

Exposing Corruption *Exploring Solutions*
Project On **Government Oversight**

September 14, 2011

By email to nihfoia@mail.nih.gov

Freedom of Information Act Request

Susan R. Cornell
Freedom of Information Officer and Chief FOIA Liaison
Office of Communications and Public Liaison
Building 31, Room 5B35
National Institutes of Health
Bethesda, MD 20892

Dear Ms. Cornell:

I am making this request under the Freedom Of Information Act (“FOIA”),
5 U.S.C. § 552.

The documents I seek are related to Final Rule RIN 0925-AA53 published in the Federal Register on August 25, 2011. The designated agency for this Final Rule is the Department of Health and Human Services (DHHS), and the subagency is the National Institutes of Health (NIH).

Specifically, I request documents exchanged between the Office of Information and Regulatory Affairs (OIRA) and the NIH during the time period starting January 20, 2009, and ending on September 9, 2011 – namely, all such documents, including emails, related to OIRA’s and the NIH’s review culminating in Final Rule RIN 0925-AA53. Please note that this time period extends beyond August 25, 2011, when the Final Rule was published in the Federal Register.

- o Among the documents requested are intermediate versions that were prepared between the publication of the Notice of Proposed Rulemaking (NPRM) on May 21, 2010, and the publication of the Final Rule on August 25, 2011.
- o If there are “red-line” versions in which possible changes are marked, these documents, too, should be provided in response to my request.

My FOIA request includes documents covered by Executive Order 12866 of September 30, 1993 (“Regulatory Planning and Review”). Specifically, the NIH must provide the public with certain information identified in Section 6(a)(3)(E) of this Executive Order:

After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

- (i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);
- (ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and
- (iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

Certain points in this Executive Order are worth noting:

- o The NIH is required to make this information public. The NIH does not have the option of dealing with these documents as if they were inter-agency or intra-agency memoranda or letters shielded by concerns over privacy or confidentiality.
- o In part ii above, the phrase “draft submitted to OIRA for review” clearly applies to all drafts submitted by NIH to OIRA or provided to NIH by OIRA after the publication of the NPRM. The phrase does not apply to the NPRM itself, since the NPRM is a final document, not a draft.
- o The NIH is required to identify the particular changes made at the suggestion or recommendation of OIRA. It is essential that this particular requirement of the Executive Order be observed in your response to my FOIA request.

Redaction

The documents I have requested under FOIA should be provided to me without redaction.

You are doubtless aware of the following statement in *Department of Justice Guide to the Freedom of Information Act*:

When administering the FOIA, it is important to first note that the President and Attorney General have issued memoranda to all agencies emphasizing that the FOIA reflects a "profound national commitment to ensuring an open Government" and directing agencies to "adopt a presumption in favor of disclosure.

I therefore ask that the documents I have requested under FOIA be provided to me in unredacted form.

I request a waiver of all costs associated with fulfilling this submission pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). Disclosure of the requested records will contribute significantly to the public’s understanding of the operations or activities of the

government and would not be primarily in the commercial interest of POGO. Specifically, POGO intends to use the requested records to highlight the FDA's responsibility to ensure compliance with 21 CFR Part 58. POGO will use the records to contribute to the public's understanding of government operations and activities.

Founded in 1981, POGO is a politically independent, nonprofit watchdog organization that promotes a government accountable to the citizenry. POGO disseminates information about its activities to thousands of concerned citizens, policymakers, and the media via email, direct mail, and its web site <http://www.pogo.org>, which receives over 500,000 hits monthly. The records provided by your agency will be used for the following activities: publication by email and on our website; publication in reports and newsletters issued by POGO; publication in the newsletters of affiliated nonprofit organizations; efforts to educate Congress, the Executive Branch, and other policymakers in Washington, DC; or investigational projects conducted in conjunction with the news media

If this request is denied in full or in part, please cite each exemption pursuant to 5 U.S.C. § 552(b) that justifies each denial. If an exemption applies, however, please consider exercising the agency's discretionary release powers to disclose the records. Any such action supports the presumption of "openness" on which FOIA is based upon. Additionally, please release all reasonably segregable portions of the records that do not meet an exemption. 5 U.S.C. § 552(b).

I look forward to your response, including an individualized tracking number, within 20 days of the receipt of this request, unless, in the case of "unusual circumstances," the time limitation is "extended by written notice." 5 U.S.C. § 552(a)(6)(B). I am aware that all fees will be waived if specified time limits are not met. 5 U.S.C. § 552(a)(4)(A)(viii). I have a right to appeal if this request is wholly or partially denied or if the agency fails to respond within 20 days, and that, if successful, a federal district court may assess "reasonable attorney fees and other litigation costs." 5 U.S.C. § 552(a)(4)(E).

Please contact me if this request requires further clarification. Thank you for your prompt attention to this matter.

Sincerely,



Ned Feder, M.D.

Staff Scientist

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