

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.”