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 MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56, plaintiff Public Citizen hereby moves for summary judgment in this case brought under the Freedom of Information Act, 5 U.S.C. § 552, the Administrative Procedure Act, 5 U.S.C. §§ 702 & 706, and the Mandamus and Venue Act, 28 U.S.C. § 1361, on the ground that there is no genuine issue of disputed material fact and plaintiff is entitled to judgment as a matter of law. Defendants Food & Drug Administration (FDA) and Department of Health & Human Services (HHS) have adopted an unlawful policy or practice of redacting non-exempt information from the curricula vitae of advisory committee members that FDA must post on its website. Moreover, defendants are unlawfully withholding records responsive to Public Citizen's FOIA request. Accordingly, judgment should be entered for plaintiff.

In support of this motion, plaintiff submits the accompanying Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment, Plaintiff's Statement of

Material Facts as to Which There Are No Genuine Issues, the Declarations of Michael Carome and Rachel Clattenburg, and the exhibits attached to those declarations.

Respectfully submitted,

/s/ Rachel Clattenburg

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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"Transparency and public participation are critical features of the advisory committee process."
FDA, Guidance for FDA Advisory Committee Members and FDA Staff (Aug. 2008) [1]

INTRODUCTION

Curricula vitae (CVs) are documents people fill with details about their education, experience, publications, and honors, curated to exhibit their accomplishments to others. The Food and Drug Administration (FDA) posts the CVs of its advisory committee members on its website, as it must because the CVs are frequently requested records under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. FDA, however, redacts information from the CVs, invoking inapplicable FOIA exemptions to shield portions of advisory committee members' backgrounds and qualifications from public view.

For example, citing FOIA's exemption for confidential commercial information, § 552(b)(4), FDA hides the amount of research money pharmaceutical companies awarded advisory committee members, the topics of members' research projects, and the titles of forthcoming articles and lectures. Pointing to FOIA's exemption for information the disclosure of which would be an unwarranted invasion of personal privacy, § 552(b)(6), FDA redacts the names of advisory committee members' co-authors and co-researchers, as well as the dates the advisory committee members received their educational degrees and various awards. But 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. Moreover, focusing on individual redactions shows that FDA cannot meet its burden of justifying the redactions. For example, by law, health care companies must disclose payments to

[1] *Available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125641.pdf.

physicians and teaching hospitals, 42 U.S.C. § 1320a-7h, and sponsors of clinical trials must disclose the topics, names, and design of their studies. 42 U.S.C. § 282(i)-(j). These laws, well known to defendant Department of Health and Human Services (HHS), which implements them, further demonstrate that exemptions 4 and 6 do not justify FDA's copious redactions.

FDA's ongoing unlawful policy or practice of withholding non-exempt information from these CVs matters for two reasons. First, the individuals serving on FDA's advisory committees wield substantial influence over decisions concerning FDA-regulated products, which include products ranging from prescription drugs to bottled water to blood products to surgical implants. Americans spend nearly 25 cents of every dollar on FDA-regulated products and have a significant interest in seeing the backgrounds of and possible outside influences on the experts who help to shape FDA regulation of these products. Second, many of the redactions are not only unlawful but silly, such as a redaction to obscure that a committee member served on the board of a children's museum. The redactions waste FDA's resources, demonstrate a lack of understanding of FOIA on the part of its employees, and suggest that FDA favors opaqueness over openness.

In this lawsuit, plaintiff Public Citizen challenges FDA's ongoing policy or practice of redacting information on committee member CVs. The members' choice to share this information publicly contradicts FDA's claim that the information is exempt. The lawsuit also challenges FDA's response, or lack thereof, to Public Citizen's FOIA request for unredacted copies of the CVs of all advisory committee members posted on FDA's website. The Court should grant summary judgment to Public Citizen, order FDA to cease its unlawful policy or practice, and compel FDA to post the complete CVs of advisory committee members on its

website on an ongoing basis. The Court should also order FDA to release in full the records responsive to Public Citizen's FOIA request.

LEGAL AND FACTUAL BACKGROUND

I. FDA Advisory Committees

For expert advice on whether to approve new medical products, request additional studies on a product, change a product's labeling, or take various other actions involving FDA-regulated products, FDA turns to its advisory committees. *See* FDA, *Advisory Committees: Critical to the FDA's Product Review Process*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143538.htm. FDA has approximately 50 advisory committees and panels composed of outside experts. *See* FDA, *Committees & Meeting Materials*, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm. Although FDA does not have to follow the recommendation of an advisory committee, it usually does. Matthew Herper, *The FDA Ignores Its Advisors a Quarter of the Time*, Forbes (Oct. 12, 2010), http://www.forbes.com/sites/matthewherper/2010/10/12/the-fda-ignores-its-advisors-a-quarter-of-the-time/.

Under the Federal Advisory Committee Act, FDA must ensure that committees are "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." 5 U.S.C. app. 2 § 5; *see also* 21 C.F.R. § 14.40(f)(2). FDA must also ensure that its committee members are free from financial conflicts of interest or the appearance of impartiality. *See generally* Dep't of Health & Human Servs., *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (Aug. 2008), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf. FDA selects advisory committee members from a pool of nominees, all of whom must submit a "complete curriculum vitae" to FDA. 21 C.F.R. § 14.82(c); FDA, *Applying for Membership*,

http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ApplyingforMembership/default.htm. FDA gives applicants no assurance that it will keep their CVs, or any portion of their CVs, confidential. *Id.*

II. FDA's Duties To Post CVs And Justify Any Redactions Under A FOIA Exemption

FOIA's goal is "to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed." *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978). FOIA sets out to achieve this goal by requiring agencies to disclose records in response to FOIA requests, 5 U.S.C. § 552(a)(3), and by requiring agencies to proactively disclose certain records, *id.* § 552(a)(1)-(2), subject to nine exclusive exemptions. *Id.* § 552(b).

FOIA also requires agencies to make available by "computer telecommunications" "copies of all records . . . [that] have been released to any person" in response to a FOIA request and that "the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records." *Id.* §§ 552(a)(2)(D)-(E).[2] Agencies must also make publicly available an index of their frequently requested records. *Id.* § 552(a)(2)(E). An agency may redact information in the proactively posted frequently requested records only if that information falls under one of FOIA's nine exemptions. *See Id.* § 552(b) (providing that section 552 "does not apply to matters that are" encompassed by one of the nine exemptions). *See also Fed. Open Mkt. Comm. of Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 360 n.23 (1979) (explaining that FOIA exemptions may protect information disclosed pursuant to 552(a)(2)); *see*

[2] The requirement to make frequently requested records available by electronic means applies to records created on or after November 1, 1996. 5 U.S.C. § 552(a)(2)(E). The records at issue in this case were created after that date.

also Dep't of Justice Office of Info. Policy, *Proactive Disclosure of Non-Exempt Agency Information: Making Information Available Without the Need To File a FOIA Request* (updated Oct. 5, 2015), *available at* https://www.justice.gov/oip/oip-guidance-5 ("The FOIA's nine exemptions apply as appropriate to any records that are required to be disclosed under any of the provisions of the FOIA, including the proactive disclosure subsections.").

FDA designates its advisory committee materials, including the CVs of advisory committee members, "frequently requested records," thus acknowledging FDA's duty to make the CVs publicly available on its website. FDA, *Electronic Reading Room*, http://www.fda.gov/RegulatoryInformation/foi/ElectronicReadingRoom/default.htm (last visited July 9, 2016) (attached as Ex. 5 to Clattenburg Decl.). Before posting the CVs online, FDA redacts several types of information, purportedly under FOIA exemptions 4 and 6, although some redactions have no indication of which exemption the agency is invoking.

III. Public Citizen's Advocacy Regarding FDA Advisory Committees And Its FOA Request

Since its founding, Public Citizen, through its Health Research Group, has evaluated the quality and efficacy of FDA-regulated drugs and devices. Public Citizen's advocacy in this area has contributed to FDA's decisions to pull 23 drugs from the market. Public Citizen's health experts frequently testify before FDA advisory committees, including over a dozen times in 2015, and also serve on FDA advisory committees. Carome Decl. ¶¶ 4-5.

To further its evaluation of drug and device safety, Public Citizen also monitors the functioning of FDA advisory committees. *Id.* ¶ 4. For instance, Public Citizen has petitioned FDA to include a staff presentation at certain advisory committee meetings and published data on how advisory committees function. *See* Public Citizen, *Petition to Include an FDA Staff Presentation at Certain Advisory Committee Meetings* (June 21, 2007), *available at*

http://www.citizen.org/Page.aspx?pid=741; Letter from Public Citizen Health Research Group, Suboptimum Use of FDA Drug Advisory Committees *in* The Lancet (Dec. 23, 2006), *available at* http://www.citizen.org/Page.aspx?pid=2723. Public Citizen has also studied and published articles on financial conflicts of interests of FDA advisory committee members. *See* Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. of the Am. Med. Assoc. 1921 (Apr. 26, 2006), *available at* http://jama.jamanetwork.com/article.aspx?articleid=202754; Larry D. Sasich & Sidney M. Wolfe, *Comments on Draft Guidance for the Disclosure of Conflicts of Interest for Participants in FDA Advisory Committees* (March 5, 2002), *available at* http://www.citizen.org/Page.aspx?pid=3464. A few years ago, Public Citizen called attention to a conflict of interest created by a committee member's planned participation at a conference, prompting her subsequent withdrawal from the conference. *See* Letter from Sidney Wolfe to FDA Commissioner Margaret Hamburg (Oct. 24, 2013), *available at* http://www.citizen.org/hrg2166; *see also* Toni Clarke, *FDA advisory panel chair pulls out of conference amid ethics flap*, Reuters (Oct. 24, 2013), http://reut.rs/1fYERj7. At that time, Public Citizen noted that FDA had redacted 32 items on the member's online CV, the disclosure of which could elucidate ties with the pharmaceutical industry. *Id.*

Concerned about FDA's redactions of information from advisory committee members' CVs, Public Citizen wrote to FDA's Commissioner and Chief Counsel on February 4, 2014, and asked FDA to post advisory committee CVs in full. Clattenburg Decl. ¶ 4 & Ex. 1. Five months later, FDA responded that it would "not be revising our web pages so that all of the CVs of advisory committee members are posted without redaction." *Id*. ¶ 5 & Ex. 2.

On May 19, 2014, Public Citizen submitted a FOIA request to FDA seeking "unredacted copies of the curricula vitae of all FDA advisory committee members whose CVs are currently posted on FDA's website." *Id.* ¶ 6 & Ex. 3, at 1. FDA acknowledged receipt of Public Citizen's request on May 27, 2014, and, a week later, granted Public Citizen's request for a public interest fee waiver. *Id.* ¶ 7 & Ex. 3, at 3-4. To date, the Office of the Commissioner and four of FDA's six Centers have responded to Public Citizen's FOIA request: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Tobacco Products (CTP), the Center for Biologics Evaluation and Research (CBER), and, in the last month, the Center for Devices and Radiological Health (CDRH). The Center for Drug Evaluation and Research and the National Center for Toxicological Research have not responded.[3]

CFSAN responded three times to Public Citizen's FOIA Request. CFSAN's first response, dated July 11, 2014, directed Public Citizen to the CVs posted online, all apparently the same ones posted at the time of Public Citizen's FOIA request. *Id.* ¶ 8 & Ex. 4, at 1. CFSAN sent Public Citizen CVs in October 2014 and a revised set of the same CVs in March 27, 2015, still with redactions purportedly under FOIA exemptions 4 and 6. *Id.* ¶¶ 12, 14 & Ex. 4, at 8. Although several of the CVs released in March 2015 have fewer redactions than the versions sent in October 2014, they also have fewer pages; a closer look shows that some of the March 2015 CVs are missing the lines and paragraphs redacted from the October 2014 CVs, but the omissions are no longer marked as redactions. *Id.* ¶¶ 110-13, 118-19 & Exs. 39, 42.

[3] Although the National Center for Toxicological Research has never responded to Public Citizen's FOIA request, the Science Advisory Board, the advisory committee located within the National Center for Toxicological Research, has not redacted the CVs of its members before posting them online.

CTP responded twice to Public Citizen's FOIA request. On August 26, 2014, it released 199 pages of CVs but withheld portions of 82 pages, citing FOIA exemptions 4 and 6. *Id.* ¶ 9 & Ex. 4, at 2. On October 20, 2014, CTP sent Public Citizen revised versions of ten CVs, still with redactions. *Id.* ¶ 13.

CBER responded to Public Citizen's FOIA request on November 19, 2015. *Id.* ¶ 15 & Ex. 4, at 9. The released CVs contain redactions purportedly under exemptions 4 and 6. *Id.* ¶ 15.

On September 18, 2014, Public Citizen appealed CFSAN's and CTP's responses to HHS, which handles FOIA appeals for FDA, and on December 2, 2015, Public Citizen appealed CBER's response. *Id.* ¶¶ 10, 16 & Ex. 4, at 3-7 & 10-12. HHS has not responded substantively to the appeals. *Id.* ¶ 21.

In May and June 2016, after Public Citizen filed this lawsuit, the Office of the Commissioner and CDRH responded to Public Citizen's FOIA request. *Id.* ¶¶ 18-20 & Ex. 4, at 14-16. Those two offices provided the CVs for the members of their advisory committees, but again made redactions purportedly under exemptions 4 and 6. *Id.*

Specifically, both online and in the responses to the FOIA request, FDA cites FOIA exemption 4 as the basis for redacting the dollar amounts of private grants, topics of research funded by private grants, titles of forthcoming journal articles, names of companies that sponsored clinical trials, titles of lectures, and current research activities, among other information. Citing FOIA exemption 6, FDA redacts the dollar amounts of research grants from companies; the dates individuals received their professional, graduate, and undergraduate degrees; professional license numbers; the names of students and PhD candidates mentored; the names of co-researchers, co-teachers, and co-authors; community service and hobbies; and military service, among other categories.

STANDARD OF REVIEW

"FOIA cases typically and appropriately are decided on motions for summary judgment." *Defs. of Wildlife v. U.S. Border Patrol*, 623 F. Supp. 2d 83, 87 (D.D.C. 2009). Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In keeping with FOIA's purpose of "facilitat[ing] public access to Government documents," *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991), and its "general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language," *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002) (quoting *Dep't of Air Force v. Rose*, 425 U.S. 352, 360-61 (1976)) (internal quotation marks omitted), the agency bears the burden of showing that the withheld information falls within one of FOIA's nine exclusive exemptions. *Multi Ag Media LLC v. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008). This Court reviews the agency's claimed exemptions de novo. 5 U.S.C. § 552(a)(4)(B); *DOJ v. Reporters Comm. For Freedom of Press*, 489 U.S. 749, 755 (1989).

ARGUMENT

FDA has a policy or practice of redacting non-exempt information from the CVs of advisory committee members that it is required to post online, thereby concealing information about the people who influence FDA's regulatory decisions. Exemptions 4 and 6 cannot apply to information on the CVs because that information is by its very nature not confidential or private, as the case law applying exemption 4 and exemption 6 confirms. Because the withheld information in the CVs is not exempt from disclosure under FOIA, FDA has violated FOIA by failing to post unredacted copies of the CVs online and by withholding from Public Citizen unredacted copies of the CVs requested through FOIA.

I. By Law, FDA Must Post Advisory Committee Member CVs On Its Website.

FOIA requires FDA to publish an index to inform the public of which records it has determined are frequently requested records that FDA must make publicly available online. 5 U.S.C. § 552(a)(2)(D)-(E). FDA's Electronic Reading Room is that index and it states: "This index contains categories of frequently requested FDA documents." *See* FDA, *Electronic Reading Room* (attached as Ex. 5 to Clattenburg Decl.).

Through its index, and since at least June 2009, FDA has conceded that advisory committee materials are "frequently requested records" under FOIA, thus triggering a statutory obligation to post the records online. *See* FDA, *Electronic Reading Room* (June 3, 2009), https://web.archive.org/web/20090603203651/http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm (link to archived FDA Electronic Reading Room index). FDA's communications to its advisory committee members also reflect that FDA considers itself under a statutory duty to post the CVs. Thus, when, in 2014, Public Citizen's Michael Carome was selected to serve on FDA's Pharmacy Compounding Advisory Committee, FDA sent Dr. Carome an email asking him to send an updated CV and explained "we are *required* to publically post your CV on the FDA website." Carome Decl. ¶ 8 & Ex. A (emphasis added).

In this litigation, pointing to a letter FDA sent Public Citizen in July 2014, FDA claims that it posts the CVs "voluntarily." *See* Defs.' Mem. In Support of Defs.' Partial Mot. To Dismiss at 12 & n.4, 15 n.5 (Dkt. No. 7-1) ("FDA Mem."); Clattenburg Decl. ¶ 5 & Ex. 2. However, the statement in that letter is inconsistent with the position FDA has for years staked out on its FOIA "frequently requested records" index, does not jibe with the fact that FDA processes the CVs under FOIA's exemptions, and flies in the face of its statement to Dr. Carome that it is "required" to publicly post the CVs, a statement that *post-dates* the letter. *See* Clattenburg Decl. ¶ 5 & Ex. 2; Carome Decl. ¶ 8 & Ex. A. FDA's public position, outside the

context of this dispute, that the CVs are frequently requested records that the agency is required to post online surely trumps its informal response to Public Citizen's request that FDA cease redacting the CVs.

II. Advisory Committee Members Have No Expectation Of Confidentiality Or Privacy In Their CVs.

A CV is created to be shared; it is the "foundation of any application for employment, funding, awards, fellowships, or grants." Univ. of Va., *Curriculum Vitae (CV)*, https://career.virginia.edu/resumes/creating-your-resume/curriculum-vitae-cv; *see* Univ. of Cal. Davis, *Internship & Career Ctr.*, https://icc.ucdavis.edu/materials/resume/resumecv.htm; Univ. of Penn., *Career Servs.: CV Guide*, http://www.vpul.upenn.edu/careerservices/gradstud/CVguide.php. Disregarding that the content of a CV "is ordinarily written down precisely so that it *will* be displayed," *Physicians Comm. for Responsible Med. v. Glickman*, 117 F. Supp. 2d 1, 6 (D.D.C. 2000), FDA relies on exemptions 4 and 6 to redact a great deal of information from advisory committee member CVs. Exemption 4, however, protects only trade secrets or confidential or privileged information. 5 U.S.C. § 552(b)(4). Exemption 6 applies only to certain records "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." *Id.* § 552(b)(6). Neither exemption applies to the information withheld here. [4]

To begin with, advisory committee members submit their CVs with no expectation that FDA will keep them confidential or private. In an email to advisory committee member Dr. Carome during his nomination process, FDA stated that it was "required to publically post your

[4] The posted CVs are replete with unjustified redactions. Below, Public Citizen points to particular advisory committee member CVs to give examples showing the unlawfulness of FDA's redactions, not to bring attention to any particular advisory committee member's experience or background.

CV on the FDA website" and thus that Dr. Carome should "remove any personal information" from his CV.[5] Carome Decl. ¶ 8 & Ex. A. Confirming that members have no expectation of (or desire for) confidentiality with regard to their CVs, many advisory committee members themselves post their CVs online.[6] Indeed, FDA redacted one CV on which the advisory committee member included a link to his own website, which contains his unredacted CV.[7] Many other committee members have websites that include much of the same information about their research, publications, education, and training as the information included on their CVs.[8]

[5] Not only does FDA give no assurance that it will keep the CVs confidential or private, it explicitly warns applicants not to include their Social Security numbers in their CVs or applications, signaling that the information will *not* be kept confidential. *See* FDA, *FDA Advisory Committee Membership Application*, https://www.accessdata.fda.gov/scripts/FACTRS Portal/FACTRS/index.cfm.

[6] *See*, *e.g.*, webpages with links to unredacted CVs for advisory committee members William Bugbee, http://www.drbugbee.com/; Amanda Corbett, https://pharmacy.unc.edu/directory/ahcorbet/; Til Stürmer, http://sph.unc.edu/adv_profile/til-sturmer-md-phd/; James Neaton, http://sph.umn.edu/faculty1/name/james-neaton/; Shrikant Bangdiwala, https://www.med.unc.edu/ibs/about-us/faculty-biographies/shrikant-bangdiwala-phd; Michael McGuire, http://guidedsmiles.periohealth.com/pdf/Michael-K-McGuire-DDS-FullCV-2009.pdf (direct link to CV); Stephen Hillis, http://perception.radiology.uiowa.edu/People/SteveHillisPhD/tabid/216/Default.aspx; Yulei Jiang, https://radiology.uchicago.edu/page/yulei-jiang-curriculum-vitae; John Holcomb, https://med.uth.edu/surgery/faculty/john-b-holcomb/; Warren Bickel, http://research.vtc.vt.edu/people/warren-k-bickel; David Brent, https://www.childpsychresearch.com/faculty; John Connett, http://sph.umn.edu/faculty1/name/john-connett/; James de Lemos, http://profiles.utsouthwestern.edu/profile/11722/james-de-lemos-biography.html; Ralph D'Agostino, Sr., http://www.bu.edu/math/people/faculty/probability-and-statistics/dagostino/; David Pickar, http://www.davidpickar.com/background/biography/; Abdelmonem Afifi, www.biostat.ucla.edu/people/afifi; Michael Jaff, http://www.primacea.com/profile/michael-r-jaff.

[7] Thomas Grieger, http://www.griegermd.com/. *See* FDA's version of his CV: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM402229.pdf

[8] *See*, *e.g.*, Johns Hopkins Med., *Deborah Armstrong, M.D.*, http://www.hopkinsmedicine.org/profiles/results/directory/profile/0000590/deborah-armstrong (listing education, residency, background, honors, activities, and publications) (Oncologic Drugs Advisory Committee); Univ. of Rochester Med. Ctr., *Jonathan W. Mink, M.D., Ph.D.*, https://www.

The members' publication of their CVs and the information contained within them shows that the members have no privacy interest in the information on their CVs and do not consider the information to be confidential. Exemptions 4 and 6 therefore do not apply to this information. *See Nat'l Ass'n of Home Builders*, 309 F.3d at 35-36 (holding that private landowners had "relatively weak" privacy interests in owl sighting information that would disclose the landowners' names and addresses, in part because they had shared the information with the expectation that it might be released); *Lepelletier v. FDIC*, 977 F. Supp. 456, 460 (D.D.C. 1997), *aff'd in part, rev'd in part on other grounds*, 164 F.3d 37 (D.C. Cir. 1999) (holding that exemption 4 did not apply to financial information submitted by businesses and individuals who had "relinquish[ed] their claims to confidentiality."). Moreover, the members' own publication precludes the FDA's redaction because FOIA's exemptions do not apply to publicly available information. *Davis v. DOJ*, 968 F.2d 1276, 1280 (D.C. Cir. 1992); *see also Nation Magazine, Wash. Bureau v. U.S. Customs Serv.*, 71 F.3d 885, 896 (D.C. Cir. 1995) (discussing exemption 7(C) and holding that an individual waives his privacy interest by voluntary disclosing the information into the public domain). This basic proposition applies both to exemption 4 and exemption 6. *See CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987) ("To the extent that any data requested under FOIA are in the public domain, the submitter is unable to make any claim to confidentiality—a *sine qua non* of Exemption 4."); *Citizens for Responsibility & Ethics in Wash. v. DOJ*, 840 F. Supp. 2d 226, 233 (D.D.C. 2012) ("One can have no privacy

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urmc.rochester.edu/people/23513877-jonathan-w-mink/patients (listing dates of education, honors received, and publications) (Pediatrics Advisory Committee).

interest in information that is already in the public domain, especially when the person asserting his privacy is himself responsible for placing that information into the public domain.").

In short, the public nature of CVs removes them from FOIA's narrowly bounded exemptions.

III. Exemption 4 Does Not Apply To The Information Redacted In The CVs.

Exemption 4 protects two categories of information: trade secrets and confidential commercial or financial information. The proposition that information voluntarily included in a CV could ever be considered "confidential commercial information" is dubious, and certainly none of the information redacted by FDA fits this description. Whether looked at in terms of CVs generally or with regard to the specific information redacted, FDA's exemption 4 claims must be rejected.

A. The Redacted Information Contains No Trade Secrets.

A trade secret is a "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 150-51 (D.C. Cir. 2001) (quoting *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983)) (internal quotation marks omitted). What FDA hides under exemption 4—dollar amounts of private research grants, titles of current research projects, and citations to forthcoming articles—has no "direct relationship" to any "productive process." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1288 (holding that reports, letters, and clinical test results related to a medical device were not trade secrets). The trade secret prong of exemption 4 does not apply.

B. The Redactions Contain No Confidential Commercial Information.

Exemption 4 also protects "commercial or financial information obtained from a person and privileged or confidential." FDA cannot bear its burden of showing either that information placed in a CV, created to be shared, is commercial or that it can reasonably be deemed privileged or confidential. On this prong, FDA's exemption 4 claim fails at every step.

1. The Redacted Information Is Not Commercial.

Exemption 4 does not cover the information FDA redacts because the information is not "commercial." Again, the FDA cites exemption 4 when redacting the dollar amounts of private research grants, titles of and names of principal investigators (when not the committee member) on current research projects, and citations to forthcoming articles. FDA cannot bear the burden of showing that this information is "commercial."

The advisory committee members on whose CVs these redactions appear are, or performed this work as, academic researchers, and their "institutional affiliations" with noncommercial organizations such as "colleges and universities," "research institutes," or "hospitals" make the possibility that their research is commercial "extremely remote." *Wash. Research Project, Inc. v. Dep't of Health, Ed. & Welfare*, 504 F.2d 238, 244-45 & n.6 (D.C. Cir. 1974) (finding that a "noncommercial scientist's research design is not literally a trade secret or item of commercial information"). As their CVs reflect, the committee members who undertake research and write articles are not marketing medical products based on their research and writing; they are not involved in a "commercial transaction in the ordinary sense." *Nat'l Ass'n of Home Builders*, 309 F.3d at 39. The exemption 4 claim here thus resembles the claim rejected in *Physicians Comm. For Responsible Med. v. NIH*, 326 F. Supp. 2d 19, 25 (D.D.C. 2004), in which this Court held that the grant application of a noncommercial scientist who had never manufactured or marketed any drug produced as a result of his research, or marketed his research

results, was not "commercial" information under exemption 4. Similarly, here, advisory committee members do not sell their research results and do not conduct the research to further their own marketing of a product, even where the research was funded by private companies. *See also National Ass'n of Home Builders*, 309 F.3d at 38-39 (holding that data maintained by a state agency about owl sightings was not commercial information because the submitters of the information had no commercial interest in it and the state did not compile the data in connection with any commercial enterprise). Because the information in the CVs neither "serves a commercial function [n]or is of a commercial nature," *id.* at 38, and the submitter of the information has no "commercial interest" in it, *Baker & Hostetler LLP v. U.S. Dep't of Commerce,* 473 F.3d 312, 319 (D.C. Cir. 2006), FDA's exemption 4 claim fails at the start.

2. The Redacted Information Is Not Confidential.

Not only is the redacted text not commercial, none of it—not even the small portion that may be considered "financial" (dollar amounts of private grants)—can reasonably be deemed "confidential." In the D.C. Circuit, the test used to assess confidentiality of exemption 4 depends on whether the government required a private party to submit the information to the government or whether the private party submitted the information voluntarily. *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992) (en banc). When submission is voluntary, the information is protected by exemption 4 "if it is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Id.* at 879. When submission is compulsory, the commercial or financial information is protected by exemption 4 if disclosure would be likely either "to impair the Government's ability to obtain necessary information in the future," or "to cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* at 878 (quoting *Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)).

Regardless of whether the CVs are considered voluntary or compelled submissions, exemption 4 does not justify the FDA's redactions. Information included in a CV is not "confidential" because it "is ordinarily written down precisely so that it *will* be displayed" publicly. *Physicians Comm. for Responsible Med.*, 117 F. Supp. 2d at 6. Indeed, many of the CVs redacted by FDA are posted in full elsewhere, usually on the website of the member's primary place of employment. *See supra* pp. 12 n.6. This common practice shows not only that redaction of the specific CVs posted elsewhere is insupportable, *see id.*, but also illustrates the fact that CVs do not contain "confidential" information but rather are created to be shared.

Because the redacted information is the kind of information customarily released to the public, exemption 4 does not apply under the *Critical Mass* test for voluntarily submitted information. *Critical Mass Energy Project*, 975 F.2d at 879. And because the *Critical Mass* test for voluntary submissions is the more lenient standard for justifying withholding under exemption 4, *Pub. Citizen v. HHS*, 975 F. Supp. 2d 81, 104 n.20 (D.D.C. 2013), the failure of FDA's exemption 4 claims to satisfy that test is the end of the exemption 4 inquiry. *See Mallinckrodt Inc. v. W.*, 140 F. Supp. 2d 1, 6 n.4 (D.D.C. 2000) ("Given the Court's conclusion that this information is protected from disclosure under *Critical Mass*, it need not reach the alternative argument that the release of this information would cause substantial competitive harm to plaintiff within the meaning of *National Parks*.").

3. The Specific Redactions Show That Exemption 4 Does Not Apply.

Focusing on the specific exemption 4 redactions highlights the broader analysis. Indeed, a great deal of the redacted information is freely available elsewhere, confirming the common-sense conclusion that CVs are not confidential but rather intended to be shared with the public. "If the information is freely or cheaply available from other sources . . . it can hardly be called confidential." *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 51 (D.C. Cir. 1981). The

following are examples of information FDA routinely redacts that is freely available elsewhere or is the kind of information customarily released to the public.

- **Payments from companies:** Congress mandates disclosure of the amount and purpose of payments from companies to doctors and teaching hospitals. FDA redacts that same information from member CVs.

Specifically, under the national disclosure program called Open Payments, which is administered by defendant HHS's Centers for Medicare & Medicaid Services (CMS), health care manufacturing companies are required to report to CMS all payments and transfers of value made to physicians and teaching hospitals, including those for consulting, research, and grants. 42 U.S.C. § 1320a-7h(a)(1)(A)(vi). CMS makes these data publicly available and searchable online at cms.gov/openpayments. For example, Open Payments shows that in 2014, health care companies provided a combined total of more than $2.58 million in funding for research projects led by four current members of FDA's Oncologic Drugs Advisory Committee. *See* Clattenburg Decl. ¶¶ 26, 28, 30, 32. Although those four members included in their CVs information about their private grants, FDA redacted information about their private funding. *See id.* ¶¶ 25, 27, 29, 31 & Ex. 6. FDA's claim that such payments are confidential contradicts Congress's determination that they must be publicly disclosed. Moreover, the fact that recent payments have been posted online by defendant HHS (through CMS) and that future payments will be posted online by HHS shows that FDA's redactions of older payments cannot be sustained. Surely if a 2014 grant award is not confidential and its disclosure has not created competitive harm, exemption 4 cannot protect the amounts of the older grant awards—some decades old—redacted by FDA.

- **Clinical trials:** Congress mandates disclosure of information about many clinical drug and device trials, whether federally or privately funded. FDA redacts from CVs a range of this same information. *See* Clattenburg Decl. ¶¶ 25, 33-37 & Ex. 7.

Specifically, by law, the sponsors of clinical trials studying a drug, biologic, or medical device that involve human volunteers must submit information to an online searchable data bank called ClinicalTrials.gov. *See* 42 U.S.C. §§ 282(i), 282(j); ClinicalTrials.gov, *Background*, https://clinicaltrials.gov/ct2/about-site/background. The database became publicly accessible in February 2000 and was greatly expanded in response to a law passed in 2007. *See* ClinicalTrials.gov, *Background*. Sponsors must submit the study's title, summary, primary purpose, and design, among other details. 42 U.S.C. § 282(j)(2)-(3); *see also* NIH, *FDAAA 801 Requirements*, https://clinicaltrials.gov/ct2/manage-recs/fdaaa. Congress's determination that certain information about privately funded trials should be public belies FDA's contrary determination that the information is protected by exemption 4.

Two specific examples highlight FDA's error: First, FDA redacted entire pages of one advisory committee member's research experience, but ClinicalTrials.gov includes eleven detailed summaries of her ongoing and completed research, including research projects sponsored by companies such as Boston Scientific Corporation, AstraZeneca, and Bristol-Meyers Squibb. Clattenburg Decl. ¶¶ 36, 38 & Ex. 8. Second, FDA redacted the names of Principal Investigators for a clinical trial listed on the CV of a CBER advisory committee member, but a summary of that clinical trial is available on ClinicalTrials.gov, including the names of the Principal Investigators. *Id.* ¶¶ 39-40 & Ex. 9. In addition, FDA redacts on some CVs the names of companies that sponsored advisory committee members' research, or that hired advisory committee members as consultants, or for which advisory committee members

served on advisory boards. *See* Clattenburg Decl. ¶¶ 41-44 & Ex. 10. The names of the companies sponsoring research are often available on ClinicalTrials.gov.

Finally, the names of companies that sponsored members' research or for which members worked are not exempt for the additional reason that the D.C. Circuit has long since rejected the argument that exemption 4 shields a list of government consultants' non-federal-government employment. *Wash. Post Co. v. HHS*, 690 F.2d 252, 266 (D.C. Cir. 1982).

- **Forthcoming publications:** FDA redacts citations to journal articles that are "in press," "forthcoming," "submitted," and "accepted for publication," as well as citations to some book chapters, poster presentations, and lectures. *See* Clattenburg Decl. ¶¶ 45-50 & Ex. 11. Yet members have no commercial interest in journal articles or lectures. Carome Decl. ¶ 16. And as to any publication in which the member has a commercial interest, that interest would lead the member to promote the publication publicly, not seek to keep it confidential. Moreover, a committee member desiring to keep research topics confidential would not seek to publish an article about the research, much less list it on his or her CV. To the contrary, academic institutions advise listing "Works in Press," "Submitted Articles" or "Works in Progress" on CVs "to show up-and-coming research." Mass. Inst. of Tech., *CVs*, https://gecd.mit.edu/jobs-and-internships/resumes-cvs-cover-letters-and-linkedin/cvs; *see also* Univ. of Wash., *Academic Careers: Curriculum Vitae* 3 (July 2012), *available at* http://careers.uw.edu/sites/default/files/all/editors/docs/10-11%20Academic%20Year/Curriculum%20Vitae%20July%202012.pdf (recommending that graduate students list their publications that are "in press" and "submitted for publication").

In addition, a free online searchable database called PubMed.gov contains most (perhaps all) of the citations to journal articles and books authored by advisory committee members.

PubMed.gov catalogs over 25 million citations for biomedical literature and is maintained by the National Center for Biotechnology Information at the U.S. National Library of Medicine, located at the National Institutes of Health. *See* Nat'l Ctr. for Biotech. Info., *PubMed Help*, http://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.PubMed. This free online resource lists citations to articles *before* they appear in print (designated as "Ahead of Print"), making FDA's protection of "in press" articles particularly ridiculous. U.S. Nat'l Library of Med., *MEDLINE, PubMed, and PMC (PubMed Central): How are they different?*, https://www.nlm.nih.gov/pubs/factsheets/dif_med_pub.html.

Moreover, many of the advisory committee members' own webpages link to the complete list of their publications compiled in online databases such as PubMed.gov and Elsevier.com, including ones FDA has redacted. *See* Clattenburg Decl. ¶¶ 51-54 & Ex. 12. For example, the physician profile page for Michael Jaff links to more than 260 of his publications on PubMed.gov, http://www.massgeneral.org/doctors/doctor.aspx?id=17575#—including the publications that FDA redacted from his CV. *See* Clattenburg Decl. ¶¶ 55-58 & Ex. 13. FDA also redacts articles designated as "ePub ahead of print." *See Id.* ¶¶ 59-60 & Ex. 14. Such redactions are inexplicable, because "ePub ahead of print" means that the article was published electronically in advance of the paper print. That is, the designation means that the articles are available online.[9]

[9] FDA cannot justify redacting citations to articles that have not yet been published by claiming that the information would provide insight into confidential research studies. Unlike in *Public Citizen Health Research Group v. FDA*, No. CIV.A. 99-0177, 2000 WL 34262802, at *4 (D.D.C. Jan. 19, 2000), in which the court held that a list of unpublished studies contained in a pharmaceutical company's new drug application—a document submitted to seek FDA approval to market a drug—might "provide insight" into the company's ongoing research, advisory committee members generally do not have a commercial interest in the products they research

Articles that are "forthcoming" or "in press" are ready for public consumption; they have been accepted for publication. *See* K. Patrias, *Citing Med.: The NLM Style Guide for Authors, Editors, & Publishers*, Chapter 11, § A (Nat'l Library of Med. 2007) (2d ed.), *available at* http://www.ncbi.nlm.nih.gov/books/NBK7240/. For this reason, it is not surprising that advisory committee members include their "in press" articles on CVs crafted for the purpose of touting their accomplishments. Clattenburg Decl. ¶¶ 61-62 & Ex. 15.

Likewise, FDA's thinking in redacting the titles of lectures and presentations seems inexplicable, as lectures and presentations are rarely secret. Certainly the fact that a member listed a lecture or presentation on his or her CV is strong evidence that the title of the lecture or presentation is not confidential. *See id*. ¶ 63 & Ex. 16.

- **Brand names and words that sound like brand names:** FDA redacts words that look like brand names. For example, FDA redacted the term "fibrin sealant" from one CV. *Id.* ¶¶ 64-65 & Ex. 17. Fibrin sealant is an FDA-approved product used to cause blood clotting and is available commercially in several forms. *See* William D. Spotnitz, *Fibrin Sealant: The Only Approved Hemostat, Sealant, and Adhesive—a Laboratory and Clinical Perspective*, ISRN: Surgery 1, 3 (2014), *available at* http://dx.doi.org/10.1155/2014/203943. In the same CV, FDA made the following redaction: "Prospective Evaluation of [redacted] EMS Ultrasound"; the

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and do not keep their areas of research confidential. Exemption 4 protects the *submitter's* commercial interest—here that of the advisory committee members. *Critical Mass Energy Project*, 975 F.2d at 873. Their interest is decidedly in favor of touting their work—*that is why they wrote the article*. The database ClinicalTrials.gov, *see supra* p. 18-19, which allows the public to access details of a wide range of clinical studies, further undermines any claim that redacting article titles is needed to protect against providing "insight" into the member's research.

unredacted version of the CV shows that FDA redacted the term "Aeromedical." *See* Clattenburg Decl. ¶¶ 64-65 & Ex. 17. "Aeromedical" simply means "relating to or involving air transportation to a hospital." *Aeromedical*, Merriam-Webster.com (July 7, 2016), http://www.merriam-webster.com/dictionary/aeromedical. FDA apparently redacted the term because it looked like a commercial brand name. (Moreover, this study is publicly reported on ClinicalTrials.gov. *See* https://clinicaltrials.gov/ct2/show/NCT01058967).

Even if some redacted words are brand names, brand names are not per se confidential commercial information and thus not per se covered by exemption 4. FDA's rote redaction of brand names and words that may be brand names appears to be unsupported.

- **Numbers are not per se exempt:** FDA has a penchant for redacting numbers, citing to exemption 4. For example, FDA redacted on an advisory committee member's CV his statement that his work on a medical school admissions board takes "6+ hours per week" during certain months of the year. Clattenburg Decl. ¶¶ 66-67 & Ex. 18. Although products that FDA clears for marketing are listed online, FDA also redacted the "10" on a CV in which an advisory committee member stated that he obtained FDA clearance for over "10 musculoskeletal tissue regeneration" products, and redacted "$10 million to over $100 million" from his boast of "growing annual product sales from $10 million to over $100 million." *Id.* ¶¶ 68-69 & Ex. 19. FDA likewise redacted the number of employees who work in an advisory committee member's department at a pharmaceutical company. *Id.*¶ 70 & Ex. 20. Exemption 4 does not support these redactions.

- **Information posted by FDA itself:** Some of the redacted information appears elsewhere *on FDA's own website*. For example, the FDA redacted the name of a drug on the CV of committee member Dr. Braunstein who gave a "clinical and regulatory presentation" at an

FDA advisory committee meeting about the drug. *See id.* Elsewhere, FDA posted the agendas for the advisory committee meeting, showing that Dr. Braunstein made a 2012 presentation concerning the drug "REGN475" for Regeneron Pharmaceuticals, Inc. FDA CDER, *Summary Minutes of the Arthritis Advisory Committee Meeting* (Mar. 12, 2012), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM307879.pdf. These unsupported redactions further illustrate the absurdity of FDA's handling of the CVs.

* * *

Given the counter-intuitive nature of deeming information freely publicized on a CV to be "confidential," the FDA's exemption 4 claims are meritless, to put it mildly, on top of the implausible designation of the redacted CV information as "commercial." The burden of proving that the redactions protect "confidential commercial or financial information" is on FDA, and it cannot sustain that burden. The Court should grant summary judgment to Public Citizen on the redactions claimed under exemption 4.

IV. Exemption 6 Does Not Apply To The Information In The CVs.

FOIA exemption 6 protects "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). On advisory committee member CVs, FDA invokes exemption 6 to withhold information such as the amount of funding that companies awarded to advisory committee members' research projects, the names of students mentored by committee members, the years in which degrees were conferred, the names of professors, the names of co-investigators on clinical studies, and the members' military service, community service, hobbies, and professional activities. FDA bears the burden of showing that disclosure of the information would constitute a

substantial invasion of privacy. *Prison Legal News v. Samuels*, 787 F.3d 1142, 1147 (D.C. Cir. 2015).

"[U]nder Exemption 6, the presumption in favor of disclosure is as strong as can be found anywhere in the Act." *Wash. Post Co.*, 690 F.2d at 261. To determine whether exemption 6 applies, the court first examines whether disclosure would compromise any privacy interest at all, and if so, how serious that privacy invasion would be. *Id.* Where disclosure would compromise only a *de minimis* privacy interest, the exemption does not apply and the information must be disclosed. *Nat'l Ass'n of Retired Fed. Employees v. Horner*, 879 F.2d 873, 874 (D.C. Cir. 1989). Where disclosure implicates "anything greater than a *de minimis* privacy interest," *Multi Ag Media LLC*, 515 F.3d at 1229-30, the court balances the public interest in disclosure against the privacy interest that would be compromised by disclosure. *Consumers' Checkbook, Ctr. for the Study of Servs. v. HHS*, 554 F.3d 1046, 1050 (D.C. Cir. 2009). The relevant public interest for purposes of exemption 6 is "the extent to which disclosure of the information sought would shed light on an agency's performance of its statutory duties or otherwise let citizens know what their government is up to." *Jurewicz v. U.S. Dep't of Agric.*, 741 F.3d 1326, 1332 (D.C. Cir. 2014) (quoting *DOD v. Fed. Labor Relations Auth.*, 510 U.S. 487, 497 (1994)) (internal quotation marks omitted).

The "scope of a privacy interest under Exemption 6 will always be dependent on the context in which it has been asserted." *Armstrong v. Executive Office of the President*, 97 F.3d 575, 581 (D.C. Cir. 1996). In this case, the context is the advisory committee members' CVs. The "information in a C.V. is ordinarily written down precisely so that it *will* be displayed." *Physicians Comm. for Responsible Med.*, 117 F. Supp. 2d at 6. FDA cannot show any "palpable threat to privacy" from releasing information that advisory committee members want to display

to others. *Carter v. U.S. Dep't of Commerce*, 830 F.2d 388, 390 (D.C. Cir. 1987).[10] Accordingly, courts have repeatedly held that FOIA does not protect information such as employment history, activities, and qualifications contained in the CVs or applications of applicants for government jobs or funds. For example, in *Physicians Committee for Responsible Medicine*, the court ordered disclosure of the CVs of approximately 140 unsuccessful applicants to the Dietary Guidelines Advisory Committee, because the information in a CV is meant to be displayed and thus is not private, and the applicants were not "given assurances of confidentiality." 117 F. Supp. 2d at 6. Similarly, in *Core v. U.S. Postal Service*, the court ordered the government to release the applications for successful job candidates, which included information such as prior "business employment, special assignments or projects, membership in any professional or civic organizations, awards and honors," because the information in the applications was "simply the type of information every applicant seeks to bring to the attention of a prospective employer." 730 F.2d 946, 948 (4th Cir. 1984). Relying on *Core*, the court in *Judicial Watch, Inc. v. Export-Import Bank* ordered the government to release the résumés of executives of companies that successfully applied for insurance from the Export-Import Bank. 108 F. Supp. 2d 19, 37-38

[10] Indeed, FDA's redactions intrude upon, rather than protect, the advisory committee members' privacy interests. "The privacy interest protected by Exemption 6 'encompass[es] the individual's control of information concerning his or her person.'" *DOD v. Fed. Labor Relations Auth.*, 510 U.S. at 500 (quoting *Reporters Comm. For Freedom of Press*, 489 U.S. at 763). FDA's redactions usurp the advisory committee members' "claim . . . to determine for themselves when, how, and to what extent information about them is communicated to others." *Reporters Comm. For Freedom of Press*, 489 U.S. at 764 n.16 (internal quotation marks and citation omitted). For example, Dr. Michael Carome, director of Public Citizen Health Research Group, serves on FDA's Pharmacy Compounding Advisory Committee. Carome Decl. ¶ 2. Dr. Carome told FDA that they could disclose his CV in full, *id.* ¶ 9, but FDA redacted his CV to hide his military awards and the amount of a National Kidney Foundation grant. *Id.* ¶¶ 12, 15. FDA's redaction does not protect his privacy; it obstructs his choice to share information about his professional career.

(D.D.C. 2000). Likewise, in *Commodity News Service, Inc. v. Farm Credit Administration*, the court held that FOIA did not protect from disclosure the résumé of the receiver selected by the government for a failed bank. No. CIV.A. 88-3146 HHG, 1989 WL 910244, at *2 (D.D.C. July 31, 1989).

In contrast, where the FOIA request sought résumés or applications of *unsuccessful* applicants for federal positions, some courts have held that they could be withheld. *See Core*, 730 F.2d at 948; *Judicial Watch, Inc. v. U.S. Dep't of Commerce*, 337 F. Supp. 2d 146, 177 (D.D.C. 2004); *Holland v. CIA*, Civ. A. 92-1233, 1992 WL 233820, at *14 (D.D.C. Aug. 31, 1992); *Barvick v. Cisneros*, 941 F. Supp. 1015, 1021 (D. Kan. 1996). Even there, however, the courts did not find a privacy interest in the information contained in the résumés, but rather found that the unsuccessful applicants had a privacy interest in the fact of their rejection, and the résumés would provide enough information to allow the individuals to be identified as the rejected candidates. According to the court in *Core*, "disclosure may embarrass or harm applicants who failed to get a job. Their present employers, co-workers, and prospective employers, should they seek new work, may learn that other people were deemed better qualified for a competitive appointment." *Core*, 730 F.2d at 949. And because the résumés would not reveal the qualifications of those selected to do the government's business, the court found little public interest to balance against the privacy interest. *Id.*; *but see Physicians Comm. for Responsible Med.*, 117 F. Supp. 2d at 6 (ordering disclosure of the CVs of unsuccessful applicants because "the asserted stigma of rejection is significantly diluted when shared among approximately 140 people" and disclosure would further the public interest in understanding the agency's selection process). These cases do not help the FDA here, where all of the CVs at issue belong to successful applicants to advisory committees.

Under exemption 6, "unless the invasion of privacy is 'clearly unwarranted,' the public interest in disclosure must prevail." *Ray*, 502 U.S. at 177. For each category of information withheld by FDA, balancing the public interest against any privacy interest shows that the exemption 6 claim lacks merit.

A. CVs Reveal Financial Ties Of Advisory Committee Members.

Disclosure of the redacted information about private research funding would not constitute a "clearly unwarranted invasion of privacy," as exemption 6 requires. On the privacy side, the interest is small—as reflected in the fact that the members routinely put the amounts on their CVs (which they do not create specifically for the FDA and often post online themselves). Indeed, the statutorily created, government-maintained database openpayments.gov makes information about the amounts paid by manufacturing companies to physicians, including for research, available to the public from 2013 on. *See* About Open Payments Data, https://openpaymentsdata.cms.gov/about. On the public interest side, information about these payments would reveal outside influences on advisory committee members. By contributing to the public's understanding of the decisionmaking of the advisory committees, disclosure will advance the goal of FOIA: "permit[ting] the public to decide for itself whether government action is proper." *Wash. Post Co.*, 690 F.2d at 264.

FDA itself recognizes that a full understanding of a member's background sheds light on how he or she contributes to advisory committees, as it instructs candidates for advisory committee membership to "provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts" in their CVs and applications. FDA, *FDA Advisory Committee Membership Application*. The CV itself is the primary element of the application. *Id.* Importantly, FDA relies on the members' CVs to screen for potential conflicts of interest. *See id.*; *see also* Gov't Accountability Office, *FDA Advisory Committees: Process for*

Recruiting Members & Evaluating Potential Conflicts of Interest, GAO-08-640, at 25 (Sept. 2008), *available at* http://www.gao.gov/new.items/d08640.pdf. The D.C. Circuit has found a "singularly strong interest" in disclosure of information about conflicts of interest of consultants to the government, explaining that, although consultants provide "the government with needed expert advice," there was the "undeniable potential for occasional abuse," and thus exemption 6 did not shield the conflicts information. *Wash. Post Co.*, 690 F.2d at 264.

The public has a significant interest in learning about possible influences on advisory committee members, as shown by the media coverage on potential sources of financial influence on advisory committee members and physicians, and disclosure of the sorts of information FDA redacts on the CVs furthers that interest. For example, in 2012, after an FDA advisory committee voted in favor of two controversial drugs, journalists discovered that four of the members of that committee had "served as paid researchers, consultants, 'key opinion leaders,' or speakers" for the drugs' manufacturers or licensees, but FDA's conflicts disclosure in connection with that meeting listed none of the four as having relevant conflicts. Jeanne Lenzer & Keith Epstein, *The Yaz Men: Members of FDA panel reviewing the risks of popular Bayer contraceptive had industry ties*, Wash. Monthly (Jan. 9, 2012), *available at* http://www.washingtonmonthly.com/ten-miles-square/2012/01/the_yaz_men_members_of_fda_pan034651.php. A recent study that examined payment data from OpenPayments.gov shows that a physician's receipt of a single free meal from a pharmaceutical company is associated with an increase in that physician's rate of prescribing the drug the free-meal pharmaceutical company was promoting. Colette DeJong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, JAMA Internal Med. (June 20, 2016), http://ja.ma/29ng1tm, *as reported in* Nicholas Bakalar, *Drug Company Lunches Have Big Payoffs*, N.Y. Times (June 20, 2016),

http://nyti.ms/28JF3G4. Similarly, revealing the research payments that FDA redacts would contribute to the public's evaluation of potential financial influence on physicians who serve on advisory committees.[11]

The public interest in the grant information is not abated by FDA's conflicts screening process, which generally focuses only on financial interests "that are currently held." *See* Dep't Health & Human Servs., *Guidance, Procedures for Determining Conflict of Interest and Eligibility for Participation* 2, 12, 18 (Aug. 2008); *see also* 18 U.S.C. § 208, 21 U.S.C. § 379d–1(c), 5 C.F.R. §§ 2635.401-402, 2635.501-502; 2640.103 (statutes and regulations prohibiting financial and appearance conflicts of interest on advisory committees). Research grants that do not rise to the level of disqualifying interests, such as smaller or older payments, may nonetheless be relevant to understanding the background and influences that affect advisory committee members in their work on FDA committees. 21 U.S.C. § 379d–1; *see* FDA, *Guidance, Public Availability of Advisory Comm. Members' Financial Interest Information and Waivers* 6-8 (Mar. 2014), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf. For example, more than one-third of the members on three FDA medical device panels from 2012-2014 had received consulting fees, research grants, food, travel, or other compensation from medical device companies, but FDA disclosed to the public only a tiny fraction of these corporate ties through the conflicts waivers FDA posts on its website when it determines that a member has a financial conflict that requires a waiver from FDA. *See* Joseph Walker, *FDA Advisers' Financial Ties Not Disclosed*, Wall St. J. (Dec. 8, 2014), http://on.wsj.com/1zlHRP2.

[11] FDA redacts the amounts of research grants under either or both exemption 4 and exemption 6. *See* Clattenburg Decl. ¶¶ 71-72 & Ex. 21.

In short, the redacted financial information would contribute to public understanding of the operations of advisory committees by disclosing the extent of outside influences on advisory committee members. FDA cannot bear the burden of showing that exemption 6 applies.

B. CVs Reveal The Non-Financial Influences On Advisory Committee Members.

Advisory committee members are influenced by non-pecuniary ties as well. They are influenced by their education, training, professional associates, and "the pursuit of professional advancement and recognition and the desire to do favors for friends, family, students, or colleagues." Inst. of Med. Comm. on Conflict of Interest, *Conflict of Interest in Medical Research, Education, & Practice* (Nat'l Academies Press 2009), *available at* http://www.ncbi.nlm.nih.gov/books/NBK22926/. Several categories of redacted information for which FDA claims exemption 6 would elucidate non-monetary influences that shape members' contributions to the committees, including the students they mentored, colleagues with whom they worked, boards and committees on which they served, and the outside activities in which they took part. Indeed, FDA views the very relationships it hides through redactions as pertinent to assessing conflicts of interest. *See* FDA, *Draft Guidance, Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees* 3 (June 2016), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM508852.pdf.

With respect to the names of mentors, mentees, and co-investigators, the law in this Circuit is clear: exemption 6 does not shield "business judgments and relationships." *Sims v. CIA*, 642 F.2d 562, 575 (D.C. Cir. 1980); *see also Wash. Post Co. v. DOJ,* 863 F.2d 96, 100-101 (D.C. Cir. 1988) (holding that the privacy protection in exemption 7(C) does not extend to information "relating to business judgments and relationships" when the information does not identify a person as a target of an investigation); *Fuller v. CIA*, No. CIV.A.04 253 RWR, 2007 WL 666586, at *4 (D.D.C. Feb. 28, 2007) (explaining that exemption 6 does not protect names

that appear in connection with professional or business relationships); *Cohen v. EPA*, 575 F. Supp. 425, 429 (D.D.C. 1983) ("The privacy exemption does not apply to information regarding professional or business activities.") (applying exemption 7(C)).

Paying no heed to the fact that exemption 6 does not protect professional relationships, FDA consistently redacts the names of third parties appearing on CVs. For example, advisory committee members regularly include on their CVs the names of mentees, often noting whether their mentees won awards, to show the members' relationships to other researchers. *See* Clattenburg Decl. ¶¶ 73-77, 80 & Exs. 22-23, 26; *id.* ¶¶ 73, 75 & Ex. 23 at 2, 19-20 (indicating where their mentees received awards). FDA, however, redacts the names of the individuals whom a committee member mentored. Clattenburg Decl. ¶¶ 73-77, 80 & Exs. 22-23, 26; *see also id.* ¶ 77 & Ex. 23 (member's online unredacted CV reveals all of the names of her mentees). Also baffling is that FDA often redacts the names of committee members' own mentors, as though it is private that a member worked for a certain academic and not a fact that was publicly known to everyone within the university department. *See id*. ¶¶ 76, 78 & Ex. 24 at 1 (names of thesis advisor and examiner redacted); *id*. at 2-3 (names of research mentors redacted); id. at 5 (name of director redacted); *id*. at 6 (names of graduate advisor and preceptor redacted); Clattenburg Decl. ¶ 75 & Ex. 22 at 13-14 (names of member's advisors redacted). Similarly, in one CV, FDA redacted the names of co-researchers for poster presentations. Clattenburg Decl. ¶ 79 & Ex. 25. In another CV, FDA redacted the names of all the students the member mentored, all of his co-investigators on research projects, and even the names of certain (presumably

noteworthy) guests who attended the "advocacy reception" he hosted at the North American Spine Society in 2010 and 2011. *See id.* ¶ 81 & Ex. 27.[12]

The above examples confirm that the D.C. Circuit case law is correct: exemption 6 does not apply to the names of professional associates—either generally or specifically with regard to the names of people included on a CV.

C. Other Specific Examples Illustrate That FDA's Exemption 6 Redactions Are Unjustified.

1. Medical License Numbers.

FDA routinely redacts the medical license numbers for advisory committee members. *See*, *e.g.*, Clattenburg Decl. ¶¶ 34, 83-85 & Ex. 29. Yet every state medical board maintains an online database for finding a physician's medical license number and most also provide a profile for the physician. ConsumersUnion, *Links to State Medical Boards* (updated Mar. 29, 2016), http://consumersunion.org/research/links-to-state-medical-boards/. For instance, a search of Georgia's Composite Medical Board website by last name gives the physician's license number, licensure date, other states where the physician is licensed, the physician's address, medical school, specialty board certifications, and any disciplinary action, among other information. *Id.* ¶¶ 83, 86 & Ex. 30 (comparing a member's CV as redacted by FDA with his state medical board online profile). Moreover, the Federation of State Medical Boards provides a centralized physician look-up database, searchable by name, which provides the state where the physician is

[12] An especially nonsensical redaction appears in the CV of a Peripheral and Central Nervous System Drugs Advisory Committee member, Caleb Alexander. Citing exemption 6, FDA redacted this note from Dr. Alexander's list of publications: "trainees' names are underlined." *See id.* ¶¶ 54, 82 & Ex. 28 (redacted information is evident from comparing the list of publications on his faculty webpage—which contains the same note about underlining—with the FDA's version of his CV). It is difficult to fathom whose privacy interest FDA purports to protect by redacting that note.

licensed, so that one can then look up the license number on the state's website. *See* DocInfo.org, http://docinfo.org/#/search/query. To call FDA's redactions of physicians' license numbers a waste of time is an understatement. "One can have no privacy interest in information that is already in the public domain." *Citizens for Responsibility & Ethics in Wash. v. DOJ*, 840 F. Supp. 2d at 233; *see Davis*, 968 F.2d at 1280. Exemption 6 does not apply.

2. Community Service.

FDA redacts information about advisory committee members' community service and hobbies. *See* Clattenburg Decl. ¶¶ 81, 87-90 & Ex. 31 (CVs with redactions of community service, "hobbies," "activities," "extracurricular achievements," and "interests" redacted). "[T]he mere fact that records pertain to an individual's activities does not necessarily qualify them for exemption. Such records may still be cloaked with the public interest if the information would shed light on agency action." *Nation Magazine*, 71 F.3d at 894-95. Information about community service that committee members share on their CVs is not private information. Even if the member had not chosen to tout the information on his CV, it would be difficult to discern what privacy interest FDA identified in the fact that an advisory committee member served as the President of the Westside Neighborhood (a point surely known at least to his neighbors). *Id.* ¶¶ 91-92 & Ex. 32 at 2, 4. Nor does a discernible privacy interest exist in the fact that a committee member served as the community advisor to the Seattle Junior League from 1991-2000 and on the Honorary Advisory Board to the Children's Museum. *Id.* ¶¶ 93-94 & Ex. 32 at 6, 9. In contrast to the absent privacy interest, the information would help the public gain a more complete understanding of the backgrounds of advisory committee members.

3. The Dates Of Degrees Conferred.

FDA routinely redacts the dates of advisory committee members' undergraduate degrees, medical degrees, internships, residencies, and fellowship training. Clattenburg Decl. ¶¶ 99-100 &

Exs. 34-35. Revealing these dates would not invade the member's privacy interest. FDA appears to recognize that exemption 6 does not protect such information because, with the exception of the year of high school graduation, FDA disclosed the dates in the CVs it released in response to Public Citizen's FOIA request. *See id.* ¶¶ 95-98 & Ex. 33 (comparing the CVs of members as posted on FDA's website—with dates redacted—to those same CVs as released, without the dates redacted); *id.* ¶¶ 121-22 & Ex. 33 at 11-12 (high school year redacted). Many advisory committee members post the dates of their degrees online anyway. *Id.* ¶¶ 101-104 & Ex. 36. Academic institutions likewise often include a graduation year in publications, such as university magazines, when they refer to alumni, or post information on their websites that includes graduation year. *See*, *e,g*., Georgetown Univ., *Alumni Authors*, http://alumni.georgetown.edu/alumni-authors; Georgetown Univ., *Class Notes*, http://alumni-resources.georgetown.edu/s/1686/alumni/index.aspx?sid=1686&gid=4&pgid=106&cid=283.

Dates of degrees in committee member CVs do not warrant protection. Any de minimis privacy interest is easily outweighed by the public interest, as the dates elucidate the duration of advisory committee members' experience.

4. Military Service.

FDA redacts information related to an advisory committee member's military service. *See* Clattenburg Decl. ¶¶ 105-109 & Ex. 37; *see also* Carome Decl. ¶¶ 12, 15 & Ex. C. This Court has found some identifying information about active duty military personnel maintained by the government protected by exemption 6. *See Schwaner v. Dep't of The Army*, 696 F. Supp. 2d 77, 83 (D.D.C. 2010) (holding that Army could withhold under exemption 6 a list of active duty personnel, their ranks and companies, and their addresses); *Schoenman v. FBI*, 575 F. Supp. 2d 136, 161 (D.D.C. 2008) (holding that, where there was no public interest in disclosure, exemption 6 protects the names of Air Force members and other identifying information in an

intelligence report). The driving concern in both of those cases was the need for enhanced security of military personnel in light of recent terrorist attacks, and in both cases, the plaintiffs failed to articulate any public interest in disclosure of the identifying information. *Schwaner*, 696 F. Supp. 2d at 82; *Schoenman*, 575 F. Supp. 2d at 161. Here, however, the service member has chosen to make the disclosure by placing it on his or her CV—a document created by the individual for the purpose of sharing the information contained within it. And here, the redactions withhold information about prior, not active service. Moreover, the fact of military service is pertinent to the public's understanding of the advisory committee member's background.

* * *

FDA has withheld information that sheds light on the qualifications and backgrounds of those who influence FDA's regulatory actions from their seats on advisory committees, and thus sheds light on "what the[ ] government is up to" when it comes to FDA-regulated products. *Reporters Comm. For Freedom of Press*, 489 U.S. at 773. Here, in light of the strong public interest in disclosure and the nonexistent privacy interest in withholding the information, FDA's exemption 6 redactions are unlawful.

V. FDA's Withholding Of Non-exempt Information From The CVs Of Advisory Committee Members Is An Ongoing Unlawful Policy Or Practice.

A. The Agency's Policy Or Practice Violates FOIA.

Under FOIA, a party may assert a "claim that an agency policy or practice will impair the party's lawful access to information in the future," separate and apart from a claim for the release of particular requested records that the agency has withheld from the complainant under FOIA. *Payne Enters., Inc. v. United States*, 837 F.2d 486, 491 (D.C. Cir. 1988). Such a claim is appropriate where "an agency's refusal to supply information evidences a policy or practice of delayed disclosure or some other failure to abide by the terms of the FOIA, and not merely

isolated mistakes by agency officials." *Id.* To state a policy or practice claim, "a plaintiff must plausibly demonstrate that: (1) the agency in question has adopted, endorsed, or implemented a policy or practice that constitutes an ongoing failure to abide by the terms of the FOIA; and (2) the plaintiff will suffer continuing injury due to this practice." *Nat'l Sec. Counselors v. CIA*, 898 F. Supp. 2d 233, 253 (D.D.C. 2012) (quoting *Payne Enters., Inc.*, 837 F.2d at 491 (internal quotation marks omitted)).

The FDA has implemented a policy or practice of withholding non-exempt information from the CVs of advisory committee members posted as frequently requested records on its website, and the CVs currently posted on FDA's website show that FDA continues to press on with its enthusiastic redactions of non-exempt information. Of the 150 CVs posted for members of Center for Drug Evaluation and Research advisory committees as of April 6, 2016, 138 have redactions—92 percent. Of the 57 CVs posted for members of Center for Biologics Evaluation and Research advisory committees, 49 have redactions—just shy of 86 percent. Of the 128 CVs posted for members of Center for Devices and Radiological Health advisory committees, 126 have redactions—more than 98 percent. All of the CVs posted for members of the Tobacco Products Scientific Advisory Committee and the Pediatric Advisory Committee have redactions. Clattenburg Decl. ¶ 2. FDA has no plans to end its practice, having told Public Citizen that it "will not be revising our web pages so that all of the CVs of advisory committee members are posted without redaction." Clattenburg Decl. ¶ 5 & Ex. 2. *See Newport Aeronautical Sales v. Dep't of Air Force*, 684 F.3d 160, 164 (D.C. Cir. 2012) (holding that plaintiff had shown that it would "suffer continuing injury" from the Air Force's allegedly unlawful practice of denying certain FOIA requests because the plaintiff's business depended on requesting and receiving

documents that the Air Force's policy prevented the plaintiff from receiving and the Air Force did not believe its policy violated FOIA).

FDA's policy or practice deprives Public Citizen of timely and complete information about advisory committee members. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998) (holding that "a plaintiff suffers an 'injury in fact' when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute"). FDA's partial response to Public Citizen's 2014 FOIA request does not remedy this harm, as the response is incomplete, replete with redactions, and so delayed that the membership of the committees has changed. *See* Clattenburg Decl. ¶ 23; *see also Payne Enters.*, 837 F.2d at 494 ("The fact that Payne eventually obtained the information it sought provides scant comfort when stale information is of little value yet more costly than fresh information ought to be.").

Nor would filing serial requests and lawsuits remedy the harm from FDA's unlawful policy and practice, as FDA suggested in its Motion to Dismiss. *See* FDA Mem., at 9-10. FDA's suggestion flies in the face of Congress's determination of the need for the "frequently requested records" provision, which Congress enacted to "help to reduce the number of multiple FOIA requests for the same records requiring separate agency responses." H.R. Rep. No. 104-795, at 21 (1996). Furthermore, Public Citizen challenges unlawful redactions on CVs that FDA is *already* publishing online, and the ongoing dispute is as to the lawfulness of redactions—a dispute that will be renewed, not resolved, with every individual request. FDA's posting of the CVs online with unlawful redactions over the past two years is akin to FDA releasing the CVs in response to individual FOIA requests with the same unlawful redactions again and again. In this regard, this case resembles *Payne*, in which the D.C. Circuit denounced the agency's practice of repeatedly withholding non-exempt records in response to individual requests and requiring the

plaintiff to file administrative appeals before releasing the records. The court held that release of the specific requested records was not enough to remedy the harm from this unlawful practice. *Payne*, 837 F.2d at 494. "Congress did not intend for" an agency "to use the FOIA offensively to hinder the release of non-exempt documents." *Id.* (quoting *Long v. IRS*, 693 F.2d 907, 910 (9th Cir. 1982)). FOIA sets out the process for releasing these CVs, but FDA refuses to follow it.

Serial requests would also be ineffective here because FDA's response to FOIA requests is so woefully delayed. Indeed, although Public Citizen submitted its FOIA request for the CVs over 25 months ago, FDA's largest Center, the Center for Drug Evaluation and Research, has not yet responded, and FDA's second largest Center, the Center for Devices and Radiological Health, responded only in the last month. Clattenburg Decl. ¶¶ 19-21. The CVs that FDA has released contain the sorts of unlawful redactions Public Citizen challenges in this suit. *Id*. ¶ 22. And defendant HHS never responded substantively to Public Citizen's appeals from the responses of three FDA Centers—two submitted in September 2014 and one submitted in December 2015. *Id.* ¶¶ 10, 21. The lengthy lag-times in responding to this particular request are not isolated incidents of delay. *See* Dep't Health & Human Servs., *Fiscal Year 2015 Freedom of Information Annual Report*, *available at* http://www.hhs.gov/foia/reports/annual-reports/2015/index.html (stating that "average number of days" for FDA to process "complex" request is 186).[13]

[13] HHS defines a "complex" request to mean a "request that an agency using multi-track processing places in a slower track based on the high volume and/or complexity of the records requested." HHS, *Fiscal Year 2015 Freedom of Information Annual Report*. Given its CV redaction policy, FOIA requests for the CVs would fall into this category, as the processing of Public Citizen's request reflects.

Accordingly, FDA cannot credibly suggest that the harm to Public Citizen is adequately remedied by serial FOIA requests that may not be fully processed for more than two years, followed by administrative appeals that receive no substantive response at all. The futility of obtaining the unredacted CVs through individual requests results as well from the fact that the membership of an advisory committee changes over time, so some individuals who were members at the time of a request would no longer be advisory committee members by the time FDA gets around to responding—a response containing unlawful redactions of the sort that prompted Public Citizen's request for "unredacted" records. *See* Clattenburg Decl. ¶ 22. And after FDA's delayed release and the HHS appeal process, Public Citizen would then have to litigate the unlawful redactions. Filing serial FOIA requests would thus leave Public Citizen in the same position it is in now: unable to obtain non-exempt information about the backgrounds of *current* advisory committee members.

Because FDA's ongoing practice violates FOIA and impedes the public's timely access to information, the court should grant summary judgment to Public Citizen and enjoin FDA from redacting non-exempt information from the CVs of advisory committee members on its website.

B. FDA Cannot Circumvent FOIA By Directing Advisory Committee Members To Make Redactions.

Sometime after Public Citizen contacted FDA about its unlawful redactions in 2014, FDA started asking committee members to send FDA new copies of their CVs with the information that FDA would otherwise unlawfully redact already deleted, thus allowing FDA to post a CV that, to the public, appears to have no redactions. *See* Carome Decl. ¶ 14 & Ex. B. To do this, FDA sends a form to members telling them to submit a version of their CVs for FDA's website with certain information removed, including medical board certification numbers, the names of graduate students mentored, pending government grants, "[a]ny information about

private grants," papers that have not been published yet, race, gender, and several other categories of information. *Id*. In other words, FDA seeks to circumvent FOIA's disclosure requirement and hide what are effectively redactions of non-exempt information by obtaining new versions of the CVs, now pre-redacted, so that it can post them online without indicating where information was redacted.

Some of the CVs Public Citizen received in response to its FOIA request appear to have gone through this process. CFSAN released the CV of Kendall Wallace in October 2014 and then a "revised" version in March 2015 that is an altogether different record than the October 2014 document: it has 11 fewer pages and is missing most of the information that FDA had redacted in the October 2014 CV, including the names of all students mentored and grant awards from companies. Clattenburg Decl. ¶¶ 110-11 & Ex. 38. For James Swain, the CV FDA released in March 2015 is missing the information FDA had redacted in the CV it released in October 2014: license numbers, the amounts of private grants, and the name of a co-investigator. *See id.* ¶¶ 112-13 & Ex. 39. Similarly, in October 2014, FDA released to Public Citizen a version of Kurt Ribisl's CV (dated February 2012) with all of the titles of his "Manuscripts Under Review" and "Manuscripts in Preparation" redacted under exemption 4. *Id.* ¶ 91 & Ex. 41 at 7. However, those sections are entirely missing from the April 2015 version of Dr. Ribisl's CV that FDA posted more recently on its website. *Id.* ¶ 117 & Ex. 41 at 23-48. The deletion of these publications' titles was likely made in response to FDA's instructions—not because they are confidential—because versions of Dr. Ribisl's CV available on his faculty page (dated June 2012 and June 2015 and June 2016) include unredacted lists of his "Manuscripts Under Review" and "Manuscripts in Preparation," thus the titles cannot be confidential. *Id.* ¶¶ 92, 115-17. & Ex. 41 at 49-63. Moreover, in another CV, FDA marked the numerous redactions as "Appears this way

on original," indicating that—again, likely in response to FDA's deletion instructions—the committee member submitted an already redacted CV for posting. *Id.* ¶ 114 & Ex. 40. The result is that FDA has impermissibly expanded FOIA's exemptions by instructing committee members to delete or redact information that FDA cannot lawfully redact under FOIA.

If the committee members had never submitted complete CVs to FDA, FDA's non-disclosure scheme might be permissible under FOIA. Here, however, advisory committee members must submit complete CVs at the time they apply for membership. 21 C.F.R. § 14.82(c). Therefore, FDA has a copy of the complete CV. FDA states that advisory committee members CVs are "frequently requested records," *see Electronic Reading Room*, and surely the frequently requested records are for member CVs (as was Public Citizen's request), not "truncated member CVs." That is, requesters seek the full CV. FDA should not be permitted to circumvent FOIA, hide the fact that it is doing so, and hide the fact of redactions by asking members to submit new versions tailored to FDA's non-disclosure preferences.

VI. The Court Has Remedial Power Under FOIA Or, Alternatively, The APA Or The Mandamus And Venue Act To Grant The Requested Relief.

The Court has sufficient remedial power under FOIA to order FDA to cease its unlawful policy or practice and to post unredacted CVs of advisory committee members on its website on an ongoing basis. FOIA grants federal courts the power to "enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B). The declaratory and injunctive relief Public Citizen seeks easily falls within the bounds of that provision.

FOIA's judicial review provision grants federal courts a broad range of equitable powers beyond ordering an agency to disclose improperly withheld records in response to individual FOIA requests. *See Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 19-20 (1974)

(explaining why "there is little to suggest, despite the [FOIA]'s primary purpose, that Congress sought to limit the inherent powers of an equity court."); *Morley v. CIA*, 508 F.3d 1108, 1120 (D.C. Cir. 2007) (directing an agency to search additional documents for records responsive to a FOIA request); *Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1315 (D.C. Cir. 2003) (ordering an agency to grant a FOIA requester a fee waiver). As this Court has explained, FOIA's "use of the conjunctive 'and'" in its judicial review provision "suggests that district courts have the power to issue injunctive relief beyond merely compelling disclosure of records." *Citizens for Responsibility & Ethics in Wash. v. DOJ*, No. 13-CV-01291, __ F. Supp. 3d __, 2016 WL 912167, at *8 (D.D.C. Mar. 7, 2016) (*"CREW"*). Specifically, "the Court has the power under FOIA and *Payne* to provide the requested declaratory and injunctive remedies" "where a plaintiff challenges an alleged pattern and practice of violating procedural requirements of FOIA in connection with the processing of the plaintiff's FOIA requests[.]" *Muttitt v. U.S. Cent. Command*, 813 F. Supp. 2d 221, 229 (D.D.C. 2011).

This Court's decision in *CREW* is not to the contrary. There, both parties took the position that FOIA did not allow the Court to order the agency to comply with its publication requirements under 552(a)(2)(A) and (B). The Court thus did not decide whether FOIA authorized a court to require proactive disclosure of records under that provision, yet it cautioned that it was "far from convinced that the parties are correct about the limited extent of the court's remedial authority under FOIA." 2016 WL 912167, at *8. In reaching that conclusion, this Court relied in part on the D.C. Circuit's recognition that "FOIA imposes no limits on courts' equitable

powers in enforcing its terms." *Payne*, 837 F.2d at 494 (citing *Renegotiation Bd.*, 415 U.S. at 19-20), *quoted in CREW*, 2016 WL 912167, at *8.[14]

Following *Payne*, courts have held that FOIA empowers them to grant prospective declaratory and injunctive relief from policies and practices that violate FOIA. In *Muttitt*, for example, the court held that it had "the power under FOIA and *Payne*" to provide declaratory and prospective injunctive relief on a claim that the agency's policy or practice of refusing to provide time estimates for responses violated FOIA. 813 F. Supp. 2d at 229; *see also Newport Aeronautical Sales*, 684 F.3d at 163-64 (reviewing under FOIA a claim seeking declaratory relief from the agency's practice of refusing to disclose certain information allegedly in violation of FOIA); *Am. Immigration Lawyers Ass'n v. Executive Office for Immigration Review*, 76 F. Supp. 3d 184, 193 (D.D.C. 2014) (reviewing claim of violation of FOIA § 552(a)(2)(A)—requiring proactive disclosure of final opinions and orders—under FOIA); *Nat'l Sec. Counselors*, 898 F. Supp. 2d at 266 (holding that the court had the power under FOIA to order declaratory and injunctive relief on plaintiff's policy-or-practice claims alleging procedural violations of FOIA).

Alternatively, if, notwithstanding *Payne* and the plain language of § 552(a)(4)(B), the Court finds it lacks authority under FOIA to remedy FDA's unlawful policy and practice, the Court has the power to order the relief sought under the Administrative Procedure Act, because FDA's policy or practice constitutes final agency action that is arbitrary and capricious and not

[14] *Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1203 (D.C. Cir. 1996), on which FDA relied in its motion to dismiss, is inapposite. *Kennecott* "addressed whether a district court has the authority to compel an agency to 'publish' materials in the Federal Register, as required by Section 552(a)(1)" and "did not address the scope of a district court's authority to afford relief for a violation of Section 552(a)(2)." *CREW*, 2016 WL 912167, at *8 n.5. Thus, *Kennecott* does not apply here, where Public Citizen seeks an order enjoining FDA from unlawfully redacting the CVs, in violation of section 552(a)(2) and § 552(b).

in accordance with law, 5 U.S.C. § 706. In addition, FDA's unlawful policy or practice also warrants relief in the nature of mandamus if no other adequate remedy is available to Public Citizen to compel FDA to post unredacted CVs online. Mandamus and Venue Act, 28 U.S.C. § 1361. Mandamus relief would be appropriate because Public Citizen has a clear right to relief and FDA has a clear duty to act under FOIA. *See In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005) (discussing the elements of a claim under the Mandamus and Venue Act).

CONCLUSION

For all of these reasons, this Court should grant plaintiff's motion for summary judgment. This Court should order defendants to cease the unlawful policy or practice of redacting non-exempt information from the CVs and order FDA to post on its website the complete, unredacted CVs of advisory committee members on an ongoing basis. This Court should also compel defendants to disclose unredacted copies of the CVs responsive to Public Citizen's 2014 FOIA request.

Respectfully submitted,

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