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Margaret Hamburg
Officer of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Elizabeth Dickinson
Office of Chief Counsel
Food and Drug Administration
White Oak 32, Room 4532
Silver Spring, MD 20993

Dear Commissioner Hamburg and Chief Counsel Dickinson:

We are writing concerning the redactions on the curricula vitae of advisory committee members that are posted on the FDA's website. A great many of the members' CVs have significant redactions with the notation either (b)(4) or (b)(6), referring to the Freedom of Information Act (FOIA) exemptions from disclosure that protect confidential commercial information and personal privacy. These redactions are unjustified under FOIA, and we ask that you promptly revise the web pages so that CVs appear in full. Further, we ask that you ensure that CVs posted in the future are not redacted in this way.

The extent of the agency's redactions is significant. The agency is redacting information from an overwhelming majority of CVs. Of the 180 CVs posted for members of Center for Drug Evaluation and Research advisory committees as of January 29, 2014, 167 have redactions—93 percent. Similarly, of the 68 CVs posted for members of Center for Biologics Evaluation and Research advisory committees, 64 had redactions—94 percent. Of the 15 posted CVs for the Food Advisory Committee, 12 are redacted—80 percent. Of the 132 CVs posted for committees of the Center for Devices and Radiological Health, 132 had redactions—100 percent. Of the 11 CVs posted for members of the Tobacco Products Scientific Advisory Committee, 10 have redactions.

The redactions appear to be wholly unwarranted by any legitimate need or the FOIA exemptions on which they purportedly are based.

The Exemptions Used

Although some CVs (including all CVs from device-related advisory committees) show redactions with no indication of the basis for them, the majority of the redactions are designated as (b)(4) or (b)(6).

The bulk of the FDA redactions are labeled “(b)(4).” Exemption 4 protects from disclosure “trade secrets or commercial or financial information obtained from a person and privileged or confidential.” 5 U.S.C. § 552(b)(4). Where, as here, the information is provided to the government as a condition of obtaining a government benefit (here, membership in an advisory committee), the exemption does not apply unless disclosure is “likely to cause” the person who submitted it “substantial competitive harm” or likely “to impair the Government’s ability to collect necessary information in the future.” *Critical Mass Energy Project v. Nuclear Regulatory Comm’n*, 975 F.2d 871, 878 (D.C. Cir. 1992). Where information is provided to the government voluntarily, exemption 4 applies only where the information “is of a kind that would customarily not be released to the public by the person from whom it was obtained.” *Critical Mass*, 975 F.2d at 880. The redactions designated (b)(4) easily fail even the less rigorous standard.

Almost by definition, the fact that information is included on a CV disqualifies it from falling within the scope of exemption 4, because information included on a CV cannot conceivably be “trade secret” or “confidential,” even if it were “commercial or financial.” Indeed, it is difficult to conceive of how an academic appointment, presentation, or delivered speech can be considered “confidential,” yet many are redacted with that designation. Some of the redacted information is decades old, making the claim even more tenuous and often simply frivolous.

Notably, in some instances, the same CV that the FDA has redacted to protect “confidential” “commercial or financial” information appears elsewhere online unredacted, such as on the website of the medical school at which a member is on the faculty. The same CVs that the FDA redacted, even some that it redacted significantly, invariably had no redactions at all when we found them elsewhere. Similarly, some members appear on the website LinkedIn, where the descriptions they created for themselves seem to reveal information that the FDA redacted on the ground that the information is “confidential.”

Exemption 6 protects from disclosure information “the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 5 U.S.C. § 552(b)(6). “[T]he test is not merely whether the information is in some sense personal but whether it is ‘of the same magnitude as highly personal or as intimate in nature as that at stake in personnel and medical records.’” *Kurzson v. HHS*, 649 F.2d 65, 68 (1st Cir. 1981) (quoting *Board of Trade of the City of Chicago v. Commodity Futures Trading Comm’n*, 627 F.2d 392, 398 (D.C. Cir. 1980)). “Information relating to business judgments and relationships does not qualify for exemption.... This is so even if disclosure might tarnish someone’s professional reputation.” *Washington Post Co. v. DOJ*, 863 F.2d 96, 101 (D.C. Cir. 1988) (citing *Sims v. CIA*, 642 F.2d 562, 574 (D.C.Cir.1980)).

On its face, the notion that a rational person would include on her CV information that satisfies this standard is hard to fathom. Again, this observation is supported by the CVs we found on other websites and on LinkedIn.

Examples of Typical Redactions

Examples illustrate the problem. We use these examples because unredacted versions of these CVs were available elsewhere online, not to say anything in particular about these individual advisory committee members. The fact that each has posted his or her unredacted CV elsewhere strongly suggests that the FDA is making the redactions on its own initiative. The unredacted versions reveal that the FDA's redactions are random and unwarranted.

For instance, the FDA redacted portions of the CV of Yu Shyr, a member of the Anti-Infective Drugs Advisory Committee, including entries under "Teaching, Workshops, and Seminars."¹ This member's CV is also posted on the website of Vanderbilt Medical School.² Comparison of the two shows that the FDA made so-called (b)(4) redactions for information about seminars and papers such as

"The Challenges of the High-Density Biomarker Adaptive Trials," seminar given at Adaptive Designs in Clinical Drug Development, London, England, 2012.

"Statistical Bioinformatics Challenges for Clinical Trial Design in the Era of High-Density Data Analysis," seminar given at AACR Annual Meeting, Chicago, IL, 2012.

Hansen AG, Freeman T, Washington MK, Fan K, Shyr Y, Beauchamp RD, Zijlstra A. Elevated alcam shedding in colorectal cancer correlates with poor patient outcome. Abstract presented at: Markers in Cancer: A Joint Meeting by ASCO, EORTC, and NCI, Hollywood, FL, October 11-13, 2012.

The (b)(6) redactions cover information including the name of a co-editor on the Journal of Concrete and Applicable Mathematics, and this item under "Academic Service": "1998 Chinese Youth Goodwill Mission from Taiwan: Co-sponsor, 1998." Other (b)(6) redactions include the fact that Dr. Shyr gave a presentation in 2005 "With Dr. Don Hong" and participation in this event: "47th Anniversary Annual Conference, The American Associate for Chinese Studies: Chair and local organizing committee: Member, Nashville, TN, 2005." In addition, the (b)(6) redactions include all content under "Mentoring," which is publicly available in full through his bio page on the Vanderbilt website.

¹ The CV is posted on the FDA's website here: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM326163.pdf>.

² The CV is available through a link from Dr. Shyr's page on the Vanderbilt website: <https://medschool.vanderbilt.edu/cqs/people/Yu/Shyr/cqs-faculty-members>.

The CV of Amanda Corbett, a member of the Antiviral Drugs Advisory Committee, is also available in full online.³ On the FDA website, her CV has extensive (b)(4) redactions in several categories.⁴ On her list of 19 funded grants, the FDA has blacked out 9, including:

Corbett A, Principal Investigator. Pharmacokinetics of Lopinavir/ritonavir in Breast milk and Breastfeeding Infants. Abbott Laboratories. October 2008 - December 2009. \$31,000.

Corbett A, Principal Investigator. Characterization of novel antiretroviral resistance among HIV-infected patients in the UNC-CH cohort. Virco Laboratories. May 2008 - December 2009. \$15,000.

Kashuba, ADM, Principal Investigator, Corbett A, Co-Investigator. Eron J, Co-Investigator. The Pharmacokinetic Interaction of a Triple Protease Inhibitor Regimen Containing Fosamprenavir, Lopinavir and Ritonavir in Healthy Volunteers. GlaxoSmithKline (Investigator Initiated Research), 2002 - 2003. \$59,000.

Kashuba ADM, Principal Investigator, Corbett A, Co-Investigator. Ortho-McNeil Infectious Diseases Academic Fellowship. American College of Clinical Pharmacy. 2002 – 2003. \$20,000.

The FDA has also redacted all 4 items on her list of “Grants and Contracts Submitted (not funded),” 17 of 18 “Research Initiatives,” and 4 of her 22 “Manuscripts and Reviews.” Not one of these redactions appears to be covered by exemption 4—even putting aside the immediately disqualifying fact that the CV is available in full online. In the latter category, all 4 redacted items are articles that have been published, such as:

Brown K, Hosseinipour M, Hoskins J, Tien H, Kazembe P, McLeod H, Kashuba A, Corbett A. Genotype correlation in nevirapine exposures in Malawians. *Pharmacogenomics* 2012;13(1):113-121.

One is even available electronically on a government website, PubMed.gov⁵:

Heil E, Corbett A. Guidelines for the use of extended-release nevirapine in HIV-infected patients. *Expert Opin pharmacother* 2011; epub ahead of print.

Yet the FDA has blacked it out, with a designation indicating that it is “confidential” and “commercial” information.

³ The CV is posted here: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCwQFjAA&url=https%3A%2F%2Fpharmacy.unc.edu%2FDirectory%2Fahcorbet%2Fcurriculum-vitae%2Fat_download%2Fcv&ei=cRlwUs3zMqOEyAGV7YDgDg&usg=AFQjCNG0piJWbNW9PnuPHicUEa2MsL7RPw&sig2=toM00bI.

⁴ The CV is posted on the FDA’s website here: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/200bDrugs/200bAntiviralDrugsAdvisoryCommittee/UCM310262.pdf>.

⁵ <http://www.ncbi.nlm.nih.gov/pubmed/22035406>.

Among the silly (b)(6) “privacy” redactions” are the number of her North Carolina pharmacy license (available online both through her unredacted CV and through the North Carolina Board of pharmacy),⁶ the fact of her Reiki training, and the names of the directors of the university programs through which she got her pharmacy education and training in 1999-2001.

The CV of Jennifer Kuzma, a member of CBER’s Blood Products Advisory Committee, similarly illustrates that the FDA’s redactions are unjustified by (b)(4) and (b)(6).^{7 8} The FDA redacted with the (b)(4) notation every one of her “Manuscripts in Preparation,” although the CV posted on her university’s website includes the full information. The FDA redacted as (b)(4) and/or (b)(6) a great deal of information about her recent grant support, although she posts it in full on her university’s website. The FDA redacted as (b)(6) the names of her student advisees and research assistants, including in one instance the name of a prize awarded to one of her advisees, and the names of her mentors in the early to mid-1990s, when she was a research fellow and a PhD candidate. Not only is this information included in the CV on her university’s website, it plainly presents no legitimate invasion-of-privacy concern.

Finally, the FDA posting of the CV of Maria Luz Fernandez, a member of the Food Advisory Committee, redacts (with no exemption indicated) her 6 most recent publications.⁹ Not surprisingly, the CV as posted on her university’s website shows all of her publications.¹⁰

Again, the Shyr, Corbett, Kuzma, and Fernandez CV redactions are illustrative of the problem, but the redactions on their CVs appear to be no different in kind from those on the many other redacted CVs on the FDA’s website. We could have chosen any number of other member CVs to make the point.

Conclusions

The very notion that a CV would include confidential commercial or financial information or information the disclosure of which a person would consider to violate his personal privacy is at odds with the very nature of a CV. The CV is written by a person for the purpose of touting her education and accomplishments to other people. The person chooses what information to include and how to state it. If the person thought that a piece of information was too private to make public or that its private nature outweighed its value on the CV, she would not include in the first place. Similarly, the fact that a piece of information is on a CV belies the notion that the information is “confidential.” Confidential information does not appear on documents crafted for the express purpose of sharing with other people.

⁶ http://www.ncbop.org/ncbop_verification.htm.

⁷ The unredacted CV on the website of the University of Minnesota is available from a link on this page: <http://www.hhh.umn.edu/people/jkuzma/>.

⁸ The CV is posted on the FDA’s website here: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM277892.pdf>.

⁹ <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm226096.htm>.

¹⁰ <http://www.canr.uconn.edu/nutsci/nutsci/hpg/mluz.html>.

The CV redactions are troubling for several reasons. First, they appear to be completely unjustified by the FOIA exemptions on which they are purportedly based and, for that reason, suggest a lack of training within the agency as to the scope of FOIA exemptions.

For example, citing “(b)(6),” the FDA has broadly redacted the names of co-investigators, mentors, trainees, and even co-authors. Exemption 6, however, does not provide a general protection from disclosure for names of individuals within a document in the government’s possession; it protects such disclosure only when revealing a name would constitute a “clearly unwarranted invasion of personal privacy.” “[I]nformation connected with professional relationships does not qualify for the exemption.” *Sims v. CIA*, 642 F.2d at 574; *id.* at 575 (“[E]xemption 6 was developed to protect intimate details of personal and family life, not business judgments and relationships.”). Similarly, the FDA has often redacted the year in which a member graduated from college or graduate school. Such information on its face does not seem “private,” but even beyond that, disclosure of the characteristics of people chosen by the FDA to serve on advisory committee sheds light on the FDA decision making, and thus serves a public interest that would seem easily to outweigh any privacy interest.¹¹

Likewise, information about professional training, experience, and publications does not fall within the scope of exemption 6. “Exemption 6 was developed to protect details of personal and family life, not information regarding professional activities.” *Camaranesi v. DOJ*, 941 F. Supp. 2d 1173, 1185 (N.D. Cal. 2013).

The FDA specifies “(b)(4)” for a range of redactions including the titles of presentations and publications, and information about research grants, both funded and unfunded. Even putting aside the problem that very little of the information would qualify as “commercial or financial,” unless the presentations were made under a cone of silence and the publications printed in secret journals (possibilities excluded by the fact that the publicly available, unredacted CVs provide citations), the information could not possibly be considered confidential. On the whole, the many (b)(4) redactions appear to be without method or pattern, making it difficult even to say what erroneous rationale was guiding the agency when it redacted the CVs.

Indeed, a great many CVs are redacted with *no* indication of why. The CVs of members of device advisory committees offers 132 examples of this practice. Further, the information redacted in these examples is hard to reconcile with any FOIA exemption. For instance, on almost all the device-committee CVs, the dates of educational degrees are redacted, and often the dates of professional training and internships. Professionals include such information on CVs because it is not private and is relevant to the assessment of professional experience. We cannot help but wonder whether the failure to indicate a FOIA exemption for such redactions reflects a recognition that none applies.

Second, we are concerned that the redactions reflect an agency view that favors secrecy over disclosure. FOIA is a pro-disclosure statute. Its exemptions, as the courts have long recognized, are to be narrowly construed. *Milner v. U.S. Dep’t of Navy*, 131 S. Ct. 1259, 1262

¹¹ One advisory committee member included his social security number on his CV, and the FDA redacted the number. This redaction seems to be a unique instance of the FDA identifying information that the member should have kept private and redacting it for the member’s own good.

(2011). “[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act.” *Dep’t of Air Force v. Rose*, 425 U.S. 352, 361 (1976). We are concerned that the CV redactions evidence a general policy that flips the FOIA presumption of disclosure, by favoring non-disclosure over disclosure.

Third, because the redaction of advisory committee member CVs is unjustified by FOIA, the FDA staff has wasted considerable time identifying lines to black out among long lists of academic credentials, presentations, and appointments on hundreds of CVs. Now, more time will be required to unredact the CVs—which should be done promptly. The decision to spend time on the unwarranted review and redaction of CVs, when the FDA’s backlog of FOIA requests is considerable, shows a poor use of resources that likely harmed FOIA requesters waiting months and sometimes years for responses to requests.

Fourth, the redactions deny the public an easy way to learn complete information about the qualifications and background of advisory committee members. Although the public may be able to find full CVs elsewhere for some members, the public should not have to search for complete information when the agency lacks justification for redacting it.

Accordingly, we request that you correct the situation by promptly unredacting the CVs. In addition, we urge that staff responsible for redacting the CVs be (re)trained on the proper approach to FOIA and that overall FDA FOIA training be evaluated to ensure that staff understand the purpose of the statute and the narrow scope of the exemptions.

Please do not hesitate to contact me if I can answer any questions. Thank you for your prompt attention to this matter.

Sincerely,



Sidney M. Wolfe, MD
Founder and Senior Advisor
Public Citizen Health Research Group



Allison M. Zieve
Director
Public Citizen Litigation Group