

Project On Government Oversight

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March 11, 2010

To Francis.Collins@nih.hhs.gov

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
One Center Drive
Bethesda, Maryland 20892

Dear Dr. Collins:

In an interview about six months ago you supported the idea of a database in which NIH grantees' financial arrangements with outside organizations would be made public. We are writing to urge that you act forcefully on the implementation of this idea.

We are, respectively, the Executive Director and the Staff Scientist of the Project On Government Oversight. POGO is a private nonprofit organization devoted to improving the performance of the federal government. Transparency is obviously a key part of good government. The NIH's reputation and its goal of improving the public's health have suffered repeatedly from the lack of transparency in the private financial arrangements of researchers funded by the NIH.

There will soon be a change in the NIH's policy on conflicts of interest. Some time in the next few months a new rule or regulation will probably be finalized and announced. All signs point to strict confidentiality on conflicts of interest as part of the NIH's policy in the future – in other words, no change in the present policy.

You sought a change in this policy in an interview last September with a correspondent for the *New England Journal of Medicine*:

I personally am in favor of the idea that sunshine is the best disinfectant. The idea of having a public database where all investigators disclose what kinds of financial arrangements they have with outside organizations is a good thing.¹

Your preference for sunshine puts you, unfortunately, in the minority. Your good ideas on public disclosure by investigators will almost certainly be ignored when the NIH promulgates its new rule, unless you assert your authority as director.

¹ Robert Steinbrook. "Opportunities and Challenges for the NIH – An Interview with Francis Collins." *New England Journal of Medicine*, October 1, 2009; 361: 1321-1323. The interview took place on September 2, 2009. At <http://content.nejm.org/cgi/reprint/361/14/1321.pdf>

Lack of transparency in the past: A policy damaging to the NIH and the public

Intramural program: scientists on the NIH campus. The reputation of the NIH's intramural program has still not recovered from the exposés, in 2003-2005, of widespread conflicts of interest. Dozens of full-time salaried NIH scientists were discovered to be receiving, on the side, consulting payments and stock options from the manufacturers of drugs and other medical products. Some of these arrangements created obvious financial conflicts of interest. The NIH leadership explicitly approved some of the questionable financial arrangements.

The conflicts of interest were well known inside the NIH, but the Congress and the public learned about them only through the skill and hard work of an investigative reporter, David Willman, of the *Los Angeles Times*. The NIH went through an excruciating span of two years as one damaging revelation after another appeared in print.

Members of Congress finally eradicated the problem by insisting on a stark, uncompromising solution. The reform was imposed over the complaints and foot-dragging of many NIH scientists and leaders, including its director at the time. At present, with narrow exceptions, the NIH's intramural scientists are no longer allowed to make *any* personally profitable financial arrangements with companies in the health sector. Problem solved? Yes, but meanwhile, the very same practices that were stopped inside the NIH now continue uncurbed, to this day, in a much larger group of NIH-funded researchers in the rest of the U.S.

Extramural program: grantees² at medical schools and universities. You are no doubt familiar with recent examples of glaring conflicts of interest in the NIH's extramural program. NIH grantees, acting privately and sometimes secretly for their own personal gain, have been receiving millions of dollars from the manufacturers of drugs and other medical products. The private financial arrangements – made by grantees at Harvard, Stanford, Emory, and other major medical schools – were discovered by Senator Charles Grassley and his staff and by investigative reporters. These arrangements by individual researchers, once they were disclosed to the public, were quickly disavowed and ended by their institutions.

Again, a lack of transparency opened the door to wrongdoing. As you know, the managing and policing of grantees' financial arrangements are left to their institutions. Almost all decisions on individual grantees' personal arrangements with industry are made in private within the institutions and are kept confidential. The public is kept in the dark, journalists are denied access to this information, and Members of Congress rarely demand to see it. Even the NIH, through its own policies, is usually kept ignorant of the details. The NIH provides guidance to universities and medical schools, but does not exercise real oversight, enforcement, or disciplinary action. All this is left to the institutions.

² Strictly speaking, the term "grantee" applies in almost all cases to grantee institutions, not to individual investigators and other persons supported by grant funds. In the present letter, however, we use the term loosely in the latter sense, namely, to refer to individuals supported by funds that their institutions receive in grants from the NIH.

The lack of public disclosure – and the large amounts of money at stake – almost guarantees that some grantees will cheat and that some of them will get away with it. That is presumably one reason why, as the NIH director, you favor a public database in which NIH grantees must disclose their financial arrangements.

The requirement for public disclosure: A minority favor the idea

In response to the string of scandals in the extramural program, the NIH will soon announce a new rule that exerts more control over grantees' private financial arrangements. In anticipation of this step, the NIH has posted the customary "Advance notice of proposed rulemaking," which outlines some proposed details of the new rule³ – for example, defining what constitutes a "Significant Financial Interest (SFI)," which in turn will be used to define financial conflicts of interest in the new rule. The advance notice contains an invitation to grantees, institutions, and the general public to submit comments, which are then posted online.

Sixty-eight comments were submitted and posted.⁴ Only three of them advocate full public disclosure of grantees' financial arrangements:⁵

- o Comment submitted by a senior official at the Cleveland Clinic, which is one of the very few research institutions that already post, on a public website, information about faculty ties to industry
- o Comment submitted by Senators Charles Grassley and Herb Kohl
- o Comment submitted on behalf of POGO by one of us (Dr. Feder)⁶

³ Department of Health and Human Services. Docket Number NIH-2008-0002. Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Request for Comments. Action: Advance notice of proposed rulemaking. Federal Register, vol. 74, no. 88, May 8, 2009, pages 21610-21613. At <http://edocket.access.gpo.gov/2009/pdf/E9-10666.pdf>.

⁴ Submitted comments are posted, under the Docket ID of NIH-2008-0002, at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2008-0002>. Accessed March 4, 2010.

⁵ The comment (submission no. NIH-2008-0002-0029) by Dr. Joseph F. Hahn, Chief of Staff of the Cleveland Clinic, is posted at <http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064809ea716&disposition=attachment&contentType=pdf>

The comment (submission no. NIH-2008-0053) by Senators Grassley and Kohl is a copy of a letter from them to the acting director of the NIH; it is posted at

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064809eb5a1&disposition=attachment&contentType=pdf>

The comment (submission no. NIH-2008-0002-0079) by Dr. Feder is posted at

<http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064809ef9cc&disposition=attachment&contentType=pdf>. In addition to these three comments, there are two that seem consistent with the idea of public

disclosure: a comment (submission no. NIH-2008-0002-0004) by a basic research scientist at University of Texas Southwestern Medical Center; and a comment (submission no. NIH-2008-0002-0035) by a senior official at Merck Research Laboratories.

⁶ In his submitted comment, Dr. Feder cites a Letter to the Editor of *Nature* in which he advocates a public database on grantees' financial arrangements, and adds: "The NIH has not supported this kind of full public disclosure in the past, but it should do so now."

Among those submitting comments were the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the American Association for the Advancement of Science (AAAS), the Federation of American Societies for Experimental Biology (FASEB), the American Physiological Society (APS), and the American Society of Clinical Oncology (ASCO). All submitted comments on the definition of “Significant Financial Interest” (SFI). None supported the idea of public disclosure of grantees’ financial arrangements.

The *Conflict of Interest* report by the IOM

The Institute of Medicine of the National Academies has, as you doubtless know, recently published a long report, *Conflict of Interest in Medical Research, Education, and Practice*.⁷ The report analyzes the problems created by researchers’ financial conflicts of interest and makes a series of recommendations. For 15 of the recommendations, the authors of the *Conflict of Interest* report apparently had little difficulty in reaching consensus. However, one important question remained: what should be done with the information about grantees’ financial arrangements? Here the harmony ended, as shown in Appendix F, “Model for Broader Disclosure,” which contains two separate sections with conflicting recommendations.

Of the 17 authors of the whole report, only 3 took a position similar to yours on the issue of public disclosure. They advocated a “broader disclosure model” of researchers’ financial relationships. They wrote that investigators or persons (which would include NIH grantees), when reporting the information about these relationships to their own institutions, should also be required to make this information publicly available in an online database.

The 14-author majority opposed the broader disclosure model. They endorsed a model in which the manufacturers of drugs and other medical products would be given the responsibility for disclosing the information about their financial arrangements with grantees and other persons. This model is similar to that in a bill awaiting action in Congress, namely, the Physicians Payments Sunshine Act (described below).

⁷ Bernard Lo and Marilyn J. Field, editors. *Conflict of interest in medical research, education, and practice*. Institute of Medicine, Washington, DC: National Academies Press, 2009. At http://www.nap.edu/catalog.php?record_id=12598

Institutions that insist on public disclosure

Only a handful of medical schools and universities require the routine public disclosure of information about financial arrangements made by their faculty. Feinberg School of Medicine (FSM) at Northwestern University is one of about a half-dozen that have a policy of public disclosure. As stated in its published announcement⁸ to faculty members, FSM:

Requires all of its faculty to report all external compensated professional activities *no matter the amount*. [Emphasis added]

The faculty is required to make a broad range of disclosures to the medical school's administration. These disclosures:

Include but are not necessarily limited to payments from industry for consultancies, speaking arrangements, promotional activities, equity, stock options, royalties, grants for research and education, and external fiduciary positions.

And finally, in order to ensure access by the public, the disclosures:

Will be posted on the FSM website and updated on a regular basis.

But there's a catch. Although the FMS administration has in its internal files a detailed report on the financial arrangements of each faculty member, only very limited information is disclosed publicly. For each FMS faculty member, the businesses or organizations (if any) that provide payments to that member are named, but the nature of the payments and the amounts are not disclosed.

A few other medical research institutions publicly disclose information about the financial arrangements of their faculty: Cleveland Clinic, Stanford, University of Pennsylvania, University of Iowa, and University of Virginia. All these institutions disclose more than FSM. At Duke University Clinical Research Institute (DCRI), fairly detailed financial information is posted online for individual faculty members.⁹ However, public disclosure is voluntary, and many faculty members choose to disclose their financial arrangements to the DCRI administration, but not the public.

By failing to require any public disclosure of grantees' financial arrangements, the great majority of medical schools and universities are in lock step with the similar failure by the NIH. While it's true that the few schools listed above require public disclosure, most of them disclose only limited information.

⁸ "Disclosure Policy," Feinberg School of Medicine, Northwestern University. Effective date: February 27, 2009. 5 pages. At: http://www.feinberg.northwestern.edu/faculty-staff/misc_pdfs/fsm-coi-effective-02-27-2009.pdf. Accessed March 1, 2010. The quoted passages are taken from page 1 of the announcement.

⁹ "Duke University Clinical Research Faculty Conflict of Interest Disclosures." A list of 37 names, each with a link to a disclosure statement. See <http://www.dcri.duke.edu/research/coi.jsp>. Accessed March 1, 2010.

Senator Grassley and proposed legislation requiring disclosure

Senator Grassley has spearheaded and cosponsored the Physician Payments Sunshine Act of 2009.¹⁰ The bill, which is in committee, requires transparency in the financial relationships between physicians and the manufacturers of drugs and other medical products. Specifically, if the bill becomes law, the manufacturers must report the details of these financial relationships to the Secretary of Health and Human Services, who in turn must make the information publicly available through an Internet website. Manufacturers must report the nature of each payment (consulting fees, stock options, and so on) and their monetary value. In the bill, it is the manufacturers, not the physicians or their institutions, which are responsible for collecting the information and reporting it.

POGO fully supports this bill. We also believe that public disclosure requirements – requirements that the NIH imposes on grantees and their institutions – should be included in the new rule that will soon be promulgated by the NIH. The NIH should require, as a condition of funding, that researchers make full public disclosure of their private financial arrangements that are directly or indirectly related to their professional responsibilities.

There are several reasons why the NIH should make this requirement a part of its new rule. First, the bill before Congress applies to physicians only. Researchers with Ph.D. but not M.D. degrees are not covered by the bill. Many NIH grantees are therefore not covered.

But there is a far stronger reason for the NIH to press ahead with its own requirement for public disclosure, regardless of what the Congress does. The reason is simple. The NIH itself bears a direct responsibility – legal and moral – to protect the public by ensuring that financial conflicts of interest do not compromise the medical research of grantees.

Earlier in this letter we briefly summarized the history of conflicts of interest that had been remedied only after they were discovered and made public by investigative reporters and Members of Congress, often with the help of whistleblowers who put their own careers at risk. This sordid history bears a message that today's leaders of the biomedical research community should heed: sunshine deters noncompliance with the NIH's rules on conflicts of interest. Compliance with these rules is obviously more likely if grantees' financial arrangements are easily accessible for examination by journalists, Members of Congress, and the public.

¹⁰ "S. 301: Physician Payments Sunshine Act of 2009." See <http://www.govtrack.us/congress/bill.xpd?bill=s111-301>. Accessed March 1, 2010. This is a summary of the bill's status prepared by GovTrack.us. There are links to a summary and full text of the bill.

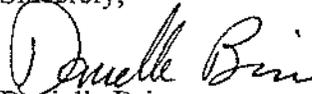
Conclusion

In the September 2009 interview you advocated a public database where investigators disclose their financial arrangements. We urge you, as the NIH director, to publicly and strongly support this kind of disclosure in such a way that those drafting the new NIH rule on conflicts of interest are likely to incorporate a requirement for public disclosure into the new rule.

The president's well-known memorandum on transparency and open government, issued on his first day in office, announced a policy of transparency, open government, and disclosure of information in forms readily available to the public.¹¹ The more detailed Open Government Directive of December 2009 sets deadlines for action.¹² The NIH's rule on grantees' disclosure of their financial arrangements should be made to comply with these policies.

We would be interested in knowing your current plans to press for this kind of public disclosure in the new rule. We would be glad to meet with you to discuss this important issue.

Sincerely,



Danielle Brian

Executive Director

Project On Government Oversight



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¹¹ Transparency and Open Government. Administration of Barack H. Obama, 2009. January 21, 2009. Memorandum for the Heads of Executive Departments and Agencies. Subject: At <http://www.gpo.gov/fdsys/pkg/DCPD-200900010/pdf/DCPD-200900010.pdf>

¹² Open Government Directive. Memorandum for the Heads of Executive Departments and Agencies. From Peter R. Orszag. December 8, 2009. 11 pages. At www.whitehouse.gov/omb/assets/memoranda_2010/m10-06.pdf

Exposing Corruption *Exploring Solutions*
Project On Government Oversight

November 19, 2010
To Francis.Collins@nih.hhs.gov

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
Bethesda, Maryland 20892

Subject: The proposed rule requiring NIH-funded investigators to make public their financial arrangements with industry

Dear Dr. Collins:

Extramural investigators funded by the NIH may soon have their financial arrangements with industry disclosed on a public website.

The NIH first announced – in the May 2009 Advance Notice of Proposed Rulemaking – that it was taking a fresh look at financial conflicts of interest among investigators in its extramural program. There was no mention in that announcement of the idea of public disclosure of investigators' financial arrangements with industry. This led us to write you urging that this kind of public disclosure be required.

We are gratified that the latest notice – the May 2010 Notice of Proposed Rulemaking (NPRM) – strongly supports the public disclosure of investigators' financial interests. In the NPRM, the NIH describes this kind of public disclosure as

an important and significant new requirement to help the biomedical and behavioral research community monitor the integrity and credibility of PHS-funded research and underscore our commitment to fostering transparency, accountability, and public trust.

We are writing to offer three comments.

- o The information about investigators' financial arrangements should be posted as a searchable database, not in some other, less useful form.¹
- o If the terms in the Notice of Proposed Rulemaking are accepted in the Final Rule, there will not be a single, central database available for public examination. Instead each institution will post the disclosures made by its own investigators. We urge a final rule in which the disclosures of the individual institutions are aggregated into a single database. (See our further comments on this point.) However, if each of the hundreds of NIH-funded institutions posts on its website the financial arrangements only of its own investigators, then that information should at least be in standardized format that facilitates nationwide aggregation.
- o Further, another issue should be faced. Suppose an investigator provides his or her institution with financial information that is substantially inaccurate, either through inadvertence or through deliberate falsification. We urge that the Final Rule deal explicitly with the issue of legal responsibility, under federal regulation or law, for such inaccuracies in the data in the public database. The Final Rule should not leave this important point unsettled.

We again urge that you use your influence, privately and publicly, to ensure that a public database is required in the Final Rule. Some medical schools and other organizations funded by NIH or affected by NIH funding are trying to kill the proposal for a public database,² and they may succeed. But the public wants more transparency, not less. In the last decade, most major medical journals have strengthened their financial disclosure policies to a remarkable degree, and there are other examples of a trend toward increased disclosure of financial arrangements in matters related to public health.

Sooner or later a public database *will* be required for the finances of those funded by NIH. And if later, then with what sorts of requirements? Lawmakers and others outside the NIH may be less careful than officials at the NIH in designing the right kind of

¹ OpenSecrets.org posts a database that includes the personal financial disclosures of each member of Congress. The specific financial arrangements for each Senator or Representative are presented in an image file (a non-searchable PDF) prepared from a printed form.

² One organization, urging a postponement of the Final Rule in a Comment responding to the NPRM, stated, "While transparency is not sufficient for the creation of proper behavior it has been used so far only as an intimidation technique and material for sensationalistic journalism." In our previous letter to you we have commented further on the resistance to public disclosure.

public database – one with the best balance of drawbacks and benefits.³ That's just one of the reasons you should press your colleagues to include a public database in the Final Rule.

Your comments to the *New England Journal of Medicine* a year ago helped kindle an interest in a public database for the financial arrangements of NIH-supported investigators. We hope that it will be a matter of months, not years, before such a database is announced.

Sincerely,



Danielle Brian

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³ The NPRM recognizes some of the drawbacks, noting that “the proposed public disclosure requirement would place an additional administrative burden on Institutions, and would also impact the privacy of Investigators who have information related to their personal financial interests posted publicly to the extent such interests are determined to be [financial conflicts of interest]. Consequently, it is important to identify the optimal balance between these more onerous impacts and the imperative to preserve the integrity of the public’s investment in biomedical and behavioral research.”

Attn: Jerry Moore
1 page

Docket: NIH-2008-0002

Public Submission Title: Comment from Ned Feder, M.D.,
Staff Scientist, Project On Government Oversight

Date Submitted: July 9, 2009, by fax, to Jerry Moore, NIH
Regulations Officer

Those considering the amendment of regulations covered by NIH-2008-0002 should examine the passage below. It comes from a Letter to the Editor, "Public disclosure could deter conflicts of interest," published in *Nature* four years ago, before Senator Grassley discovered shocking financial conflicts of interest among NIH grantees.

The NIH should require grantees to make public disclosures of their paid arrangements with pharmaceutical, investment and other companies, as well as their ownership of stock and stock options, as a condition of having their medical research funded by the government. The private finances of any US senator or representative can be checked in an instant through links at www.opensecrets.org/pfds. Why not create, by law, a similar system for medical researchers who receive government funding? [*Nature*, vol. 437, page 620, Sept. 29, 2005]

The NIH has not supported this kind of full public disclosure in the past, but it should do so now.

Sincerely,



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nature

29 Sept 2005; 437: 620
Correspondence

Public disclosure could deter conflicts of interest

SIR — Your Business story "Fears rise over leaks of clinical trial results" (*Nature* 437, 191; 2005) describes a conflict-of-interest scandal in which US medical researchers with inside knowledge of ongoing clinical trials are being paid for information they provide as consultants to Wall Street analysts and investors.

The National Institutes of Health (NIH) could start fixing this problem, at least for its own grantees. NIH-funded researchers are required to provide details of any consulting arrangements to their universities, which in turn approve or veto the plans. This information is confidential and usually cannot be seen by the public.

The NIH could require grantees to make public disclosures of their paid arrangements with pharmaceutical, investment and other companies, as well as their ownership of stock and stock options, as a condition of having their medical research funded by the government. The private finances of any US senator or representative can be checked in an instant through links at www.opensecrets.org/pfds. Why not create, by law, a similar system for medical researchers who receive government funding?

A proposal to require readily accessible financial disclosure will probably be fought tooth and nail by those who benefit from leaving things as they are: some university researchers and administrators, officials at the NIH and scientists in industry.

It is an inescapable fact, however, that the partnership of academia, government and industry is plagued by unseen practices that are ethically or legally suspect.

One way to attack this problem is through a requirement for financial disclosure that the public can see.

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