PROJECT ON GOVERNMENT OVERSIGHT
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March 26, 2012
As email attachment to: president@whitehouse.gov
By fax to: 202-456-2461*

President Barack Obama
The White House
Washington, DC

Subject: OMB and OIRA: Noncompliance with Executive Order

Dear President Obama:

We are writing about the failure by senior government officials to comply with an Executive Order that requires transparency in certain operations of the Office of Management and Budget (OMB) and the Office of Information and Regulatory Affairs (OIRA). The requirements for transparency, though spelled out clearly in the Executive Order, appear to have been systematically ignored, thus hiding the influence of competing interests on new regulations that affect the public health and welfare.

The Project On Government Oversight (POGO), a nonprofit, nonpartisan organization, is concerned that the lack of transparency sometimes favors special interests over the public interest.

Summary

Executive Order 12866, signed by President Clinton on September 30, 1993, contains explicit requirements for the full public disclosure of the roles of OIRA and the rulemaking agency in the creation of new regulations.[1] In the present letter we discuss a particular rulemaking agency, the Department of Health and Human Services (HHS), and an entity within HHS, the National Institutes of Health (NIH).

* This letter will be posted on the POGO website at http://pogoarchives.org/m/ph/pogo-to-obama-oira-20120326.pdf

[1] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993. http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo12866_10041993.pdf (Downloaded March 22, 2012)

Executive Order 13563, which you signed on January 18, 2011, "reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993." [2]

Mr. Jacob Lew, Mr. Cass Sunstein, and Dr. Francis Collins (and perhaps also Ms. Kathleen Sebelius and Mr. Jeffrey Zeints) failed to comply with the requirements for public disclosure spelled out in the 1993 Order and reaffirmed in your 2011 Order.[3]

Transparency requirements of the Executive Order

Two provisions of Executive Order 12866 are of particular interest. These provisions require that the roles of OIRA and the rulemaking agency in the creation of a new rule (new regulation) *must be made public* when the new rule is published – specifically, that the roles of OIRA and the rulemaking agency must be disclosed to the public in a "complete, clear and simple manner." Moreover, those parts of the Final Rule that were introduced or changed "at the suggestion or recommendation of OIRA" must be identified for the public.

The transparency requirements are spelled out in Section 6 of the 1993 Executive Order. Excerpts are printed below.

From Section 6(b)(4)(D), which applies to OIRA:

> After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

From Section 6(a)(3)(E), which applies to the rulemaking agency:

> 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.

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[2] Executive Order 12563, "Improving Regulation and Regulatory Review," 76 *Federal Register* 3821, Jan. 21, 2011.http://www.gpo.gov/fdsys/pkg/DCPD-201100031/pdf/DCPD-201100031.pdf (Downloaded March 22, 2012)

[3] Jacob Lew was the Director of OMB during the period covered by the present letter. He became the White House Chief of Staff on Jan. 27, 2012. Cass Sunstein is the Administrator of OIRA. Francis Collins is the Director of NIH. Kathleen Sebelius is the Secretary of Health and Human Services. Jeffrey Zeints is the Deputy Director of OMB.

The passages above use the term "review" without qualification. Executive Order 12866 does not distinguish between "informal review" and "formal review" – a point to which we will return.

Redefinition of "all" and other reinterpretations of the text of E.O. 12866

The sweep of the required disclosures is striking – particularly the requirement that *all* the documents that are exchanged between OIRA and the agency must be disclosed. However, the leaders of OMB and OIRA evidently decided long ago that "all" means "some" or "none."

OMB and OIRA have applied the same kind of thinking to the term "review" – the word chosen by President Clinton and his advisors when they wrote E.O. 12866. They presumably chose the term carefully. They could have elected to use the phrase "formal review, but not informal review." However, they did not.[4]

OIRA's noncompliance with the transparency requirements of E.O. 12866 was criticized soon after the Executive Order was issued.[5] However, OIRA Administrators have successfully defended their position – which is to say that they've had their way. Because of their success, they've evidently seen no need to replace the troublesome terms we have just identified. The three Administrators of OIRA from 1993 to the present evidently didn't ask their respective presidents to rewrite this part of the Executive Order. Thus the term "all documents" still stands in the Executive Order, as does the term "review," without qualification as informal or formal.

Although the language of E.O. 12866 is clear, all three OIRA Administrators have failed to comply with its terms. In a letter of September 2, 2003, OIRA Administrator John Graham

[4] The idea that OIRA would use only a single review process, rather than one split into informal review and formal review, is supported by a government document on the history of OMB during the Clinton administration. The document has a 2-page section entitled, "Regulatory Oversight and Executive Order 12866," which describes the background and objectives of E.O. 12866, including its theme of openness and accountability. This section of the history uses the term "review" ten times, but neither this section nor the rest of the 112-page history makes a single mention of "informal review." The document (*A History of the U.S. Office of Management and Budget During the Clinton Administration, 1993-2001*) was prepared for the Clinton Administration History Project on the directive of White House Chief of Staff John Podesta. http://www.clintonlibrary.gov/assets/storage/Research - Digital Library/ClintonAdminHistoryProject/41-50/Box 44/1504319-office-of-management-budget-official-history-1993-2001.pdf (Downloaded March 22, 2012)

[5] In a series of articles in the summer of 1986, *Washington Pos*t reporter Judith Havemann described a bipartisan congressional attempt to force OMB to disclose additional documents and more information by threatening to cut its funding. On July 31 she wrote that Senator David Durenberger (R-MN) and Senator Carl Levin (D-MI) had worked out a "sunshine agreement" in which OMB promised to reveal how it influences the outcome of rules. But Havemann added: "Within days after announcement of the agreement, however, a hitch developed. The OMB failed to implement the sunshine rules and Durenberger and Levin wrote Miller [the OMB Director] accusing him of reneging on the deal." To download Havemann's articles, which are pay for view, go to the *Post*'s Archives and search on the reporter's name from May 20 to August 20 of 1986.

explained his position in response to a draft GAO report.[6] According the the GAO report, Dr. Graham referred to "the 'longstanding practice' of limiting the disclosure of documents exchanged during the review process to only documents that were exchanged at the OIRA branch chief level and above." The GAO then notes that most exchanges of documents occurred below the branch chief level. Therefore, wrote the GAO in its report, "only requiring disclosure of documents exchanged at a level at which they rarely are exchanged seems inconsistent with the spirit of transparency."

The GAO also objected to the short time period chosen by OIRA to be covered by the transparency requirements. The GAO found that "formal OIRA review periods can be as short as 1 day, but informal review periods can go on for weeks or even months in advance of formal reviews. Therefore, restricting the transparency requirements in Executive Order 12866 to only a brief period of formal review seems antithetical to the intent of those requirements."

Dr. Graham also wrote: "GAO's draft report recommends that OMB disclose changes that the rulemaking agencies make to their draft rules during OIRA's 'informal' review of a draft rule. Such disclosures are not required by statute and have not been required by E.O. 12866 or its predecessor, Executive Order No. 12291 (E.O. 12291)." Dr. Graham then defends his position by citing court rulings as well as precedents in the Freedom of Information Act that preclude disclosure of certain information held by the government. He does not comment, however, on the plain English language meaning of the statement, "OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section" in E.O. 12866.

Soon after the publication of the 2003 GAO report, Senators Joe Lieberman (D-CT) and Richard Durbin (D-IL) wrote Dr. Graham:[7]

> GAO found that OIRA's current regulatory review practices circumvent the transparency that the Executive Order is intended to achieve . . . . Do you agree that the intent of Executive Order 12866 was to provide for the public an understanding of changes to agencies' rules during OIRA's review and at OIRA's suggestion? How can you justify a policy that allows changes to be made behind closed doors and out of public view, which is what occurs during the informal review process?

But OIRA held its ground. In a follow-up report in April 2009, the GAO noted that OIRA had failed to implement seven of the eight recommendations that GAO had made in its 2003 report as

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[6] *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929. Sept. 2003. http://www.gao.gov/new.items/d03929.pdf (Downloaded March 22, 2012)

The views expressed by Dr. Graham in his September 2, 2003, letter are consistent with those stated in his memorandum of October 18, 2001, "OIRA Disclosure Memo-B." In this memo, Dr. Graham defined the OIRA disclosure procedures. Under the subtitle "E.O. 12866 OIRA Disclosure Procedures," he cited Section 6(b)(4) and stated that, upon request by the public, OIRA makes *certain* materials available after the publication of a rule that has been reviewed. Nowhere in his memo to his OIRA subordinates does Dr. Graham refer to or quote or paraphrase the sentence containing the phrase "all documents."

[7] Senate Committee on Homeland Security and Governmental Affairs. Press release. *Lieberman, Durbin Press OIRA On Openness, Accountability.* Nov. 7, 2003. http://www.hsgac.senate.gov/media/majority-media/lieberman-durbin-press-oira-on-openness-accountability (Downloaded March 22, 2012)

a way for OMB and OIRA to comply with the transparency requirements of E.O. 12866.[8] In particular, OIRA continued in 2009 to withhold documents created during what OIRA considered to be informal review. Since 2009 there has been no announced change in this policy.

In a hearing of the House Subcommittee on Oversight and Investigations last June, the chair, Representative Cliff Stearns (R-FL), and committee member Diana DeGette (D-CO) questioned Mr. Sunstein, the Administrator of OIRA, about the transparency requirement, quoting some of the same passages in E.O. 12866 that we printed at the beginning of the present letter. From the comments of Representative Stearns, Representative DeGette, and Mr. Sunstein (pages 32-34), it appears that OIRA still regards most of the exchanges between the rulemaking agencies and OIRA as "informal" and considers that these informal exchanges are not covered by the transparency requirements of E.O. 12866.

Members of Congress seem to have grudgingly accepted the idea of informal review by OIRA as being outside the actual review process. Because OIRA has followed its narrowed definition of the review process for almost twenty years with occasional complaints from Congress but without serious congressional challenge, OIRA has acquired "squatters rights" over its prerogative to disclose documents or not – a license to continue ignoring the transparency requirements of E.O. 12866, just because it's been ignoring them successfully for so long.

OIRA makes no secret of its narrow interpretation of the transparency requirements. A current Q&A on OIRA's website has the question "What are OIRA's disclosure requirements?"[9] According to the Q&A, after a rule is published, OIRA will "make publicly available certain documents" – rather than all documents – exchanged between OIRA and the rulemaking agency. This narrow interpretation is also apparent from the contents of many other documents on the OMB and OIRA websites.[10] Furthermore, on direct questioning Mr. Sunstein sidestepped the

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[8] *Federal Rulemaking. Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews.* GAO-09-205. April 2009. http://www.gao.gov/new.items/d09205.pdf (Downloaded March 22, 2012)

[9] *Office of Information and Regulatory Affairs (OIRA) Q&A's.* Nov. 2009. http://www.whitehouse.gov/omb/OIRA_QsandAs (Downloaded March 22, 2012)

[10] On a search of the hundreds of documents, including OIRA documents, posted on the OMB website, we found the phrase "all documents" nowhere except in the actual text of E.O. 12866 and in a summary of the history of the Clinton administration's issuance of E.O. 12866. (The latter document, Chapter I, The Role of Economic Analysis in Regulatory Reform, with a subsection 2d entitled "The Clinton Review Program, is posted at http://www.whitehouse.gov/omb/inforeg_chap1, downloaded March 22, 2012.) The original idea has vanished from the OMB and OIRA websites – the idea that OIRA should actually disclose publicly "all documents exchanged between OIRA and the agency" during the review by OIRA.

Similarly, the OMB website has a section entitled *OIRA – For Agencies*, (posted at http://www.whitehouse.gov/omb/inforeg_regpol_agency_review, downloaded March 22, 2012) with links to 28 documents, mostly PDFs of memoranda and announcements with instructions for rulemaking agencies. In not one of these documents does OIRA remind the agencies about the relevant requirements of E.O. 12866, namely, the requirement that the agency "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 also the requirement that the agency "Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA."

issue of the transparency requirements after he was nominated but not yet confirmed as Administrator of OIRA.[11]

Since the issuance of E.O. 12866 in 1993, OIRA's redefinition of "all" and its narrowed interpretation of "review" has allowed OIRA and the rulemaking agencies to withhold many if not most of the documents whose public disclosure is required by the language of E.O. 12866.

Members of Congress are not alone in seeking fuller public disclosure of the exchanges between OIRA and the rulemaking agency at all stages of review. Among the organizations arguing that the lack of disclosure is harmful to the public interest, there are a few that go further. These organizations, which include POGO, argue that the consistent lack of disclosure is not only undesirable and harmful but illegitimate, that the lack of disclosure is an actual violation of the requirements of E.O. 12866. The Center for Progressive Reform (CPR) made this point in a report, "Behind Closed Doors at the White House: How Politics Trumps Protection of Public Health, Worker Safety, and the Environment."[12] In its report CPR analyzes compelling evidence that OIRA and the rulemaking agencies are violating the disclosure requirements of E.O. 12866. CPR concludes that OIRA has "routinely flouted" these requirements and that the "most important consequences of these secretive practices is the nondisclosure of communications between OIRA and the agencies, which makes it impossible for the public to undertake a systematic, rule-by-rule analysis of the impact of OIRA review." See also other discussions by CPR and OMB Watch.[13]

Many rulemaking agencies are even less forthcoming than OIRA in explaining their noncompliance with the transparency requirements of E.O. 12866. If the NIH has provided a public explanation for the particular noncompliance we describe next, we have been unable to find it.

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[11] A written comment addressed to Mr. Sunstein by members of a U.S. Senate committee (posted at http://www.ombwatch.org/files/regs/PDFs/Sunstein_questions.pdf, downloaded March 22, March 22, 2012) noted that Executive Order 12866 requires agencies to "identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA," and then followed with the question: "Do you believe that agencies should be required to disclose all of the changes that were made at OIRA's recommendation, even those during informal review?" In reply Mr. Sunstein wrote : "A balance must be achieved between protecting the deliberative process and ensuring transparency. I would look forward to a careful investigation, with Congress and the Director, of how that balance is best achieved." Mr. Sunstein gave a similar noncommittal answer when asked if he would disclose written communications between OIRA and the issuing agency regarding regulations.

[12] The 92-page report, with title listed above, was authored by Rena Steinzor, Michael Patoka, and James Goodwin and posted in November 2011. http://www.progressivereform.org/articles/OIRA_Meetings_1111.pdf

[13] (a) *The Goose, the Gander, and an OIRA Checklist*, by James Goodwin. Center for Progressive Reform. Nov. 11, 2010. http://www.progressivereform.org/CPRBlog.cfm?idBlog=378397B7-D465-EDF3-8A62B3F65473CD0E (Downloaded March 22, 2012)

(b) *Eye on OIRA: Regulation Goes Opaque*, by Rena Steinzor. Center for Progressive Reform. June 22, 2010. http://www.progressivereform.org/CPRBlog.cfm?idBlog=5C7955F2-A0D9-B017-5A5D963250256AAF (Downloaded March 22, 2012)

(c) *The Obama Approach to Public Protection: The Regulatory Process.* OMB Watch. Jan. 2011. http://www.ombwatch.org/files/regs/obamamidtermregprocessreport.pdf (Downloaded March 22, 2012) and http://www.ombwatch.org/obamamidtermregprocessreport (Downloaded March 22, 2012)

An example: A recent failure to comply with transparency requirements of E.O. 12866

We now describe a failure to comply with the transparency requirements of the Executive Order in relation to a particular Final Rule, RIN 0925-AA53, published in the Federal Register on August 25, 2011.[14] This Final Rule applies to researchers – most of whom are physicians and scientists – whose institutions receive funding from the NIH. The requirements imposed by the Final Rule deal with possible financial conflicts of interest among the researchers. The Final Rule contains a requirement for public disclosure of these possible conflicts of interest. But when this Final Rule applying to the NIH was published, the requirement for disclosure was not as strong as it seemed it would be at an earlier stage of the rulemaking. Something both unexpected and unexplained happened inside OIRA and the NIH before the Final Rule was finished and published.

Furthermore, the disclosure requirements of the Final Rule were and still are controversial. This makes it particularly important for officials at OIRA and NIH to disclose the respective roles of their agencies during the period when government officials were discussing and drafting the Final Rule. In an Appendix to this letter we describe this controversy in greater detail.

The publication, on August 25, 2011, of the Final Rule affecting NIH-funded researchers was not in compliance with the transparency requirements of the Executive Order. Specifically:

- o Publication of the Final Rule on this date was not accompanied by the public disclosure of all relevant documents exchanged between the agencies, namely, the documents explaining the roles of OIRA and NIH in preparing the Final Rule,
- o Nor have these documents been disclosed since then, as far as we know,
- o Nor have we been able to obtain the documents through a Freedom of Information Act (FOIA) request, as we discuss next.

Unsuccessful FOIA requests

On September 13 and 14, 2011, the Project On Government Oversight filed FOIA requests for the documents related to the Final Rule, RIN 0925-AA53, published on August 25, 2011. Separate requests were filed with the NIH FOIA office and the OMB FOIA office.[15] Each request noted that the public release of the documents being requested under FOIA was required by the 1993 Executive Order. Each request quoted the relevant passages in this Executive Order – the same passages that we quote on a previous page of the present letter.

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[14] *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.* Final rule. RIN 0925-AA53. Department of Health and Human Services. 76 *Federal Register* 53256, Aug. 25, 2011. http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf. (Downloaded March 22, 2012)

[15] The three FOIA requests are posted on the POGO website as follows: (a) To Dionne Hardy, FOIA Officer, OMB, from Ned Feder, POGO. Sept. 13, 2011. http://pogoarchives.org/m/ph/request-omb-1-feder-pogo-20110913.pdf (Downloaded March 22, 2012). (b) To Dionne Hardy, FOIA Officer, OMB, from Ned Feder, POGO. Sept. 14, 2011. http://pogoarchives.org/m/ph/request-omb-2-feder-pogo-20110914.pdf (Downloaded March 22, 2012). (c) To Susan R. Cornell, FOIA Officer, NIH, from Ned Feder, POGO. Sept. 14, 2011. http://pogoarchives.org/m/ph/request-nih-feder-pogo-20110914.pdf (Downloaded March 22, 2012).

After filing the FOIA requests, we made many inquiries by email and phone on the status of the requests. The FOIA officials replied politely, but they did not let us know when we might expect to receive the documents responsive to the requests. We have not yet received any of these documents.

In our latest emails (sent to the FOIA offices on February 8) we asked if we would receive a completed response to our FOIA requests before December 31, 2012. We have not received a reply to this question.

Other criticisms of the Executive Order

Executive Order 12866 has been a constant target of other kinds of criticism – criticism not directly related to the transparency requirements. The Executive Order enables the president to exert substantial control over rulemaking by the agencies – control that began to intensify during the Reagan administration (in E.O. 12291), was reinforced and extended in 1993 by E.O. 12866, and more recently, in the current administration, reaffirmed by E.O. 13563. The controversy continues to the present day, between those who favor centralized presidential regulatory control and those who favor rulemaking conducted mainly in the agencies, with a minimum of presidential involvement.

In the present letter, POGO is not choosing sides in this controversy, which has received far more attention than the issue of the transparency requirements. Instead we are focusing on the latter issue alone. We believe, however, that regardless of disputes over presidential control of rulemaking, it is essential that the review process by which regulations are enacted be as transparent as possible, as required by E.O. 12866.

Final comment

The violation of E.O. 12866 is no small matter. The goal of the transparency requirements is clear. The goal is primarily – almost solely – to ensure that important steps in the rulemaking process are not concealed from the public. If OIRA operates away from public scrutiny and challenge, its officials can more easily favor special interests over the public interest. Conversely, compliance with the Executive Order is a good way to help allay concerns that pressure on OMB, OIRA, or the rulemaking agency led to a Final Rule favoring special interests over the public interest.

Although we have focused here on research funding by NIH and on a single example of noncompliance with the transparency requirements of the Executive Order, we are of course writing with a broader objective in mind. We seek a decision on your part to enforce compliance with the transparency requirements of the Executive Order in future rulemaking within the entire federal government. We note again that your own E.O. 13563 reaffirms the principles established by E.O. 12866.

For many years there has been no incentive for the top officials of OMB and OIRA to comply with the transparency requirements of E.O. 12866 and no penalty for failure to comply. Similarly, there has been no incentive or penalty for officials in the rulemaking agencies. On the contrary, all these officials – those at OMB, OIRA, and the agencies – have a strong incentive to violate the transparency requirements of E.O. 12866. Each violation saves time and trouble for these officials and helps them avoid justifying decisions that might prove hard to justify to the Congress and the public.

OMB and OIRA proclaim transparency while embracing secrecy. The disparity between words and practice, underscored by the facts we have presented here, does not reflect well on the Office of the President.

The requirements of the Executive Order add an admirable level of transparency to the work of the federal government – but only if OMB, OIRA and the rulemaking agencies comply with these requirements.

Sincerely,

Danielle Brian,
Executive Director

Ned Feder, M.D.
Staff Scientist

Project On Government Oversight
1100 G Street, NW
Washington, DC 20005
202-347-1122
pogo@pogo.org

cc: Jacob Lew, White House Chief of Staff; formerly Director, OMB
Cass Sunstein, Administrator, OIRA
Kathleen Sebelius, Secretary, DHHS
Francis Collins, Director, NIH
Jeffrey Zeints, Deputy Director, OMB

APPENDIX

CONTROVERSY AND REVISIONS DURING RULEMAKING: THE FINAL RULE OF AUGUST 25, 2011, ON DISCLOSING POSSIBLE CONFLICTS OF INTEREST OF NIH-FUNDED RESEARCHERS

Government officials at NIH and OIRA discussed and revised the requirements of the Final Rule of August 25, 2011, RIN 0925-AA53, over a period of about two years.[16] During this period, one of the more controversial provisions was a requirement for the public disclosure, by institutions, of certain financial arrangements made by researchers funded by NIH – arrangements creating possible conflicts of interest. There have been several instances of NIH-funded researchers who privately received large payments from companies making medical products closely related to their research. Some of these researchers did not disclose the payments at the time they received them. However, the payments were eventually discovered and became well publicized. The resulting furor was among the reasons the NIH began the process that finally led to the publication of the Final Rule, RIN 0925-AA53, on August 25, 2011.

The requirement for public disclosure of possible financial conflicts of interest was unwelcome among the some of the institutions and individuals to whom it will apply when the Final Rule takes effect. The requirement for public disclosure is still controversial.

As is clear from the description of rulemaking that follows, the requirement for public disclosure changed strikingly with the passage of time:

May 8, 2009. The Advanced Notice of Proposed Rulemaking (ANPRM) was published.[17] The ANPRM did not contain a requirement for public disclosure of possible conflicts of interest or any indication that such a requirement was under consideration.

July 9, 2009. During the comment period of the ANPRM, POGO submitted a comment advocating public disclosure of researchers' financial arrangements.[18] In addition, in a letter to NIH Director Francis Collins on March 11, 2010, we urged Dr. Collins to publicly and strongly support a requirement for a public database in which NIH-funded researchers would disclose their financial arrangements.[19] We also urged him to support the inclusion of a requirement for public disclosure in the Notice of Proposed Rulemaking (NPRM). In our letter to Dr. Collins we noted that he himself had advocated a public database in an interview in September 2009.

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[16] Final Rule. RIN 0925-AA53. Aug. 25, 2011. http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf. (Downloaded March 22, 2012)

[17] ANPRM. RIN 0925-AA53. May 8, 2009. http://www.gpo.gov:80/fdsys/pkg/FR-2009-05-08/pdf/E9-10666.pdf. (Downloaded March 22, 2012)

[18] Comment submitted by Ned Feder, Staff Scientist, POGO, for Docket NIH-2008-0002. July 9, 2009. http://www.regulations.gov/ - !documentDetail;D=NIH-2008-0002-0079. (Downloaded March 22, 2012). Click on small icon labeled PDF in right margin.

[19] Letter to Francis Collins, Director, NIH, from Danielle Brian, Executive Director, POGO, and Ned Feder, Staff Scientist, POGO. March 11, 2010. http://pogoarchives.org/m/ph/pogo-letter-to-collins-20100311.pdf. (Downloaded March 22, 2012)

May 21, 2010. The NPRM was published.[20] It contained a requirement for the public disclosure of certain financial arrangements of NIH-funded researchers. The disclosure was to be made on the public website of the institutions in which they worked – a quickly and easily accessed form of disclosure.

May 24, 2010. In an article published in the *Journal of the American Medical Association* (*JAMA*), Dr. Collins repeated the NPRM's disclosure requirement for certain financial arrangements of NIH-funded researchers.[21] He specifically stated that the required disclosure would be on a publicly accessible website.

June 2011. We heard from a source outside the federal government that the disclosure requirement, favored by Dr. Collins and by the NIH, was under attack by OIRA.

July 11, 2011. In a letter to OMB Director Jacob Lew we wrote we were "concerned that OMB may weaken or block an important part of the proposed new rule," namely, the requirement for public disclosure of certain financial arrangements of NIH-funded researchers.[22] Subsequent events bore out our concern.

August 25, 2011. The Final Rule was published. It contained a requirement for public disclosure of certain financial arrangement of NIH-funded researchers. However, institutions are free to choose either of two options. They can post the financial information on their institutional website (as proposed in the NPRM and as repeated by Dr. Collins in his article in *JAMA*), or they can provide the information, in writing, in response to a request by a requestor. The NPRM had not included the latter possibility, nor had Dr. Collins mentioned it in his *JAMA* article. Thus during the transition from NPRM to Final Rule, the requirement for public disclosure was unexpectedly weakened.

The requirement for public disclosure was and still is controversial. The final decision on public disclosure was marked by differing views not only outside the federal government, but in all likelihood among officials within OMB, OIRA, and NIH. These are exactly the circumstances where the transparency requirements of the Executive Order should apply. Indeed in these cases it is particularly important that the intragovernmental controversies and their resolution be explained publicly. The lack of a public explanation raises a reasonable concern that this part of the Final Rule was influenced by improper pressure from special interests inside and outside government.

The term "transparency" appears more than a dozen times in the Final Rule – each time as a desirable goal. But senior officials in OMB, OIRA, and NIH made an about-face when it came time for them to comply with the transparency requirements of the Executive Order.

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[20] NPRM. RIN 0925AA53. May 21, 2010. http://www.gpo.gov/fdsys/pkg/FR-2010-05-21/pdf/2010-11885.pdf. (Downloaded March 22, 2012)

[21] "Managing Financial Conflict of Interest in Biomedical Research." Sally J. Rockey and Francis S. Collins. *Journal of the American Medical Association*, vol. 303, p. 2400-2402, June 16, 2010. Epub May 24, 2010, p. E1–E3. http://www.nih.gov/about/director/articles/jama_052410.pdf. (Downloaded March 22, 2012)

[22] Letter to Jacob Lew, Director, OMB, from Danielle Brian, Executive Director, POGO, and Ned Feder, Staff Scientist, POGO. July 11, 2011. http://pogoarchives.org/m/ph/pogo-letter-to-lew-ph-iis-20110711.pdf. (Downloaded March 22, 2012)