IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN FOUNDATION, INC., 1600 20th Street NW Washington, DC 20009, Plaintiff, v. FOOD & DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993-0002, and DEPARTMENT OF HEALTH & HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201, Defendants.	)	Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiff Public Citizen Foundation, Inc., brings this action to compel the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) to produce unredacted copies of curricula vitae (CVs) of all FDA advisory committee members posted on FDA's website and to compel FDA to cease its practice of unlawfully withholding information from the CVs of advisory committee members posted on FDA's website. This action arises under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 & 706, and the Mandamus and Venue Act, 28 U.S.C. § 1361.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1361, and 5 U.S.C. § 552(a)(4)(B). Venue is proper under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff Public Citizen is a nonprofit research, litigation, and advocacy organization that represents the public interest before the executive branch, Congress, and the courts. Among other things, Public Citizen fights for openness and democratic accountability in government; for strong health, safety, and environmental protections; for safe, effective, and affordable medicines and health care; and for the right of consumers to seek redress in the courts.

4. Defendant FDA is a component of defendant HHS. Defendants FDA and HHS are agencies of the United States and have possession and control over the records that Plaintiff seeks.

STATUTORY FRAMEWORK

5. Subject to nine specific exemptions, FOIA requires agencies to promptly disclose records responsive to a FOIA request. 5 U.S.C. § 552(a)(3).

6. FOIA also requires agencies to proactively disclose online records 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).

7. The agency must provide an index of the frequently requested records that it makes available to comply with its proactive disclosure obligations. *Id*. § 552(a)(2)(E).

8. When making frequently requested records electronically available, an agency may redact material only by relying on one of FOIA's nine exemptions. 5 U.S.C. § 552(b); *see also* Department of Justice, Office of Information Policy, OIP Guidance, *Proactive Disclosure of*

Non-Exempt Agency Information: Making Information Available Without the Need To File a FOIA Request, https://www.justice.gov/oip/oip-guidance-5 ("Agencies should therefore review documents they intend to proactively disclose just as they review documents for disclosure in response to FOIA requests[.]").

FACTUAL BACKGROUND

FDA's Advisory Committees

9. Advisory committees furnish expert advice to federal government agencies. FDA has approximately 50 advisory committees and panels. *Committees & Meeting Materials*, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm.

10. FDA's advisory committee members give advice to the agency on issues related to FDA-regulated products, such as whether FDA should approve new medical products, request additional studies, or change a product's labeling. *Advisory Committees: Critical to the FDA's Product Review Process*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143538.htm.

11. An advisory committee's recommendations to FDA are not binding, but FDA usually follows them. *See* James G. Dickinson, *FDA and advisory panels mostly on the same page*, Med. Marketing & Media (Jan. 1, 2014), http://www.mmm-online.com/legalregulatory/fda-and-advisory-panels-mostly-on-the-same-page/article/326368/.

12. By law, advisory committees must be "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(b)(2). FDA advisory committee members include academics, physicians, consumers, patients, and industry representatives. *FDA 101: Advisory Committees*, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048040.htm.

13. FDA selects advisory committee members from a pool of nominees. To be considered for selection, nominees must submit a "complete curriculum vitae" to FDA. 21 C.F.R. § 14.82(c); *Applying for Membership*, http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ApplyingforMembership/default.htm. FDA gives applicants no assurances that it will keep their CVs confidential.

14. People create CVs to document their educational background, training, employment history, and career highlights in a format that they can share with other people.

Advisory Committee Members' CVs Posted on FDA's Website

15. FDA posts on its website a roster of the members serving on each advisory committee. *Committees & Meeting Materials*, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm. FDA also frequently posts members' CVs. *See, e.g., Arthritis Advisory Committee Roster*, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/ucm094138.htm (9 out of 10 members' CVs posted).

16. FDA's online Electronic Reading Room is an "index [that] contains categories of frequently requested FDA documents" and links to those documents. *Electronic Reading Room,* http://www.fda.gov/RegulatoryInformation/foi/ElectronicReadingRoom/default.htm; *see also* 21 CFR § 20.26(b) (setting forth FDA's duty to make indexes of certain records, including frequently requested records, available on its website).

17. FDA's Electronic Reading Room contains links to the CVs and other advisory committee meeting materials for all FDA advisory committees. Therefore, FDA has determined that the CVs are "frequently requested records" under 5 U.S.C. § 552(a)(2)(D).

FDA's Practice of Unlawfully Redacting CVs

18. Despite the fact that CVs are by their very nature intended to be shared, FDA redacts information from most of the advisory committee members' CVs that it makes electronically available.

19. By letter dated February 4, 2014, Public Citizen wrote to FDA's Commissioner and Chief Counsel and asked FDA to revise its web pages so that committee members' CVs appear in full and asked FDA to ensure that the CVs the agency posted in the future not contain unjustified redactions.

20. By letter dated July 2, 2014, from Sarah B. Kotler, Deputy Director, Division of Freedom of Information, FDA, 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." The FDA letter stated that FDA's practice is to categorically redact certain information from advisory committee members' CVs including, among other categories, information concerning non-government funded grants, pending clinical trials, pending publications, dates degrees were conferred, medical board and professional association certification numbers, names of graduate or doctoral students supervised, military service, and information related to hobbies and outside activities.

21. Information FDA categorically redacts from advisory committee member CVs does not fall within any FOIA exemption.

22. FDA's practice of unlawfully redacting the CVs of advisory committee members posted on its website is ongoing. Nearly all CVs currently posted on FDA's website contain improper redactions. 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. All of the 16 CVs posted for members of Center for Radiation Emitting Products advisory committees have redactions. FDA has posted unredacted CVs for all members of only one of its advisory committees, the Science Advisory Board to the National Center for Toxicological Research.

23. FDA continues to update its advisory committee websites to post unlawfully redacted CVs. Therefore, Public Citizen and others will continue to be denied timely information about advisory committee members to which Public Citizen is lawfully entitled and that is needed to enable Public Citizen and the public effectively to assess the backgrounds and potential biases of advisory committee members.

Public Citizen's FOIA Request for Advisory Committee Members' CVs

24. Since its founding in 1971, Public Citizen has evaluated the quality and efficacy of FDA-regulated drugs and devices. Public Citizen's advocacy in this area has contributed to 23 drugs being pulled from the market.

25. Public Citizen's health experts frequently testify before FDA advisory committees, including at least 13 times in 2015 alone, and also serve on FDA advisory committees. *See generally HRG Publications*, http://www.citizen.org/hrgpublications.

26. Public Citizen advocates for the proper functioning of FDA advisory committees. For instance, Public Citizen has called attention to conflicts of interests between committee members' activities and their participation on advisory committees, petitioned FDA to include a

staff presentation at certain advisory committee meetings, published data on how advisory committees function, and studied and published articles on financial conflicts of interests for advisory committee members.

27. 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" and requesting a public interest fee waiver. Public Citizen asked that FDA "respond to the request by posting unredacted copies of the CVs online, rather than by sending the CVs to Public Citizen."

28. By letter dated May 27, 2014, FDA acknowledged receipt of Public Citizen's FOIA request.

29. By letter dated June 3, 2014, FDA granted the request for a public interest fee waiver.

30. By letter dated July 11, 2014, the Center for Food Safety and Applied Nutrition (CFSAN), a Center located within FDA, replied to Public Citizen's FOIA request. The letter merely directed Public Citizen to CFSAN's website where CVs are posted. At that time, the posted CVs had redactions that appeared to be the same redactions as in May, when Public Citizen submitted its FOIA request. CFSAN's letter did not state that it was a final decision and did not say how to appeal.

31. By letter dated August 26, 2014, the Center for Tobacco Products (CTP), a Center located within FDA, responded to Public Citizen's FOIA request. CTP stated that it had located 199 pages responsive to the request, but it withheld portions of 82 pages, citing FOIA exemptions 4 and 6.

32. On September 18, 2014, Public Citizen submitted an appeal of the partial denial by CTP and the constructive denial by CFSAN.

33. By letter dated September 19, 2014, HHS acknowledged receipt of the September 18, 2014, appeal.

34. On October 10, 2014, Public Citizen received from CFSAN a compact disc containing CVs.

35. By email dated October 20, 2014, CTP sent Public Citizen revised versions of ten CVs. In an email sent on November 4, 2014, CTP explained that it had "revised the records in light of your appeal" and explained that the revised CVs were not a response to Public Citizen's appeal, to which HHS would respond.

36. Public Citizen responded by email, reiterating that it would like its appeal processed because CTP's supplemental response included records with a number of unlawful redactions.

37. In a March 27, 2015, email, an FDA official sent revised copies of CFSAN's CVs "as they will be posted online." Most of the CFSAN CVs still contained redactions.

38. Furthermore, in some cases, CFSAN released a CV that was an altogether different record than what CFSAN had previously released. For instance, in its October 10, 2014, release, CFSAN sent a 25-page CV for committee member K.B. Wallace, with redactions. In its March 27, 2015, release, CFSAN sent a 14-page CV for K.B. Wallace, which did not indicate redactions but omitted the sections of the originally-sent CV that contained redactions. Similarly, for James Swain, CFSAN originally released a 15-page CV with redactions and then, in March 2015, sent a "revised" 14-page CV that indicated no redactions.

39. By letter dated November 19, 2015, the Center for Biologics Evaluation and Research (CBER), responded to Public Citizen's FOIA request and enclosed a disc containing CVs. All of the released CVs contain redactions purportedly under exemptions 4 or 6.

40. Because it took CBER over 378 business days to produce the CVs, well over half of the individuals whose CVs CBER released are no longer serving on CBER advisory committees.

41. By letter dated December 2, 2015, Public Citizen appealed CBER's response.

42. By letter dated December 7, 2015, HHS acknowledged receipt of the FOIA appeal of CBER's partial denial (although HHS mistakenly referred to it as an appeal of CTP's and CFSAN's responses).

43. FDA has not responded at all to the request with respect to advisory committees formed to advise FDA's Office of the Commissioner and two of its five Centers that have advisory committees—the Center for Drug Evaluation and Research and Center for Devices and Radiological Health—and the online posting of CVs for those committees continue to have redactions. (The National Center for Toxicological Research has not responded, but it has posted online unredacted CVs for all members of the Science Advisory Board.)

44. Under 5 U.S.C. § 552(a)(6)(A)(i), FDA had 20 working days to respond to Public Citizen's FOIA request. More than 480 working days have passed since FDA received Public Citizen's request.

45. Under 5 U.S.C. § 552(a)(6)(A)(ii), HHS had 20 working days to respond to Public Citizen's appeal of CFSAN's, CTP's, and CBER's responses. More than 20 days have passed since HHS received the appeals.

46. Public Citizen has exhausted its administrative remedies with respect to its request.

FIRST CLAIM FOR RELIEF
(FOIA)

47. Plaintiff has a statutory right under FOIA to the entirety of the requested records. Defendants have no legal basis for refusing to produce these records in full.[1]

SECOND CLAIM FOR RELIEF
(FOIA and APA)

48. Public Citizen has a statutory right under FOIA to inspect by electronic means the CVs of advisory committee members because the CVs are frequently requested records under FOIA, as determined by FDA. 5 U.S.C. § 552(a)(2).

49. FDA may withhold information from the CVs it is required to make electronically available under 5 U.S.C. § 552(a)(2) only if FOIA authorizes the withholding under one of its nine exemptions. 5 U.S.C. §§ 552(a)(2), 552(b). FOIA's exemptions do not justify the withholdings FDA makes in the CVs.

50. FDA's policy and practice of redacting non-exempt information from the CVs of advisory committee members that it must make electronically available violates FOIA, 5 U.S.C. § 552(a)(2), and constitutes action that is arbitrary and capricious and not in accordance with law, 5 U.S.C. § 706.

51. Defendants' policy and practice of redacting non-exempt information from the CVs of advisory committee members that it must make electronically available impairs Public

[1] Public Citizen noted one CV on which the redaction appears to be the member's social security number. Public Citizen does not seek disclosure of that number.

Citizen's right to access by electronic means information in CVs about current advisory committee members.

52. Public Citizen has been and will continue to be harmed by Defendant's unlawful policy and practice because FDA continues to withhold non-exempt information from the CVs of advisory committee members posted on its website.

THIRD CLAIM FOR RELIEF
(Claim for mandamus relief)

53. Public Citizen has a statutory right under FOIA to inspect by electronic means the CVs of advisory committee members because the CVs are frequently requested records under FOIA, as determined by FDA. 5 U.S.C. § 552(a)(2).

54. Defendants have a nondiscretionary duty under 5 U.S.C. § 552(a)(2) to make the CVs available for public inspection by electronic means, with redactions only for information that falls within one of FOIA's nine exemptions.

55. FDA's policy and practice of unlawfully redacting non-exempt information from the CVs of advisory committee members that it must make electronically available warrants relief in the nature of mandamus if no other adequate remedy is available to Public Citizen to compel the action required of FDA by law.

56. Public Citizen has been and will continue to be harmed by Defendants' unlawful policy and practice because FDA continues to redact non-exempt information from the CVs of advisory committee members posted on its website.

PRAYER FOR RELIEF

Wherefore, Plaintiff requests that this Court:

A. Declare that Defendants' withholding of the requested records in response to Public Citizen's FOIA request is unlawful under FOIA, 5 U.S.C. § 552(a)(3);

B. Declare that Defendants' policy and practice of redacting non-exempt information from advisory committee members' CVs that Defendants make electronically available is unlawful under 5 U.S.C. § 552(a)(2);

C. Order Defendants to make the records responsive to Plaintiff's FOIA request available to Plaintiff at no charge within 14 days of the Court's order;

D. Set aside Defendants' policy and practice of unlawfully withholding information from the CVs of advisory committee members that it makes electronically available;

E. Order Defendants to make electronically available to the public in their entirety the CVs of all current and future advisory committee members, or issue an order in the nature of mandamus compelling Defendants to carry out their nondiscretionary duty to make the CVs of all current and future advisory committee members electronically available to the public in their entirety;

F. Award Plaintiff its costs and reasonable attorney fees under 5 U.S.C. § 552(a)(4)(E) and the Equal Access to Justice Act, 28 U.S.C. § 2412, as applicable; and

G. Grant all other appropriate relief.

Dated: April 27, 2016

Respectfully submitted,

/s/ Rachel M. Clattenburg

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