. U.S. Dep't of Just.*, 331 F.3d 918, 926 (D.C. Cir. 2003); 5 U.S.C. § 552(a)(4)(B).

III. ANALYSIS

This case involves only one FOIA exemption: Exemption 5. That exemption permits an agency to withhold or to redact "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). This exception encompasses "the privileges available to [g]overnment [agencies] in civil litigation," including the deliberative process privilege. *U.S. Fish & Wildlife Serv. v. Sierra Club, Inc.*, 592 U.S. 261, 263 (2021).

The deliberative process privilege applies to "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (quoting *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)) (internal quotation marks omitted). The deliberative process privilege applies only to records that are both predecisional and deliberative. "Documents are 'predecisional' if they are 'generated before the adoption of an agency policy,' and 'deliberative' if they 'reflect[ ] the give-and-take of the consultative process.'" *Judicial Watch, Inc. v. U.S. Dep't of Def.*, 847 F.3d 735, 739 (D.C. Cir. 2017) (alteration in original) (quoting *Public Citizen, Inc. v. Off. of Mgmt. & Budget*, 598 F.3d 865, 874 (D.C. Cir. 2010)).

In addition to demonstrating that the record falls within a privilege encompassed by Exemption 5, the withholding agency must also satisfy the foreseeable-harm requirement, *see* 5 U.S.C. § 552(a)(8)(A), which "applies with special force to deliberative process withholdings under Exemption 5," given the "particular risks of 'overuse'" of that privilege. *100Reporters v. U.S. Dep't of State*, 602 F. Supp. 3d 41, 61 (D.D.C. 2022) (quoting *Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 106 (D.D.C. 2019)). To satisfy the foreseeable-harm requirement, an agency must show that it is reasonably foreseeable that "disclosure would harm an interest protected by the deliberative-process privilege," *Machado Amadis v. U.S. Dep't of State*, 971 F.3d 364, 371 (D.C. Cir. 2020)—that is, that disclosure would cause "injury to the quality of agency decisions," *Sears*, 421 U.S. at 151.

Here, the FDA has invoked Exemption 5 to withhold, in whole or in part, 471 pages of records responsive to Juul's FOIA requests. Dkt. 19-4 at 8. In challenging these with holdings, Juul maintains both that the privilege is inapplicable to these materials and that FDA has failed to carry its burden of establishing foreseeable harm. The Court considers each set of arguments in turn.

A. Deliberative Process Privilege

In defending its application of the deliberative process privilege, the FDA asserts that the withheld materials—the second TPL Review Memo and the nineteen corresponding Discipline Review Memos—were all part of its "decision-making process on Plaintiff's PMTAs, which resulted in a Marketing Denial Order . . . for the subject PMTAs issued on June 23, 2022." Dkt. 16-3 at 5 (German Decl. ¶ 17). These documents are deliberative and predecisional, in the FDA's view, because "[t]hey contain the thinking of CTP scientists developed during review of Plaintiff's PMTAs, for the purpose of helping the agency make its decision on whether to

authorize marketing of Plaintiff's products." *Id.* at 7 (German Decl. ¶ 24). The Discipline Review Memos, in particular, "contain CTP scientists' recommendations to other OS scientists, and to their superiors, regarding each individual scientist's views of the data and information that [the] scientist reviewed." *Id.* (German Decl. ¶ 25). And, in the case of the second TPL Review Memo, the withheld material "express[es] the TPL's individual judgment regarding synthesis of the applicable Discipline Review Memos" with respect to whether "the statutory standard required for marketing authorization" has been met. *Id.* The CTP scientists that authored these materials did not have the authority to decide whether to approve Juul's PMTAs or to issue an MDO; that authority, the FDA explains, rests with the CTP Director, the CTP Deputy Director, and the Director of OS. Dkt. 16-2 at 2, 3 (Mital Decl. ¶¶ 7, 10). And, finally, the FDA explains that the memos were all predecisional; they were prepared "during [the agency's] review of [Juul's] PMTAs, for the purpose of helping the agency make its decision on whether to authorize marketing of [Juul's] products," and they were "finalized before the decision to which they are relevant" was made. Dkt. 16-3 at 7 (German Decl. ¶ 24). The FDA contends that these facts, taken together, establish that the materials appropriately fall within the deliberative process privilege. Juul offers three counterarguments.

1. T*he Additional Disciplines TPL Review Memo Postdates the Agency Decision*

Juul first argues that FOIA Exemption 5 does not apply to the Additional Disciplines TPL Review Memo because that memo "postdates the FDA's decision" to deny Juul's PMTAs, and, thus, it is not predecisional. Dkt. 19-1 at 28–29; *see also Jud. Watch, Inc. v. U.S. Dep't of Just.*, 20 F. Supp. 3d 260, 269 (D.D.C. 2014) ("[C]ourts determine whether a document is predecisional by looking at the timing of the document's release relative to the date the decision

is made." (citing *Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 151 (D.C. Cir. 2006))). The Court is unpersuaded.

Juul premises its argument, in large part, on an article published in the Wall Street Journal on June 22, 2022, which reported that, "according to people familiar with the matter," the FDA was "preparing to order Juul Labs Inc. to take its e-cigarettes off the U.S. market." Dkt. 19-7 at 2. The article noted that "[t]he marketing denial order would follow a nearly two-year review of data presented by the vaping company, which sought authorization for its tobacco- and menthol-flavored products" and that "[t]he FDA could announce its decision as early as this week." *Id.* Noting that the second TPL Review Memo is dated June 23, 2022, Juul argues that the Wall Street Journal article, which was published the previous day, "shows [that the] withheld memo postdates [the] FDA's decision" and that, accordingly, it is not predecisional. Dkt. 19-1 at 28–29.

Juul overstates the import of the Wall Street Journal article. Even accepting the reporting from unnamed sources as fact, the article merely states that the FDA "*was preparing*" to issue an MDO to Juul and that "[t]he FDA *could* announce its decision *as early as* [that] week." Dkt. 19-7 at 2 (emphasis added). The article does not say that the FDA *had* rendered *a final decision* to deny Juul's PMTAs. History is replete with stories of preparation for actions that were never taken and impending announcements that never came. Here, moreover, the FDA has submitted a declaration attesting, under the penalty of perjury, that all of the withheld records—including the second TPL Review Memo—were "predecisional" and "were finalized *before* the decision to which they are relevant" was made. Dkt. 16-3 at 7 (German Decl. ¶ 24) (emphasis added). As the D.C. Circuit has repeatedly observed under similar circumstances, "[a]gency affidavits are accorded a presumption of good faith, which cannot be rebutted by" speculation. *SafeCard*

Servs., Inc. v. SEC, 926 F.2d 1197, 1200 (D.C. Cir. 1991). Here, even accepting the reporting contained in the Wall Street Journal article as fact, it merely shows that the FDA "was preparing" to issue an MDO, not that the responsible agency official had already made a final decision to do so. Juul's contention that the agency had crossed the Rubicon and had, in fact, made its final decision on or before June 22, 2022, accordingly, is both unduly speculative and insufficient to overcome the agency declaration to the contrary.

It is possible, of course, that Juul does not mean to suggest that all press reports about anticipated agency actions are sufficient to draw the line between pre- and post-decisional records but only that, here, there are other reasons to believe that the FDA had, in fact, reached a final decision about Juul's PMTAs while the Additional Disciplines TPL Review Memo was still in the works. Notably, the Additional Disciplines TPL Review Memo was not signed until June 23, 2023, Dkt. 19-4 at 8, the same day that the MDO was issued, Dkt. 19-8 at 2, and the same day that the Toxicology TPL Review Memo and Mital Memo were signed.[2] From this proximity, one might argue that senior OS and CTP officials must have discussed the issue and must have reached a common understanding about how they believed the agency should proceed before the Additional Disciplines TPL Review Memo was actually signed.

[2] Based on the Court's review of the record and the *in camera* submission, it appears that documents were signed in the following order: First, the two TPL review memos, the Toxicology TPL Review Memo and the Additional Disciplines TPL Review Memo, were signed by the TPL at 7:56 a.m. and 7:57 a.m., respectively. *See* Dkt. 19-5 at 2; In-Camera Review Submission (FDA_00427). Then, Director of OS Holman signed both TPL review memos: Holman indicated that he concurred with the Toxicology TPL Review Memo's recommendation to deny Juul's PMTAs because of their toxicological deficiencies at 8:11 a.m., and then signed the Additional Disciplines TPL Review Memo at 8:21 a.m. *See id.*; In-Camera Review Submission (FDA_00427). At 8:56 a.m., Acting CTP Director Mital "concur[red]" with Holman's recommendation and the Toxicology TPL Review Memo's conclusions. Dkt. 16-2 at 29. And at 9:54 a.m., Holman signed the MDO for Juul's PMTAs. *Id.* at 44.

That argument, however, proves too much and, if accepted, would require the very type of intrusive discovery and inquiry that the deliberative process privileged is designed to prevent. Attempts to discern at what point prior to taking a formal the decisionmakers' planned course of action had essentially come to rest would raise the specter, for example, of depositions in many (or most) Exemption 5 cases. It would require courts to intrude into agency deliberations and processes to decide when—as a practical matter—a decision was effectively final, even if the agency had yet—as a legal matter—to take any final action or to announce or to implement the "decision" in any respect. It would introduce significant uncertainty in many (or most) Exemption 5 cases. It would chill last minute (and, often, critically important) deliberations. And, most significantly, it would discount the possibility that the decisionmakers might have a last-minute change of heart or moment of lucidity before signing an order or publicly announcing a policy change

In considering this question, context is paramount. Agency decision-making processes can be more or less formal, and they can take many different forms. Not every agency decision, for example, is embodied in a formal opinion letter, memorandum, other operative document, or official announcement. Here, however, the FDA's decision was embodied in two documents—the MDO, which denied Juul's PMTAs, and the Mital Memo, which reflected OCD's concurrence in the Toxicology TPL Review Memo and which declined to adopt the recommendations contained in the Additional Disciplines TPL Review Memo. Dkt. 16-2 at 29-44. Both of those documents were signed after the Additional Disciplines TPL Review Memo was signed, and thus, even if the Court were to assume (against common sense) that the advice contained in that memo was not offered until the moment that it was actually signed—the memo would still be predecisional. What matters most for present purposes is that the agency

decisionmakers remained "free to change their minds" until the operative documents were executed, *Renegotiation Bd. v. Grumman Aircraft Eng'g Corp*., 421 U.S. 168, 189-90 & n.26 (1975), and the Court cannot cut short the deliberative process or the deliberative process privilege based on the "unsupported assumption that" those decisionmakers must have made a conclusive and unalterable decision before finalizing the Mital Memo and formally issuing the MDO, *id.* at 190. Simply put, "[d]ocuments are 'predecisional' if they were generated before the agency's final decision on the matter," *Sierra Club*, 592 U.S. at 268, and, here, the agency's denial of the PTMAs was not final until after the Additional Disciplines TPL Review Memo was finalized and signed.

It bears emphasis that this is not a one-size-fits-all enterprise, and "[i]t is not always self-evident whether a document represents an agency's final decision." *Id.* Circumstances matter. The Supreme Court has, however, offered a helpful rule of thumb for courts to apply in deciding whether a document is predecisional for purposes of Exemption 5:

> To decide whether a document communicates the agency's settled [or final] position, courts must consider whether the agency treats the document as its final review on the matter. . . . When it does so, the deliberative "process by which the governmental decisions and policies are formulated" will have concluded, and the document will have "real operative effect. . . ." In other words, once cited as the agency's final view, the document reflects "the consummation of the agency's decisionmaking process" and not a "merely tentative" position. . . . By contrast, a document that leaves agency decisionmakers "free to change their minds" does not reflect the agency's final decision.

Id. at 268–69 (citations omitted). Applying that guidance here, the Court has little difficulty concluding that the Additional Disciplines TPL Review Memo was "generated before the agency's final decision on the matter," *id*. at 268. The Mital Memo makes clear that OCD retained ultimate decision-making authority and that, before reaching a final decision, it had received the second TPL Review Memo and had expressly declined to adopt the

recommendations contained in that document. According to the Mital Memo, "OCD initiated review of the conclusions reached by OS;" it concurred with the conclusions reached in the Toxicology TPL Review Memo; because it concurred with those conclusions, it was "not necessary for OCD to review and resolve (and thus CTP has not resolved) any other aspects of the applications;" that the conclusions reached in the second TPL Review Memo "have not been adopted by OCD and do not reflect complete agency consideration or final agency decision;" and, finally, that "the MDO letter should indicate that the list of deficiencies supporting denial is not necessarily exhaustive." Dkt. 16-2 at 29–30. It is difficult to imagine a more definitive indication that the Additional Disciplines TPL Review Memo preceded the agency's final decision and that its conclusions were not adopted by the agency decisionmakers.

To the extent Juul intends to argue that the Additional Disciplines TPL Review Memo was not deliberative because it could not have received meaningful review in the short interval between when that memo was finalized and when the MDO was issued, that argument fails as well. Most notably, it does not matter whether the decisionmakers actually took the time to review the recommendations contained in that memo before acting; what matters is that the memo was prepared for the purpose of providing predecisional advice to them, regardless of whether they followed or even considered that advice. *Reps. Comm. for Freedom of the Press*, 3 F.4th at 362 ("A document is deliberative when it is 'prepared to help the agency formulate its position." (quotation omitted)). At times, for example, "a proposal dies on the vine," *Sierra Club, Inc*., 592 U.S. at 268, but that does not mean that staff recommendations for or against that proposal lose their privileged status merely because they never reached the decisionmaker's desk. Similarly, where a decisionmaker is persuaded by recommendation #1, and thus never considers recommendations #2, #3, and #4, that does not mean that the unconsidered

recommendations lose their privileged status. The privilege is premised on the recognition "that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news." *Klamath Water Users Protective Ass'n*, 532 U.S. at 8–9. Agency staff would take little comfort in knowing that only those memoranda or emails that their supervisors bother to read (or, in the end, need to read) will be protected.

Juul further argues that the decision to deny its PMTAs based solely on toxicological deficiencies, in fact, came much earlier in the process, long before the Mital Memo or the MDO were signed. In particular, it argues that Mital, in explaining the decision-making process that led to the MDO, stated that early on in that process "OS proposed to OCD that a decision denying [Juul]'s application bundle should issue based solely on identified toxicological deficiencies" and that, "[c]onsistent with this approach . . . , the TPL prepared two separate TPL Review Memos." Dkt 16-2 at 4–5 (Mital Decl. ¶ 15). It was at this point—when the FDA decided to bifurcate the TPL review process—that, on Juul's telling, the FDA made the decision to deny its PMTAs based on the toxicological deficiencies and that, as a result, the second TPL Review Memo is not predecisional. Dkt. 27 at 17. Instead, it was merely an "after-the-fact explanation" for a course of action that the FDA had already decided to take. *See Access Reps. v. Dep't of Just.*, 926 F.2d 1192, 1194 (D.C. Cir. 1991). Juul argues, in other words, that the second TPL Review Memo is not predecisional because "at the time [it] was prepared, it was not contemplated to be a document that would form any part of the basis for the outcome on Plaintiff's applications." Dkt. 26 at 14.

The Court is unpersuaded for many of the reasons provided above. Most notably, so long as agency decisionmakers remain "free to change their minds," and so long as they have yet to issue a decision or to announce a policy, documents prepared to communicate candid advice

within the agency are predecisional. Here, moreover, the record shows that the decision to prepare two TPL Review Memos did not represent a final agency decision, and it does not support Juul's contention that the Additional Disciplines TPL Review Memo constituted an "after-the-fact explanation" for a course of action that the FDA had already decided to take. As Mital explains, OCD reserved final decision authority regarding Juul's PMTAs for itself. Dkt. 16-2 at 4 (Mital Decl. ¶ 14). Juul is correct that OS "proposed" that the agency base its decision only on the Toxicology TPL Review Memo, *id.* (Mital Decl. ¶ 15), but that was just a proposal, and according to Mital, that proposal was not adopted until OCD concurred—"agree[ing] that CTP should issue an MDO for the application bunder on the basis of the toxicological deficiencies alone," *id.* at 5 (Mital Decl. ¶ 16), at the very end of the administrative process, *see* Dkt. 16-2 at 29. Moreover, even if there were evidence that OCD had concurred in the decision to prepare two TPL memos before OS took that path, that subsidiary decision would not have foreclosed OCD from considering both memos and making a decision informed by more, rather than less, advice. *See Khatchadourian v. Def. Intel. Agency*, 597 F. Supp. 3d 96, 115 (D.D.C. 2022) ("[A] record generated after one decision" may still be predecisional if it is "the basis of another, future decision."). Juul, for its part, offers no cogent theory for why the agency would have gone to the trouble of preparing the Additional Disciplines TPL Review Memo, if not for the purpose of fully advising OCD regarding the decision that OCD had to make and about whether to accept OS's proposal to rely exclusively on the Toxicology TPL Review Memo.[3]

[3] At times, Juul appears to acknowledge the deliberative nature of the Additional Disciplines TPL Review Memo. In its opening brief, Juul argued that "[b]ureaucrats at CTP with no scientific training told [the Director of OS] what his decision should be after choosing between not one, but two different final decisions authored by the agency's scientists." Dkt. 19-1 at 7. This characterization of the Additional Disciplines TPL Review Memo as constituting one of two possible decisions cuts against Juul's contention that the memo is merely an ex-post explanatory document.

Finally, as explained above, the fact that the Additional Disciplines TPL Review Memo was not ultimately relied upon as the basis for the MDO is of no moment. As the D.C. Circuit has observed:

> A Presidential speechwriter may prepare a draft speech that the President never gives. A Justice Department aide may give the Attorney General a draft regulation that the Attorney General never issues. Those kinds of documents are no less drafts than the drafts that actually evolve into final Executive Branch actions.

Nat'l Sec. Archive v. CIA, 752 F.3d 460, 463 (D.C. Cir. 2014). This is because "[a] privilege contingent on later events—such as whether the draft ultimately evolved into a final agency position—would be an uncertain privilege, and . . . an uncertain privilege is 'little better than no privilege at all.'" *Id.* (quoting *Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981)).

2. *When the Additional Disciplines TPL Review Memo Was Signed, It Was Adopted by the FDA*

Juul argues, in the alternative, that the Additional Disciplines TPL Review Memo is not predecisional because it was signed by the Director of OS, "an agency official with authority to 'approve or deny applications.'" Dkt. 19-1 at 29. To Juul, that signature demonstrates that the memo "reflected the agency's 'settled position' and 'final view on an issue.'" *Id*. "There would have been no reason for [the Director of OS] to sign or give his final concurrence," in Juul's view, "if the document were only a draft, subject to further deliberation about whether a holistic review of the analysis performed by all the relevant scientific disciplines . . . supported granting or denying [Juul]'s applications." *Id.* Or, simply put, "[a]gency officials do not sign working drafts." *Id.* Thus, according to Juul, the signed Additional Disciplines TPL Review Memo was adopted by the agency, regardless of whether the MDO itself ultimately relied on the reasoning it contained.

Juul is correct that "a document can lose its predecisional character—and the protections of privilege—if an agency adopts the document as its own." *Judicial Watch, Inc.*, 847 F.3d at 739. But the soundness of Juul's argument ends there. As the D.C. Circuit has explained, to "adopt a deliberative document, it is not enough for an agency to make vague or equivocal statements implying that a position presented in a deliberative document has merit; instead, the agency must make an 'express[ ]' choice to use a deliberative document as a source of agency guidance," *id.*, or whether it otherwise represents "the agency's settled position" on a matter within the agency's authority, *Sierra Club, Inc.*, 592 U.S. at 268. To make that determination, the Court "must consider whether the agency treats the document as its final view on the matter"—that is, whether "the document reflects the consummation of the agency's decisionmaking process." *Id.* at 268–69 (internal quotation marks omitted); *see also Abtew v. U.S. Dep't of Homeland Sec.*, 808 F.3d 895, 899 (D.C. Cir. 2015) ("Initialing a memo may suggest approval of the memo's bottom-line recommendation, but it would be wrong and misleading to think that initialing necessarily indicates adoption or approval of all of the memo's reasoning. Neither the Supreme Court nor any court of appeals has held that initialing alone renders an otherwise exempt document non-exempt." (internal citations and quotation marks omitted)).

Here, the evidence points decisively in the other direction. Most notably, the MDO letter—the true "consummation of the agency's decisionmaking process"—makes no reference to the reasoning in the Additional Disciplines TPL Review Memo. To the contrary, consistent with the decision set forth in the Mital Memo *not* to adopt Additional Disciplines TPL Review Memo and to convey to Juul that the agency was not taking a position with respect to the additional disciplines, Dkt. 16-2 at 29–30, the MDO emphasizes that the list of deficiencies

included in the MDO "is not necessarily exhaustive" and that the "FDA has not reached a final agency decision on other aspects of [Juul's] application, including for example, the potential benefit to adults as compared to the risk to youth posed by [Juul's] tobacco or menthol products," *id.* at 43. It is not possible to square the FDA's express refusal to reach a final decision with respect to the non-toxicological considerations posed by Juul's PMTAs and Juul's contention that the Director of OS—without authorization from the Director of OCD, who retained final decision-making authority—issued a final determination regarding those very considerations.

Any doubt, moreover, is put to rest by the Mital Memo and Mital's first declaration in this matter, both of which affirm that the "conclusions in the Additional Disciplines TPL Review Memo 'have not been adopted by OCD and do not reflect complete agency considerations or a final agency decision.'" Dkt. 16-2 at 5 (Mital Decl. ¶ 17); *id.* at 29. The Court has no reason to doubt the veracity of these assertions, made by the person with decision-making authority, and supported by a declaration offered under the penalty of perjury. *See SafeCard Servs.,* 926 F.2d at 1200 ("Agency affidavits are accorded a presumption of good faith.").

Careful review of the relevant documents further supports Mital's characterization of the relevant events. When the OS Director signed the Additional Disciplines TPL Review, he did so next to line reflecting "Supervisory OS *Review*" and indicating that he "concur[red] with TPL Findings and Conclusions." In contrast, when he signed the Toxicology TPL Review Memo, he did so next to a line for "Signatory Decision" and indicated that he "concur[red] with TPL recommendation and basis of recommendation." Dkt. 19-5 at 2. As explained in the Supplemental German Declaration, the designation "'Signatory OS Review' does not relate to delegated authority to make a final agency decision; it simply means that an individual at lest one

level above the document's author in the organization performed the review." Dkt. 25-2 at 2 (Second German Decl. ¶ 5). Juul argues that this is a distinction without a difference because the OS Director's signature means that he "concur[red]" with the TPL's reasoning, and the OS Director typically has the authority to grant or deny PMTAs.[4] But that contention ignores the facts of this case, where the CTP Director made clear to the OS Director that the final decision was hers to make, Dkt. 16-2 at 29 (Mital Decl. ¶ 18) ("OCD advised OS that OCD would review any conclusions reached by OS for this bundle before those conclusions became a final agency decision."), and, indeed, she made the final decision, *id.* at 29–30.

3. *Withheld Materials Are Not Deliberative Because They Are Scientific Reports*

Finally, Juul argues that the withheld materials are not deliberative in nature because the review memos are "scientific reports, [and] not policymaking documents." Dkt. 19-1 at 31. It follows, according to Juul, that the reports must be released—or, at the very least, the factual material contained within them must be segregated and released. *Id.* at 33–35.

Once again, Juul's argument starts on sound footing before going astray. Although "materials embodying officials' opinions are ordinarily exempt" from disclosure under the deliberative process privilege, Juul is correct that "factual information generally must be disclosed." *Petroleum Info. Corp. v. U.S. Dep't of Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992). That is because "the prospect of disclosure [of this material] is less likely to make an

[4] Juul also asserts that the "FDA has already told the D.C. Circuit [that] a signed TPL Review memo is "properly considered [] part of the agency's decision." Dkt. 27 at 16 (quoting Oral Arg. at 44:59–45:03, *Fontem US, LLC v. FDA*, No. 22-1076 (D.C. Cir. Jan. 25, 2023)). Juul's representation, however, leaves out some key details—namely, that the FDA represented that a TPL Review Memo signed by the MDO decisionmaker next to the line denoting that the signatory concurred with TPL's recommendation and basis of recommendation could fairly be understood to be part of the administrative record supporting an MDO decision. That representation is squarely in line with the representations the FDA makes here.

advisor omit or fudge raw facts, while it is quite likely to have just such an effect on materials reflecting deliberative or policy-making processes." *Quarles v. Dep't of Navy*, 893 F.2d 390, 392 (D.C. Cir. 1990) (internal quotation marks omitted). But the "[t]he fact/opinion distinction . . . is not always dispositive; in some instances, 'the disclosure of even purely factual material may so expose the deliberative process within an agency' that the material is appropriately held privileged." *Petroleum Info. Corp.*, 976 F.2d at 1434 (quoting *Mead Data Central, Inc. v. Dep't of Air Force*, 566 F.2d 242, 256 (D.C. Cir. 1977)). In other words, "the legitimacy of withholding does not turn on whether the material is purely factual in nature or whether it is already in the public domain, but rather on whether the selection or organization of facts is part of an agency's deliberative process." *Ancient Coin Collectors Guild v. U.S. Dep't of State*, 641 F.3d 504, 513 (D.C. Cir. 2011) (citations omitted); *see also Mapother v. Dep't of Just.*, 3 F.3d 1533, 1539 (D.C. Cir. 1993) ("[T]he selection of the facts thought to be relevant clearly involves 'the formulation or exercise of . . . policy-oriented judgment' or 'the process by which policy is formulated,' in the sense that it requires 'exercises of discretion and judgment calls.'" (quoting *Petroleum Info. Corp.*, 976 F.2d at 1435, 1438) (emphasis omitted)).

In the FDA's view, the Discipline Review Memos fall easily within this exception; they are documents in which the "selection or organization of facts is part of an agency's deliberative process." As Jennifer German, a Regulatory Policy Analyst within the CTP FOIA office explains,

> [I]n both the Withheld Discipline Review Memos and the Additional Disciplines TPL Review Memo, the selection and presentation of factual data and information to include is itself deliberative, in that it outlines the staff scientists' internal thought processes in analyzing Plaintiff's applications. In the withheld records, the staff scientists summarize and distill the voluminous data and information they reviewed in reaching their recommendations regarding Plaintiff's PMTAs. The withheld Discipline Review Memos contain summaries of studies submitted by Plaintiff and other information available to FDA. The

> summaries describe, in an intertwined fashion, the design of various studies and their key features; the strengths, weaknesses, and limitations of the studies; comparisons among and across studies; study outcomes and the scientists' assessment of those outcomes, and data or information that was not submitted or otherwise available to the staff scientists that could have been relevant if present. These summaries intertwine fact and opinion, simultaneously explaining and supporting the discipline reviewers' recommendations to the TPL regarding their individual scientific disciplines, to aid the TPL in making more-comprehensive recommendations to the agency decisionmaker.

Dkt. 16-3 at 9–10 (German Decl. ¶ 33).

Given the fact-intensive nature of this inquiry, the Court ordered (as Juul requested) that the FDA file the contested records *ex parte* and under seal, so the Court could ensure that the agency properly distinguished purely factual material, which reveals little or nothing about the agency's deliberative process, from the selection and synthesis of factual material, which reveals internal, agency deliberations. According to the FDA, it performed a "line-by-line, exacting re-review of the records that were withheld in full . . . to determine whether any portions of them are reasonably segregable," that is, whether the factual matter could be untangled from the analysis. Dkt. 31-1 at 3 (Third German Decl. ¶ 5). This efforts, according to the FDA, permitted the agency to "identify a limited amount of factual information that is not inextricably intertwined with deliberative information," "such as tables of contents; metadata; digital signatures and other agency identifiers; titles and headings; headers and footers; non-application-specific appendices; summaries of Plaintiff's submission history; and a limited amount of introductory language, inspection summary information, and information from Plaintiff's applications." *Id.* (Third German Decl. ¶ 5).

After conducting an *ex parte* review of the withheld material, the Court concludes that the FDA's characterization of the withheld material is largely—although not entirely—correct; the material either constitutes "predecisional and deliberative analysis of FDA staff scientists" or

consists of "factual information that cannot be segregated and disclosed without effectively revealing the substance of the protected analysis and deliberations." *Id.* at 3 (Third German Decl. ¶ 6). That said, there appears to be some material in the *in camera* submission that is purely descriptive in nature and that does not reveal agency deliberations. For example, the First Engineering Discipline Review contains a description of the packaging in which Juul's new tobacco products would be sold: the packaging descriptions do not contain any analysis; nor is it evident that the author, in describing Juul's packaging, separated the wheat from the chaff in a deliberative manner. *See* In-Camera Review Submission (FDA_00161–62). Other portions of the withheld material seem to consist of summaries of what Juul included in its PMTAs, such as descriptions of the Juul device with no analysis regarding Juul's claims about its functionality or safety, *see, e.g.*, In-Camera Review Submission (FDA_00144–47), or abstracts from studies Juul submitted regarding perceptions about its e-cigarette devices, *see, e.g.*, In-Camera Review Submission (FDA_00222–33). Because Juul's PMTAs are not included in the administrative record, however, the Court is unable to discern how much of this material (including the images and tables) is simply lifted from Juul's applications without the addition of any analytical varnish or deliberative selection.

The majority of the withheld material appears to be well-justified. But to ensure that the FDA has met its "burden to disclose all reasonably segregable information" within the withheld documents, *Willis v. U.S. Dep't of Just.*, 581 F. Supp. 2d 57, 77 (D.D.C. 2008), the Court will order the agency to conduct a further review to identify what, if any, material is simply lifted from Juul's PMTAs without deliberative selection. The Court cautions the FDA that to the extent it maintains that purely descriptive material is subject to protection because it reflects deliberative choices about what to include (and what to omit), the agency will need to justify any

such conclusions in a supplemental declaration or *Vaughn* index that explains how the selection of particular facts might reveal agency deliberations. *See Stolt-Nielsen Transp. Grp., Ltd. v. United States*, 534 F.3d 728, 734 (D.C. Cir. 2008) (noting that the district court must "make specific findings of segregability"); *Vaughn v. Rosen*, 484 F.2d 820, 825 (D.C. Cir. 1973) ("[A]n entire document is not exempt merely because an isolated portion need not be disclosed. Thus, the agency may not sweep a document under a general allegation of exemption, even if that general allegation is correct with regard to part of the information."). The parties should also notify the Court if any of the material at issue may contain trade secret information that Juul would oppose the release of pursuant to the Trade Secrets Act, 18 U.S.C. § 1905, or any similar law. *See AAR Airlift Grp., Inc. v. United States Transportation Command*, 161 F. Supp. 3d 37, 41–42 (D.D.C. 2015).

As for the remaining material, the Court concludes that the agency properly applied the deliberative process privilege. The withheld portions of the Discipline Review Memos contain analyses in which agency scientists "distill[ed] the raw data and information submitted by [Juul] in its PMTAs," "separat[ed] the significant facts from the insignificant facts," "weigh[ed] the significance of various types of information against each other, and dr[ew] conclusions therefrom." Dkt. 25 at 9. Analysis of this type necessarily "requires [the] 'exercise[] of discretion and judgment calls,'" *Mapother*, 3 F.3d at 1539 (quoting *Petroleum Info. Corp.*, 976 F.2d at 1438), and the Court, accordingly, concludes that many of the withheld portions of the Discipline Review Memos are deliberative in nature.

This conclusion is consistent with decisions that have held that agencies may withhold records that summarize large quantities of largely factual material and that were prepared to facilitate the making of a specific decision. In *Montrose Chemical Corporation of California v.*

Train, 491 F.2d 63 (D.C. Cir. 1974), for example, the D.C. Circuit held that summaries of a more than 9,200-page record to help the EPA Administrator determine whether the pesticide DDT was injurious to the environment were properly withheld pursuant to the deliberative process privilege. The Court reasoned that "[t]o probe the summaries of record evidence would be the same as probing the decision-making process itself" because those summaries contained "the evaluation and analysis of the multitudinous facts made by the Administrator's aides and in turn studied by him in making his decision." *Id.* at 68. In other words, the process of "separating the wheat from the chaff is surely . . . part of the deliberative process." *Id.* at 71.

Similarly, in *Mapother v. Department of Justice*, 3 F.3d 1533 (D.C. Cir. 1993), the D.C. Circuit held that a 204-page document that detailed the wartime activities of a specific individual for the purpose of deciding whether to permit him to enter the United States was lawfully withheld pursuant to the deliberative process privilege. *Id.* at 1535. In that case, the authors of the document "cull[ed] the relevant documents, extract[ed] pertinent facts, organize[d] them to suit a specific purpose, and . . . identif[ied] the significant issues they encountered along the way." *Id.* at 1538. The court explained: "It is true that the products of such labors can loosely be characterized as factual, in the sense that the issues ultimately being addressed have a prominent factual component." *Id.* at 1538. But when "the selection of the facts thought to be relevant clearly involves 'the formulation or exercise of . . . policy-oriented *judgment*' or 'the process by which *policy* is formulated,' . . . in the sense that it requires 'exercise of discretion and judgment calls,'" *id*. at 1539 (citation omitted), the deliberative process privilege applies. In this respect, the Discipline Review Memos are similar to the records lawfully withheld in *Mapother* and *Montrose*: they "distill the voluminous data and information" contained in Juul's PMTAs, Dkt. 16-3 at 9 (German Decl. ¶ 33), which, by Juul's own description, contain "over 125,000 pages of

information, data, and analysis," Dkt. 19-1 at 11. The memos "extensively intertwine the facts with their evaluations" and make recommendations that "are a critical part of the agency's . . . decision[-]making process" as to whether to approve Juul's PMTAs. Dkt. 16-3 at 10 (German Decl. ¶ 35).

Juul attempts to distinguish *Mapother* and *Montrose* by emphasizing the scientific nature of the Discipline Review Memos. Juul notes that the withheld memos "analyze[] [Juul]'s products 'from a microbiology perspective,' 'from a social science perspective,' 'from a medical perspective,' and 'from an epidemiology perspective.'" Dkt. 19-1 at 31 (quoting the *Vaughn* index). The Discipline Review Memos, Juul maintains, thus "reflect the fact-based conclusions of FDA's scientific reviewers, not discretionary policy-making judgments." *Id.* at 32. For support, Juul invokes *Center for Biological Diversity v. EPA*, 279 F. Supp. 3d 121 (D.D.C. 2017). In that case, the Court concluded that the EPA had "not shown with sufficient particularity that the withheld documents reflect 'policy judgments' exempt from disclosure under the deliberative process privilege." *Id.* at 150. The Court noted that not all "scientific determinations" involve the "kinds of policy determinations protected by the deliberative process privilege." *Id.* at 151. Courts from outside this circuit, for example, have concluded that "'adverse modification' decision[s] under § 7 of the [Endangered Species Act]" were "factual and scientific rather than a legal or policy determination." *Id.* (citing *Greenpeace v. National Marine Fisheries Serv.*, 2000 WL 151915, *2 (W.D. Wash., Feb. 2, 2000)); *see also Greenpeace v. National Marine Fisheries Serv.*, 198 F.R.D. 540, 544 (W.D. Wash. April 11, 2000) ("Section 7 of the ESA does not require, nor permit, discretionary policy-making," and "[a] determination of jeopardy or adverse modification is limited to objective, fact-based scientific conclusions.").

The Court is unpersuaded. In determining whether a tobacco product is "appropriate for the protection of the public health," the FDA is required by statute to make a judgment "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products" and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4). As the D.C. Circuit has explained, this type of "public health inquiry" requires "a high-level balancing test as to the overall public health consequences of the product at issue." *Fontem*, 82 F.4th at 1218; *see also Prohibition Juice Co. v. U.S. Food & Drug Admin.*, 45 F.4th 8, 19–20 (D.C. Cir. 2022) (rejecting an argument that in engaging in this public health assessment, the FDA is limited to only considering the "'physiological health risks' of individual tobacco products without taking account of a 'broader concept of risk"). Here, the "balancing" required to assess "the public health" implications of approving Juul's PTMAs involves far more than the recitation of settled facts and cannot be separated from the exercise of discretion.

* * *

For these reasons, the Court concludes that the FDA has met its burden of showing that most (but not all) of the materials it withheld are predecisional and deliberative and thus protected by Exemption 5.

B. Foreseeable Harm

Establishing that the deliberative process privilege applies does not end the inquiry. To withhold records pursuant to Exemption 5, an agency must also demonstrate that it "reasonably foresees that disclosure would harm an interest protected by [the] exemption" to justify nondisclosure under the FOIA. 5 U.S.C. § 552(a)(8)(A)(i)(I). The foreseeable-harm

requirement "impose[s] an independent and meaningful burden on agencies." *Reps. Comm. for Freedom of the Press,* 3 F.4th at 369 (quotation marks omitted). "To satisfy this burden, agencies must do more than 'rely on mere speculative or abstract fears, . . . [a] fear of embarrassment,' or 'generalized assertions' of harm." *100Reporters*, 602 F. Supp. 3d at 71 (quoting *Reps. Comm. for Freedom of the Press*, 3 F.4th at 369–70). Instead, agencies must "specifically and thoughtfully" explain "why disclosure of the particular type of material at issue will, in the specific context of the agency action at issue, actually impede" the interest protected by the exemption "going forward." *Reps. Comm. for Freedom of the Press*, 3 F.4th at 370–72.

Agencies can meet this burden by grouping like records together and describing, "on a category-by-category basis," "the harm that would result from the release of each group." *Reps. Comm. for Freedom of the Press*, 3 F.4th at 369. But "the basis and likelihood of that harm must be independently demonstrated for each category." *Id.* "A 'perfunctory state[ment] that disclosure of all of the withheld information—regardless of category or substance—would jeopardize the free exchange of information between senior leaders within and outside of the [agency]' will not suffice." *Id.* at 370 (alterations in original) (quoting *Rosenberg v. Dep't of Defense*, 342 F. Supp. 3d 62, 79 (D.D.C. 2018)).

Here, the FDA points to two types of harms to the deliberative process. According to the agency: (1) it is "reasonably foreseeable that revealing the substance of unfinished staff scientist-level deliberations would cause confusion regarding the basis of FDA's MDO," Dkt. 16-2 at 7 (Mital Decl. ¶ 24), and (2) "it is reasonably foreseeable that the [its] current and future deliberations regarding the same data and information, as analyzed by scientists from various disciplines other than toxicology, would be adversely impacted" by the release of the withheld documents. *Id.* at 6 (Mital Decl. ¶ 23). Juul maintains that neither ground is sufficient to

establish foreseeable harm sufficient to justify the withholdings. For the reasons explained below, the Court concludes that the FDA has satisfied its burden of demonstrating foreseeable harm.

1. *Public confusion*

The FDA first argues that release of the withheld information would cause foreseeable harm by confusing the public about important questions of public health. *See* Dkt. 16-2 at 7 (Mital Decl. ¶ 24); Dkt. 31-2 at 3 (Third Mital Decl. ¶¶ 6–7). As the Deputy Director of the CTP explains:

> In its role as a public health agency, [the] FDA endeavors to ensure that the American public understands the Agency's views on public health issues. This is particularly important with respect to [the] FDA's regulation of tobacco products. In enacting the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009), Congress found that consumers are "likely to be confused and misled" by certain statements and implications made by manufacturers about FDA regulation of their products. Sec. 2(46); *see also id.* at Sec. 2(17) (finding that tobacco product advertising often misleads youth by, e.g., portraying tobacco us as "healthful"); 21 U.S.C. § 331(tt) (prohibiting express or implied statements or representations directed to consumers that would mislead consumers into believing certain conclusions about [the] FDA's position on a tobacco product). Public misunderstanding over [the] FDA's perspective on tobacco products, including the Agency's regulatory conclusions regarding a specific tobacco product, may make nonusers of tobacco products, including youth, more like to use a tobacco product—and also make existing users of tobacco products more likely to continue their consumption—and incur health risks as a result.

Id. at 3 (Third Mital Decl. ¶ 6). The Deputy Director, moreover, does not rely on mere generalities but, instead, ties the release of the specific records at issue to a specific interest protected by Exemption 5. She explains:

> Disclosure of the records at issue, which reflect unfinished Agency deliberations, would cause public confusion regarding the basis of [the] FDA's marketing denial order ("MDO") for Plaintiff's products. More specifically, their release would likely give the public the wrong impression that [the] FDA has reached a final decision on the issues contained in them. Such public confusion could result in serious health harms. For example, statements in these

> records may be presented and viewed out of context to misrepresent [the] FDA's perspective on the risk and benefits of the subject products, which, in turn, could impact the likelihood of nonusers of tobacco products initiating use, and of existing users of tobacco products continuing their use. The deliberative process privilege exists to, among other things, protect against the public confusion that would result from the dissemination of documents that would suggest reasons for an agency's action different from those that were the ultimate reason for the action. . . .

Id. at 4 (Third Mital Decl. ¶ 7).

This detailed explanation satisfies the foreseeable harm requirement. The explanation is neither conclusory nor boilerplate. *See Reps. Comm. for Freedom of the Press*, 3 F.4th at 370. It is not based on "'abstract fears[] or fear of embarrassment.'" *Id.* at 369 (citation omitted). It carries the required "link between the specified harm and specific information contained in the material withheld." *Id.* (citation omitted). And, most significantly, it satisfies the statutory nexus requirement by connecting the foreseeable harm to the "interest protected by [the FOIA] exemption" at issue. 5 U.S.C. § 552(a)(8)(A)(i)(I).

Courts are, of course, required to construe FOIA exemptions narrowly, and the "ultimate aim" of the deliberative process privilege "is to prevent injury to the quality of agency decisions." *Pavement Coatings Tech. Council v. U.S. Geological Surv.*, 995 F.3d 1014, 1022 (D.C. Cir. 2021) (citation and internal quotation marks omitted). For this reason, "public confusion" is typically considered a "subsidiary rationale for the deliberative process privilege." *Petroleum Info. Corp.*, 976 F.2d at 1436 n.10. But a consistent line of D.C. Circuit precedent from the 1970s to the present recognizes that the deliberative process privilege serves multiple purposes, including protecting "the public from the confusion that would result from premature exposure to discussions occurring before the policies affecting it had actually been settled upon." *Jordon v. U.S. Dep't of Just.*, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc); *see also Russell v. Dep't of the Air Force*, 682 F.2d 1045, 1048 (D.C. Cir. 1982); *Judicial Watch, Inc. v. U.S.*

Dept' of Defense, 847 F.3d 735, 739 (D.C. Cir. 2017); *Pavement Coatings Tech. Council*, 995 F.3d at 1022; *Reps. Comm. for Freedom of the Press*, 3 F.4th at 361. And that same precedent ties this purpose to the "ultimate aim," *Pavement Coatings Tech. Council*, 995 F.3d at 1022, or "goal" of preventing "'injury to the quality of agency decisions,'" *Reps. Comm. for Freedom of the Press*, 3 F.4th at 361 (quoting *Sears*, 421 U.S. at 151).

When an agency asserts a concern about public confusion, courts should proceed with caution. They must consider whether the agency is merely attempting to avoid the public vetting of "information marred by errors," *Petroleum Information Corp.*, 976 F.2d at 1436 n.10, or information that could cause "embarrassment," *Reps. Comm. for Freedom of the Press*, 3 F.4th at 369. The Court must also bear in mind that Congress adopted the foreseeable harm requirement, in significant part, to address "increasing agency overuse and abuse of Exemption 5 and the deliberative process privilege." *Id.*

But even viewed through this lens of caution, the FDA's concern about public confusion rings true in this case for several reasons. To start, the FDA is an expert, public health agency. Its pronouncement that a product is safe or unsafe has serious consequences. In addition, based on the FDA's representations and the Court's review of the withheld records, the Court is persuaded that their release would likely cause public confusion. In the words of CTP's Deputy Director, release of the deliberative memoranda at issue here "would likely give the public the wrong impression that FDA has reached a final decision on the issued contained in them." Dkt. 31-2 at 4 (Third Mital Decl. ¶ 7). After all, as the FDA emphasizes, its review of Juul's PMTAs is ongoing in light of the supervisory review that Juul itself requested. *Id.* at 4–5 (Third Mital Decl. ¶ 8). Release of the withheld records would risk misleading the public about the status of

the agency's ongoing review and about the significance of those internal, staff-level recommendations.

Juul, for its part, offers no reason to doubt that release of the withheld records would likely cause public confusion on a matter affecting the public health, which, in any event, the withheld records themselves bear out. Their release would have authoritative force, and, even if the agency publicly disavowed any final, agency imprimatur, the distinction between the views of the agency and the views of the scientists who work for the agency would likely be lost on many members of the public. Members of the public would likely conclude that the FDA had rendered a series of decisions that, in fact, the agency has not rendered—and that it is still considering. *See Nat'l Ass'n of Minority Veterans v. United States Dep't of Veterans Affs*., No. 21-cv-1298, 2024 WL 810032, at *8 (D.D.C. Feb. 27, 2024) ("[P]ublic confusion . . . applies primarily to 'premature exposure to discussions occurring before the policies affecting it had actually been settled upon.'" (quoting *Jud. Watch, Inc. v. U.S. Dep't of Def*., No. 19-cv-1384, 2021 WL 270503, at *4 n.2 (D.D.C. Jan. 27, 2021))).

For these reasons, this case differs in important—and dispositive—respects from prior cases in which this Court has found insufficient agency declarations that generically assert that the release of deliberative, predecisional documents will "confuse the public" without reference to how that confusion relates to the quality of the agency's decision-making processes. *See, e.g., Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 107 (D.D.C. 2019) (finding insufficient a declaration that stated that "releasing these documents could result in confusion regarding reasons and rationales that may not ultimately be the grounds for any actions [the agency] may take"); *Americans for Fair Treatment v. U.S. Postal Serv.*, 663 F. Supp. 3d 39, 60 (D.D.C. 2023) (finding insufficient the agency's statement that release of

draft would cause foreseeable harm because that draft "'differ[s] from the final version' of a policy or statement"); *Reps. Comm. for Freedom of the Press*, 3 F.4th at 371 (finding insufficient the agency's statement that release of the documents would "potentially confuse the public about the reasons for the [agency]'s actions in this matter"); *cf. Pavement Coatings Tech. Council*, 995 F.3d at 1022 (finding insufficient claims that "releasing the model runs will enable criticism of USGS" because "criticism" untethered to agency decision-making "is not a recognized harm against which the deliberative process privilege is intended to protect").

Instead, the FDA's showing is more in line with agency declarations that this Court has concluded sufficiently "articulate[] a specific link between the specified harm—public confusion—and the nature of the withheld documents," *Pub. Emps. for Env't Resp. v. Dep't of Homeland Sec.*, 575 F. Supp. 3d 34, 51 (D.D.C. 2021), that is the "context and purpose" of those materials, *Reps. Comm. for Freedom of the Press*, 3 F.4th at 371. In *Public Employees for Environmental Responsibility v. Department of Homeland Security*, for example, this Court considered whether foreseeable harm would result from the disclosure of predecisional, deliberative "drafts of DHS's Strategic National Risk Assessment," which "address systemic risks to national security (e.g., natural disasters and terrorist attacks)." 575 F. Supp. 3d at 40. The agency's declaration stated that "disclosure of the SNRA would harm FEMA 'by prematurely revealing threats and hazards . . . [which] would . . . cause confusion to the public and may result in members of the public taking action on potential threats and hazards where no action is warranted,' or in a manner not 'suggested by a recommendation contained in the documents.'" *Id.* at 51. The Court concluded that the declaration was sufficient because "explained not just that release of the [draft in question] would cause public confusion, but specifically articulated how the nature of the information contained within the documents—

threats, hazards, and recommendations—would cause such confusion." *Id.* at 52. Here too, the FDA has not just relied on a generic specter of public confusion to justify withholding these materials, but has specifically explained why the information contained in the withheld drafts would confuse the public in such a way to undermine the agency's internal processes. *See also Energy Pol'y Advocs. v. SEC*, No. 22-cv-1497, 2023 WL 6976071, at *6 (D.D.C. Oct. 23, 2023); *Reps. Comm. for Freedom of the Press v. U.S. Customs & Border Prot.*, 567 F. Supp. 3d 97, 122 (D.D.C. 2021).

The Court, accordingly, is satisfied that the FDA has established that release of the withheld memos would cause foreseeable harm.

2. *Chilling effect*

Although that conclusion suffices, the Court is also persuaded that those involved in reviewing PMTAs would be "discourage[d] . . . from appropriately refining or revising [the agency's] analysis based on further discussion and deliberation" if the prior deliberations, enshrined in the withheld materials, were disclosed. Dkt. 16-2 at 7 (Mital Decl. ¶ 23). Juul, for its part, does not dispute that a well-founded assertion by an agency that internal agency deliberations would be chilled by the disclosure is ordinarily sufficient to meet the foreseeable-harm requirement. Instead, it argues that the risk of chilling future deliberations is not present here because the withheld documents are of types that are routinely made available to the public—even if the PMTA is not approved and an MDO is issued. Dkt. 19-1 at 21.

For support, Juul cites to *Vanda Pharmaceuticals, Inc. v. FDA*, 2023 WL 2645714 (D.D.C. March 27, 2023). In that case, Vanda Pharmaceuticals ("Vanda") had filed a FOIA request for the clinical and statistical reviews that the FDA had generated during the assessment of Vanda's supplemental New Drug Application ("sNDA"). Typically, when the FDA reviews

an sNDA, it "assembles an interdisciplinary review team of clinicians and scientists to review the submission and compile its opinions and recommendations." *Id.* at *1. "After consulting the reviews," the FDA will "either approve[] the drug" or will "send[] the manufacturer [a response] detailing the application's deficiencies." *Id.* Vanda had sought the reviews that were created as part of the sNDA review process, but, invoking the deliberative process privilege, the FDA declined to release those material. *Id.* The Court sided with Vanda, concluding that "regardless of whether the reviews [were] predecisional or deliberative," the FDA had not "satisfied its obligation to show a foreseeable harm from publication." *Id.* at *3.

In *Vanda Pharmaceuticals*, the FDA had argued that the foreseeable harm requirement was satisfied because "the agency scientists who review sNDAs do not anticipate that their comments [will] be used for anything but internal deliberations and publication of their views would thus deter the scientists from giving their honest assessments." *Id.* (internal quotation marks omitted). The Court was unconvinced for several reasons. It first noted that "the agency is required by statute to publish underlying reviews whenever an *NDA* is approved" and that the agency "will release reviews from approved *sNDAs* in response to a FOIA request." *Id.* (second emphasis added). The Court then explained that, even if "the FDA [is] correct that it does not have a practice of releasing statistical and clinical reviews underlying *pending* sNDAs," "reviews associated with pending sNDAs would be subject to release . . . should the application ultimately be approved." *Id.* at *4 (emphasis in original). As a result, the Court reasoned, sNDA reviewers must always be prepared when drafting their reviews for the eventuality that their work will be disclosed; they are "unaware during the review process whether their work will be made public" after the drug is approved. *Id.* The FDA, accordingly, failed to meet its burden of establishing

foreseeable harm; as the Court explained, "[d]isclosure cannot chill deliberations if those deliberating do not reasonably expect their deliberations to remain private." *Id.*

Comparing this case to *Vanda Pharmaceuticals*, Juul notes that the "FDA regularly makes its TPLs and disciplinary reviews available for authorized tobacco products." Dkt. 19-1 at 20. Indeed, FDA regulations expressly contemplate the disclosure of such materials. *See* 21 C.F.R. § 1114.47(c) (permitting the "[d]isclosure of [certain] data and information after issuance of a marketing granted order" to the public "upon request or at FDA's own initiative, including information from amendments to the application and FDA's reviews of the application"). "Even for denied applications," moreover, the FDA will release "reviewer notes and other materials the FDA 'considered,' 'reviewed,' or 'relied on' in its final decision." Dkt. 19-1 at 20. Given this practice of releasing materials, Juul argues, "a reviewer cannot reasonably expect that a review will remain private," Dkt. 27 at 9, and, as a result, the FDA cannot reasonably expect that a reviewer's participation in the review process will be chilled going forward if the materials Juul requests are released.

The FDA concedes that Juul is correct up to this point. At a hearing held on December 1, 2023, however, the agency "narrow[ed] [its] argument" and explained that it is "not taking the position that the authors of the [D]iscipline [R]eview [M]emos have an expectation of confidentiality at the time [that] they author those decisions." Dkt. 33 at 14 (Dec. 1, 2023 Hr. Tr. 14:13–18). Later, the FDA further clarified that its assertion of foreseeable harm is, instead, focused on the chilling effect that releasing the withheld materials would have on the on-going *supervisory review*. As the third Mital declaration explains:

> [The] FDA is presently engaged in a supervisory review process involving [Juul]'s MDO, and such review may involve further consideration of issues preliminarily considered in these records. The release of these records, while the supervisory review process remains ongoing, would foreseeably chill

> deliberations pertaining to the Agency's reconsideration of [Juul]'s PMTAs. . . . The premature disclosure of the withheld records, and the preliminary analyses set forth therein, would foreseeably chill that candor by exposing to public scrutiny the Agency's preliminary and unfinished deliberations, while the Agency's decision-making process is still ongoing. Such scrutiny could, for example, place undue pressure on the relevant Agency staff to hew to these preliminary assessments—or, conversely, change them. In either scenario, such scrutiny would foreseeably distort the decision-making process, to its detriment.

Dkt. 31-2 at 4–5 (Third Mital Decl. ¶ 8). In other words, the FDA fears that release of the withheld materials would chill the agency officials who are currently conducting the supervisory review of the MDO decision and would, in that respect, adversely affect the agency's ongoing deliberations.

This supervisory-review-focused framing of the chilling effect is different from the chilling effect that *Vanda Pharmaceuticals* considered. In that case, the agency was concerned that the scientists who authored the requested materials would be chilled from providing candid recommendations in the future (on the same, revised application or on a different application entirely). The Court discounted that concern because the scientists never had a reasonable expectation that any analyses that they produced would remain confidential. Here, in contrast, the FDA is concerned that releasing the requested materials at this time will adversely affect the deliberations of the supervisors—including the new CTP Director—who are currently reviewing the MDO in light of "scientific issues unique to this application that warrant additional review," Dkt. 1 at 19. The FDA is concerned that publicly disclosing the internal agency materials, which agency officials are relying on now to inform their review of the MDO, will distort and hinder their review forcing the agency "to operate in a fishbowl," *EPA v. Mink*, 410 U.S. 73, 87 (1973).

The FDA's concern about this supervisory-review-focused chilling effect is well taken. When the FDA conducts a supervisory review of a prior agency decision and reconsiders the administrative file, *see* 21 C.F.R. § 10.75(d), disclosure of internal, working recommendations

will likely impede robust agency deliberations. Consider, for example, the impact that release of a respected scientist's internal recommendation might have on a supervisor's consideration of the same issue: a supervisor could (and likely would) feel at least some pressure to adopt those views because (1) she might be criticized for disagreeing, even in small part, with a respected scientist or, more seriously, (2) she might feel compelled to support a colleague in public, even if she might privately disagree at least in part, to avoid embarrassing her colleague and to preserve a good working relationship with her staff. By way of analogy, imagine for a moment the staffer who secretly (and improperly) leaks a deliberative record with the hope of forcing the decisionmaker's hand in one way or the other. Situations like these, where a supervisor's ability objectively to review the agency's prior decision is impaired by the public disclosure of deliberative material, is why the deliberative process privilege exists. The "privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news." *Klamath Water Users Protective Ass'n*, 532 U.S. at 8–9.

Juul argues that the FDA's concern is overstated. Noting that the governing regulation limits a supervisory review to the "information in the administrative file," 21 C.F.R. § 10.75(d), and that a "interested" third-party may request such review, *id.* § 10.75(c), Juul contends that the "regulation[] contemplate[s] reassessing files that will have already been released"—otherwise how could a third party effectively request a supervisory review. Dkt. 32 at 6. And it then argues that public release of that file could not seriously undermine the supervisory review process. But the premise of Juul's argument—that the regulations necessarily contemplate release of the files, in their entirety, to third parties—is unsound. Not only can a third party request supervisory review without access to the complete administrative file, but that is

precisely what Juul did here, and Juul is not even a third party. Juul requested supervisory review of the MDO decision, without access to the withheld materials, and FDA agreed to conduct such a review.

Juul offers one final retort: it asserts that the FDA exaggerates the impact that releasing the withheld materials would have on the ongoing supervisory review. Dkt. 19-1 at 23. Juul points out that it has identified three cases where the "FDA has voluntarily rescinded marketing denial orders or had those orders set aside by a federal court, with FDA placing the application back in scientific review."[5] *Id.* Juul asserts that in each of those cases, the administrative record "included the scientific discipline reviews and [the] TPL memo supporting FDA's subsequently rescinded marketing denial order," and that notwithstanding the release of those materials, the FDA was able to reevaluate its prior MDOs. *Id.* But, in support of this view, Juul cites only to the indices of the administrative records in those three cases, *see* Dkt. 19-30 (*Al Khalifa Group v. FDA*, No. 21-71340, Dkt. 21-2 at 2–3 (9th Cir.)); Dkt. 19-31 (*Bidi Vapor LLC v. FDA*, No. 21-13340, Index to Administrative Record, at 4 (11th Cir. Oct. 25, 2011)), and from those indices all the Court can ascertain is that certain "technical reviews" were released; it cannot determine whether those technical reviews are analogous to the Discipline Review Memos at issue here.[6]

[5] Juul asserts that it was able to identify "at least a dozen cases over the past three years" where this was the case. But to support this assertion, Juul attaches a table that lists company names, the "MDO issuance date" and "update[s]" for each of those companies' entries. The vast majority of the entries on this table have no "update[s]." Those that do, lack case numbers or any ability for the Court to verify what was listed in this table as an "update." In addition, Juul cites to two cases, *My Vape Order Inc. v. FDA*, No. 21-71302 (9th Cir.), and *Fumizer, LLC v. FDA*, No. 21-71315 (9th Cir.), which it suggests involved a "subsequently rescinded marketing denial order," Dkt. 19-1 at 23, but from what the Court can ascertain, the supervisory review in *My Vape Order* is still ongoing and *Fumizer* was dismissed for failure to prosecute.

[6] Nor do the dockets in each of those cases provide any clarity about what documents were included in the administrative record. In *Bidi Vapor*, the Eleventh Circuit's opinion provides a brief overview of materials in the administrative record, but that overview does not appear to

But even assuming Juul's characterization of the records is correct—that is, that the administrative records include the "scientific discipline reviews and [the] TPL memo supporting" each of the FDA's MDOs—Juul's argument is unconvincing. The fact that the FDA was able to conduct a supervisory review, even though certain underlying documents were released, does not mean that the review was not considerably harder or that the quality of the decision was not lessened because of the availability of those materials. The inquiry at issue is whether the release of the withheld materials would impair "the quality of agency decisions," *Sears*, 421 U.S. at 151, not whether disclosure would render agency decision-making impossible. And, as to that former question, Juul has provided no basis from which to conclude that the agency's discussion in its declaration of the challenges of conducting a supervisory review when all the materials that are part of that review are made public is inaccurate.[7]

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discuss the "technical reviews" at issue. *Bidi Vapor LLC v. FDA*, No. 21-13340, Memorandum Opinion, at 18–19, Dkt. 77-1 (11th Cir. August 23, 2022).

[7] As Juul itself acknowledges, the administrative record in each of those three other cases included only those materials that "support[ed]" the MDO, Dkt. 19-1 at 23, or said differently, were "considered, reviewed, or relied on" by the agency, Dkt. 25-1 at 3 (German Suppl. Decl. ¶ 9). The withheld materials Juul seeks, however, do not fall within that category. As Mital makes explicit in her June 23, 2022 memorandum, she did not "consider, review, or rely on" the Additional Disciplines TPL Review Memo and the Discipline Review Memos it assessed when she decided to deny Juul's PMTAs solely on the basis of the applications' toxicological deficiencies. *See* Dkt. 16-2 at 29 (Mital Memo) ("OCD completed review of the TPL Review (Toxicology) and hereby concurs with its conclusions. Because OCD concurs that the toxicological issues are dispositive of the applications, it is not necessary for OCD to review and resolve (and thus CTP has not resolved) any other aspects of the applications."). Therefore, unlike the materials released in those other three cases (and the materials released to Juul to date), the materials Juul seeks were not those relied upon by the agency when it decided to issue the MDO. There is a distinction between reconsidering a decision rendered on the basis of already-considered (and publicly available) materials and reconsidering a decision based on new information; the fish-bowl effect may be more pronounced for the latter category than the former.

Accordingly, the Court is persuaded that the risk that the ongoing supervisory review process will be chilled by the release of these materials adds substantially to the FDA's showing of foreseeable harm.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** in part and **DENIES** in part the FDA's motion for summary judgment, Dkt. 16, and **GRANTS** in part and **DENIES** in part Juul's cross-motion for summary judgment, Dkt. 19.

In addition, the FDA is directed to conduct a further review of the withheld materials to identify what portions of that material (if any) simply parrot what Juul included in its PMTAs, without additional analysis or deliberative selection, and whether any such material includes trade secret information as to which Juul opposes release. The parties are **ORDERED** to submit a joint status report on the status of this review on or before May 24, 2024.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: April 23, 2024