IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN FOUNDATION, INC., Plaintiff, v. FOOD & DRUG ADMINISTRATION and DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendants.	Civil Action No. 16-781 (APM)

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

In their opposition to plaintiff Public Citizen's Motion for Summary Judgment (Dkt. No. 9), defendants Food and Drug Administration and Department of Health and Human Services (collectively, FDA) ask this Court to deny the motion as premature. *See* FDA Opp. (Dkt. No. 13). FDA's argument has no merit, and the Court should flatly reject FDA's effort to engineer an open-ended stay of the briefing on Plaintiff's motion.

INTRODUCTION

For more than two years, FDA has drawn out its response to Public Citizen's FOIA request for unredacted advisory committee member curricula vitae (CVs), trickling out responsive documents that contain essentially the same redactions that FDA made before posting the CVs to its website. FDA has never substantively responded to any of Public Citizen's three administrative appeals. Clattenburg Decl. to Pl. Mot. For Summ. J. ¶¶ 10, 16, 21 & Ex. 4 at 3-7

& 10-12. FDA sought an extension to file its responsive pleading after Public Citizen filed suit, and it then filed a partial motion to dismiss (Dkt. No. 7), followed by a reply that argued for the first time that Public Citizen's policy and practice claim should be dismissed based on a theory that boils down to the fact that the complaint's second claim for relief is entitled "FOIA *and* APA" rather than "FOIA *or* APA."

Now, in the guise of an opposition, FDA seeks to delay indefinitely the briefing and, thus, resolution of this dispute. Whereas in some FOIA cases the agency necessarily must complete processing the FOIA request before summary judgment briefing can occur, and whereas in some cases a *Vaughn* index is needed to allow the plaintiff and the court to understand the agency's position, neither is true in this case. As Public Citizen's memorandum in support of its motion for summary judgment shows, the nature of the redactions and FDA's reason for redaction are already apparent. Unlike the "typical course" of FOIA litigation, as described by FDA, FDA Opp. at 2, FDA did not respond to the complaint in this case with an answer, but with a partial motion to dismiss. The Court thus already has before it substantive briefing addressing an important legal issue in the case. Delay of the summary judgment briefing for some unspecified but lengthy period of time (on the basis of FDA's own pending motion, its own incomplete FOIA response, and an unneeded *Vaughn* index) would prejudice Public Citizen and be of no assistance to the Court. Rather, for the Court simultaneously to consider FDA's partial motion to dismiss and Public Citizen's motion for summary judgment would further the efficient resolution of this case.

The Court should order FDA promptly to file a substantive response to the motion for summary judgment.

ARGUMENT

A. FDA's tactical decision to file a motion in lieu of an answer does not render Plaintiff's summary judgment motion "premature." FDA's "position ignores the language of Rule 56," *First Am. Bank, N.A. v. United Equity Corp.*, 89 F.R.D. 81, 87 (D.D.C. 1981), which permits a motion to be made "at any time until 30 days after the close of all discovery." Fed. R. Civ. P. 56(b). Although Rule 56 at one time provided that the plaintiff could not move for summary judgment until after the defendant filed its answer, *see Krug v. Santa Fe Pac. R.R. Co.*, 158 F.2d 317, 319 (D.C. Cir. 1946), the rule was amended specifically "to permit a plaintiff to move for summary judgment while a pre-answer rule 12(b) motion was pending," *Stein v. Oshinsky*, 348 F.2d 999, 1001 (2d Cir. 1965). "In view of the language of the rule, an answer to the complaint is not a prerequisite to the consideration of a motion for summary judgment." *First Am. Bank, N.A.*, 89 F.R.D. at 87 (deferring decision on summary judgment, but ordering the defendants to file supplemental oppositions of a "substantive nature" to the motion for summary judgment at the same time defendants filed their responsive pleadings); *see also HS Res., Inc. v. Wingate*, 327 F.3d 432, 440 (5th Cir. 2003) (relying on *First Am. Bank*); *CBS Interactive Inc. v. Nat'l Football League Players Ass'n, Inc.*, 259 F.R.D. 398, 417 (D. Minn. 2009) ("Although Defendants have not yet filed an answer in this action, . . . [t]he Court finds Defendants' prematurity argument unavailing in the face of the evidentiary record that has been submitted by the parties, the pre-trial discovery allowed, and the several months that have elapsed since the suit was filed.").

Here, delaying the summary judgment briefing until after the Court decides its partial motion to dismiss, after which—however the Court decides that motion—FDA will then file an answer, would *not* make for a more "just, speedy, and inexpensive determination" of this case. FDA Opp. at 8 (citing Fed. R. Civ. P. 1). FDA argues that, until its partial motion to dismiss is

granted, the "scope of the complaint" has not yet been determined. FDA Opp. at 8-9. FDA did not move to dismiss Plaintiff's first claim for relief, however, so, at a minimum, that aspect of the case (to which the bulk of the summary judgment briefing is pertinent) need not await a decision on the partial notion to dismiss. As to the second and third causes of action, little additional briefing is required beyond that needed to address the first claim for relief and that included in FDA's motion to dismiss briefing.[1] Accordingly, deferring briefing on the summary judgment motion until after the Court decides the partial motion to dismiss will not appreciably enhance efficiency in this case. Yet it will appreciably prejudice Plaintiff by adding more delay on top of the over two years of delay FDA has already generated in resolving this FOIA dispute. Indeed, because the partial motion to dismiss is "partial" and because of the nature of the dispute—a challenge to categorical redactions made to records disclosed under both § 552(a)(2) and (a)(3)—the Court can most efficiently resolve this case by having both FDA's partial motion to dismiss and Public Citizen's motion for summary judgment before it at the same time.

Public Citizen filed its motion for summary judgment 76 days after commencing this lawsuit, and FDA has had more than adequate notice of the issues it presents, as the exhibits attached to the Kotler Declaration filed by FDA make plain. With regard to timing, Public Citizen offered to consent to an extension of time for FDA's response and to work out a joint

[1] In particular, the first claim alleges that various categories of information FDA routinely redacts on advisory committee members' CVs are not exempt under FOIA exemption 4, for confidential commercial information, or FOIA exemption 6, for information that implicates privacy interests. *See* Compl. ¶ 47; 5 U.S.C. § 552(b)(4), (b)(6). The second and third claims for relief allege that FDA has an unlawful policy and practice of redacting that non-exempt information from the CVs of advisory committee members that FOIA requires it to make publicly available electronically. Compl. ¶¶ 48-56. Therefore, a decision on the first claim for relief would resolve whether FDA's redactions on CVs are unlawful, which is a significant and necessary element of the policy and practice claims.

briefing schedule, *see* FDA Opp., Attachment A, but FDA did not respond. The Court should not let FDA drag out the litigation by refusing to proceed to the merits of the dispute.

B. FDA asks this Court to adhere to what FDA considers the "typical course" for a FOIA case, which FDA describes as giving the agency additional time to complete production and then giving the agency additional time to prepare a *Vaughn* index, before allowing summary judgment briefing to commence. FDA Opp. at 2. FDA's preferred course would be a waste of time and resources in this case.

1. The facts of this case belie FDA's assertion that the motion for summary judgment is premature because one of FDA's several centers, the Center for Drug Evaluation and Research (CDER), has not yet responded to the May 2014 FOIA request. FDA Opp. at 9-10. Regardless of which FDA center processes the CVs, the redactions on the advisory committee member CVs fall into the same categories. *See* Carome Decl. ¶ 14 & Ex. B (list sent by FDA to advisory committee members of categories of information that FDA "request[s] be removed from [each member's] CV"); Kotler Decl. ¶¶ 30-32.[2] Neither Public Citizen nor the Court need to see each CDER CV to assess the categorical redactions, as the categories are known and the CVs are posted on FDA's website. Importantly, FDA has never suggested that CDER redacts the CVs of its advisory committee members any differently than the other FDA Centers, and both the online CVs and FDA's instructions to committee members show that it does not.[3] Carome Decl. Ex. B; *see, e.g.*, Clattenburg Decl. ¶¶ 25, 27, 29, 31, 33-34, 36-37 & Exs. 6-7. Thus, more than two

[2] One category listed by FDA, *see* Carome Decl. Ex. B, is "Social Security number." If any committee member included a social security number on his or her CV, Public Citizen would not contest redaction of that number.

[3] *See* CDER Advisory Committee Materials, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm.

years after the statutory deadline has passed, CDER's failure to respond provides no basis for delaying the progress of this litigation.

The case FDA cites to support its contention that the Court should authorize FDA to further delay the resolution of this case until CDER processes the May 2014 FOIA request is inapposite. *See* FDA Opp. 10 (citing *Willis v. United States*, 581 F. Supp. 2d 57, 64-65 (D.D.C. 2008)). In *Willis,* the *pro se* plaintiff filed "numerous motions during the pendency" of defendants' combined motion to dismiss and for partial summary judgment, including "an Emergency Motion for Order directing the government to release all requested records" and a "Motion for Order to stop conspiracy by defendants." The court "denied these and similar motions brought by Plaintiff as either premature (i.e., they related to the merits of the parties' FOIA/Privacy Act arguments that were yet to be determined) or unrelated to the FOIA action brought by Plaintiff (and that were presumably addressed and ruled upon in the criminal case related to Plaintiff in another jurisdiction)." *Id.* at 64–65. The case offers no support to FDA here.

2. Likewise, the facts of this case fail to support FDA's claim that it should produce a *Vaughn* index before Public Citizen can move for summary judgment. In FOIA cases, "ordinarily, the agency alone possesses knowledge of the precise content of documents withheld" and "the FOIA requester and the court both must rely upon its representations for an understanding of the material sought to be protected." *King v. U.S. Dep't of Justice*, 830 F.2d 210, 218 (D.C. Cir. 1987). Therefore, in many FOIA cases, the agency files its motion for summary judgment, along with a *Vaughn* index or declaration, before the FOIA plaintiff moves for summary judgment because, in advance of the agency's filing, the plaintiff lacks sufficient information to move for summary judgment. The D.C. Circuit devised the *Vaughn* index as a

way to remedy the "lack of knowledge by the party see[k]ing disclosure" which "seriously distorts the traditional adversary nature of our legal system's form of dispute resolution." *Vaughn v. Rosen*, 484 F.2d 820, 824 (D.C. Cir. 1973). The *Vaughn* index is for the benefit of the *requester*, "to correct, however, imperfectly, the asymmetrical distribution of knowledge that characterizes FOIA litigation." *King*, 830 F.2d at 218.

Here, where the sort of information FDA has redacted is evident from the redacted advisory committee CVs, where the bulk of the CVs (both posted online and produced in response to the FOIA request) indicate the exemption on which FDA bases its exemption claim, and where many of the CVs are publicly available without redaction, *see* Pl. Mem. In Supp. Of Mot. For Summ. J. ("Pl. Mem.") at 8, 12 & n.6, Public Citizen did not need to wait for either a *Vaughn* index or an FDA motion. Thus, FDA is wrong to state that the summary judgment motion is "in effect seeking to force defendant to produce a *Vaughn* index . . . *immediately*." FDA Opp. at 10 (emphasis FDA's). The agency has the burden of justifying any exemptions claimed, 5 U.S.C. § 552(a)(4)(B), and it is up to the agency to figure out how to sustain its burden. A *Vaughn* index is not always required; the agency can, and often does, "satisfy its burden by other means, such as submitting the documents in question for an *in camera* review or by providing a detailed affidavit or declaration." *Voinche v. FBI*, 412 F. Supp. 2d 60, 65 (D.D.C. 2006), *aff'd per curiam Voinche v. FBI*, No. 06-5130, 2007 WL 1234984, at *1 (D.C. Cir. Feb. 27, 2007). "The materials provided by the agency may take any form so long as they give the reviewing court a reasonable basis to evaluate" the claimed exemptions. *Delaney, Migdail & Young, Chartered v. IRS*, 826 F.2d 124, 128 (D.C. Cir. 1987) (holding that where the nature of the redacted information is obvious from the records themselves, it is appropriate for the district court to evaluate the lawfulness of the redactions without referring to the *Vaughn* index). If, after

reviewing the summary judgment papers, the Court finds that a *Vaughn* index is needed, the proper course would be for the Court to order an index and further briefing at that time. But the Court should not deny or postpone briefing and consideration of the summary judgment motion, when Public Citizen did not request a *Vaughn* index and the agency's description of "categories" of redactions supports Public Citizen's position that one is not needed in this case. *See* FDA Opp. at 13; Kotler Decl. ¶¶ 30-32; *see also* Carome Decl. ¶ 14 & Ex. B (FDA instructions to advisory committee members listing categories of information that FDA "request[s] be removed from [each member's] CV").

As a result, FDA's contention that courts "routinely reject" efforts by FOIA plaintiffs to compel a *Vaughn* index early in litigation—even if accurate—is irrelevant. The cases FDA cites on this point involved plaintiffs who moved to compel the filing of a *Vaughn* index, which Public Citizen has not done. FDA Opp. at 11 n.5. In the cases cited, the court denied the motion to compel precisely because the index was not needed in advance of summary judgment briefing or because—as here—the filing of summary judgment motions might show that a *Vaughn* index was unnecessary. *See U.S. Comm. on Refugees v. Dep't of State*, No. CIV. A. 91-3303, 1992 WL 35089, at *1 (D.D.C. Feb. 7, 1992) (explaining that "preparation of a *Vaughn* index is unwarranted *before* the filing of dispositive motions in FOIA actions because" the dispositive motion and affidavits may make an index unnecessary) (emphasis added).[4] None of the cases

[4] FDA also cites to the following cases that involve motions to compel *Vaughn* indices: *Mullen v. U.S. Army Criminal Investigation Command*, No. 1:10CV262 JCC/TCB, 2011 WL 5870550, at *6 (E.D. Va. Nov. 22, 2011) (denying plaintiff's request for production of a *Vaughn* index before either party filed its motion for summary judgment); *Ioane v. C.I.R.*, No. 3:09-CV-00243-RCJRAM, 2010 WL 2600689, at *7 (D. Nev. Mar. 11, 2010) (denying plaintiff's request that the government produce a *Vaughn* index in advance of the briefing); *Gerstein v. CIA*, No. C-06-4643 MMC, 2006 WL 3462659, at *5 (N.D. Cal. Nov. 29, 2006) (denying plaintiff's request for a *Vaughn* index where no dispositive motion had yet been filed and plaintiff failed to demonstrate that the *Vaughn* index was necessary); *Bassiouni v. CIA*, 248 F. Supp. 2d 795, 796–

cited by FDA supports its position; to the extent that they are relevant at all, the cases support Public Citizen.

In short, Public Citizen had sufficient information to move for summary judgment at this time, and without first seeking a *Vaughn* index. The Court should reject FDA's invitation to transform the *Vaughn* index into an instrument for creating delay.

C. FDA complains that the summary judgment motion "does not even purport to comprehensively address all redactions and categories of redactions in CVs that have been processed and released in response to the request," and instead shows "examples" of unjustified categorical redactions. FDA Opp. at 13. That statement is accurate, but Public Citizen's approach is appropriate. As the memorandum in support of the motion makes clear, in Public Citizen's view, redacting a CV based on exemptions 4 and 6 is unjustified because of the nature of a CV. Pl. Mem. at 1 ("The nature of a CV belies the notion that information within its margins is confidential or private, because a CV is created with the purpose and expectation of sharing the information contained in it."). Discussing numerous categories of information that FDA routinely redacts on the CVs (such as the names of mentors, names of mentees, amounts of private research grants, titles of forthcoming publications), the summary judgment memorandum highlights examples to support this point. FDA, however, bears the burden of justifying each

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97 (N.D. Ill. 2003) (denying plaintiff's motion to compel production of a *Vaughn* index before the parties had filed dispositive motions); *Stimac v. U.S. Dep't of Justice*, 620 F. Supp. 212, 213 (D.D.C. 1985) (denying plaintiff's motion for preparation of a *Vaughn* index before the filing of dispositive motions, because the dispositive motions and detailed affidavits "may obviate the need for indexing the withheld documents."); *Pyne v. C.I.R.*, No. 98-00253 HG, 1999 WL 112532, at *3 (D. Haw. Jan. 6, 1999) (denying motion for a *Vaughn* index where no dispositive motions had been filed and it was not clear a *Vaughn* index would be necessary); *Payne v. U.S. Dep't of Justice*, No. CIV.A. 95-2968, 1995 WL 601112, at *1 (E.D. La. Oct. 11, 1995) (denying the motion for a *Vaughn* index where neither party had filed a dispositive motion and the agency had denied the FOIA request on the basis that it had located no responsive records).

redaction. 5 U.S.C. § 552(a)(4)(B). If FDA had chosen to defend any redaction or category of redactions not specifically discussed in the memorandum, this reply would have then addressed that additional item. Importantly, Public Citizen does not bear the burden of showing that a redaction is not warranted; FDA bears the burden of justifying each redaction.

D. A few loose ends remain. First, FDA complains that, in its summary judgment motion, Public Citizen should have made a "significant effort to distinguish between records responsive to plaintiff's FOIA request" and those CVs currently posted online. FDA Opp. at 12. FDA does not explain how that complaint bears on its argument that the summary judgment motion is premature. In any event, the point is incorrect. The Clattenburg Declaration submitted in support of Plaintiff's motion states whether each CV cited was found online or was released to Public Citizen by FDA. *See, e.g.*, Clattenburg Decl. ¶¶ 36-37, 40-41. In addition, Public Citizen has argued that FDA has an unlawful policy and practice of redacting information from CVs—whether released in response to the FOIA request or posted online by FDA. Both the CVs released and the CVs posted online reflect the same categories of redactions challenged in this lawsuit and in the motion for summary judgment.

Second, FDA asserts that the FOIA exemptions themselves support FDA's request for further delay. FDA claims that "the agency has proceeded with understandable caution, mindful of the third-party interests protected under FOIA exemptions 4 and 6, as well as the agency's own obligations under its regulations, the Trade Secrets Act, and the Privacy Act." FDA Opp. at 14. FOIA, however, states strict time limits, 5 U.S.C. § 552(a)(6)(A), and neither exemption 4 nor 6 excuses an agency's delay, either at the administrative stage or in litigation, particularly two years after those time limits expired.

Finally, throughout its opposition memorandum, FDA misleadingly suggests that Public Citizen was not open to the "meet-and-confer process," FDA Opp. at 13, or FDA's attempts "to avoid or minimize the need to litigate," *id*. at 5. Although FDA's argument is immaterial to resolution of a motion for summary judgment, Public Citizen will respond because FDA repeatedly returns to this theme. The facts are these: Public Citizen wrote a letter to FDA more than *two years ago* detailing why FDA's redactions of advisory committee member CVs posted on FDA's website were not justified. Clattenburg Decl. ¶ 4 & Ex. 1; Kotler Decl. ¶ 5. FDA responded five months later, offering no compromise. Clattenburg Decl. ¶ 5 & Ex. 2. Public Citizen then filed a FOIA request, *id.* ¶ 6 & Ex. 3 at 1, to which the agency's first response was to tell Public Citizen to access the CVs posted on FDA's website, all apparently with the same redactions that prompted Public Citizen's FOIA request. *Id.* ¶ 8 & Ex. 4 at 1. Since then, FDA has trickled out records—still with the same types of redactions—over the course of two years, and Public Citizen has submitted three appeals, each explaining why the redactions are unlawful. *Id.* ¶¶ 10, 16, 21 & Ex. 4 at 3-7 & 10-12. FDA has not provided a substantive response to the appeals. Moreover, Public Citizen was open to discussing the case with counsel for FDA when he asked to do so *after* FDA filed its own motion, although by that point Public Citizen was well into drafting its summary judgment motion. During the call, Public Citizen's counsel informed counsel for FDA of the imminent motion for summary judgment and also that filing the motion need not preclude ongoing discussions. Public Citizen's counsel also stated then and in an email on the day of filing that she was open to discussing a briefing schedule to accommodate FDA's counsel. That said, based on its communications with FDA, Public Citizen does not believe that this case can be resolved other than through a motion for summary judgment.[5]

[5] Sarah Kotler states in her declaration that Allison Zieve of Public Citizen emailed her

E. In opposing the summary judgment motion, FDA was required under Rule 7(h)(1) to provide "a separate concise statement of genuine issues setting forth all material facts as to which it is contended there exists a genuine issue necessary to be litigated, which shall include references to the parts of the record relied on to support the statement." FDA failed to do so. The D.C. Circuit "has repeatedly warned litigants against shirking their duties under Rule 56 and Local Rule 7(h) in responding to motions for summary judgment." *Lawrence v. Lew*, No. 11-1854, __ F. Supp. 3d __, 2016 WL 154903, at *3 (D.D.C. Jan. 12, 2016). "Requiring strict compliance with the ... rule[s] is justified both by the nature of summary judgment and by the rule[s'] purposes…." *United States v. Speqtrum, Inc.*, 47 F. Supp. 3d 81, 88 (D.D.C. 2014) (ellipsis in original) (quoting *Jackson v. Finnegan, Henderson, Farabow, Garrett & Dunner*, 101 F.3d 145, 150 (D.C. Cir. 1996)). Thus, "the Court may assume that facts identified by the moving party in its statement of material facts are admitted." Dist. Ct. Local Civ. R. 7(h)(1). Here, because FDA is a frequent and sophisticated litigant with significant experience before this Court, the Court should consider deeming the facts in the statement of material facts to be admitted.

CONCLUSION

For the foregoing reasons and the reasons set forth in Plaintiff's Memorandum in Support of Plaintiff's Motion for Summary Judgment, the Court should order Defendants promptly to file

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after a telephone conversation on May 23, 2014, saying that "to the extent any portion of any currently redacted CV is exempt from disclosure under FOIA, we are requesting 'any reasonable segregable portion,' as required by FOIA." Kotler Decl. ¶ 11 & Ex. F. This email was sent "to confirm" that Public Citizen expected FDA's compliance with this aspect of FOIA because, in the telephone discussion, Ms. Kotler had suggested that CVs on which FDA maintained any redactions at all would be non-responsive because the FOIA request sought "unredacted" CVs. As the email makes clear in its next sentence, clarifying that the request sought "any reasonable segregable portion" should not be taken as a suggestion that Public Citizen believed that redactions were proper.

a substantive response to Plaintiff's motion. In the alternative, the Court should grant summary judgment to Plaintiff and enter judgment against Defendants.

Dated: August 4, 2016

Respectfully submitted,

/s/ Rachel M. Clattenburg

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