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**Project On** **Government Oversight**

July 11, 2011

By email: ombdirector@omb.eop.gov

The Honorable Jacob Lew  
Director  
Office of Management and Budget  
725 17th Street, NW  
Washington, DC 20503

**Subject:** OMB should allow NIH to issue its final rule

Dear Mr. Lew:

An intrusion by the Office of Management and Budget (OMB) may be about to undermine the integrity of medical research supported by the National Institutes of Health (NIH). A new rule proposed by NIH will increase transparency in the financial arrangements of NIH-funded researchers in medical schools and universities. However, the Project On Government Oversight (POGO) is concerned that OMB may weaken or block an important part of the proposed new rule.

Time and again NIH-funded medical researchers at the nation's medical schools and universities (in the NIH's extramural program) have been caught performing and publishing research tainted by hidden financial arrangements from which they personally benefit. For researchers in academia, financial arrangements undisclosed to the public are common.

There is an obvious way to deal with questionable financial arrangements not disclosed to the public: require that they be disclosed. This is exactly what NIH leaders are planning through the proposed new rule, under which NIH-funded physicians and scientists in the NIH's extramural program would be required to publicly disclose certain financial arrangements they make with private companies.<sup>1</sup>

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<sup>1</sup> See "Notice of Proposed Rulemaking," *Federal Register*, vol. 78, no. 98, May 21, 2010, pages 28688-28712. The part of the rule that would require the posting of financial information on a publicly accessible website is on pages 28697-28698.

## **Background: The NIH's *intramural* program (government scientists in Bethesda)**

The NIH's proposed rule requires financial disclosure by *extramural* researchers in medical schools and universities. This proposed requirement is much less intrusive than the constraints now imposed on government scientists working in the NIH's *intramural* program at its campus in Bethesda.

Six years ago the NIH banned almost all private payments by pharmaceutical companies and other businesses to the approximately 4000 researchers in the NIH's *intramural* program. This prohibition was unpopular with an influential group of *intramural* NIH scientists, some of whom were receiving large payments allowed under the old rules. The prohibition was forced on an unwilling NIH by an impatient Congress when the *Los Angeles Times*, in a series of articles from 1998 to 2005, described scandal after scandal involving senior NIH researchers with undisclosed conflicts of interest. Finally, in August 2005, the Director of the NIH could delay no longer, and the new rule was imposed.

## **Current plans for the NIH's *extramural* program**

Last year Dr. Francis Collins, the Director of the NIH, explained why changes are needed in NIH policies for dealing with financial conflicts of interest:

The public may not always understand the intricacies of rigorous science, but most individuals quickly grasp the concept of bias. Plain and simple, Americans do not want financial conflicts of interest (FCOI) to influence the federally funded research they hope will yield better ways to fight disease and improve health.

[Article by Francis Collins and Sally Rockey, *Journal of the American Medical Association*, May 2010]

In May 2009 and in a revision in May 2010, the NIH announced proposals for changes in the existing rules for conflicts of interest in its *extramural* program. POGO takes a particular interest in one change: a new requirement for public disclosure. Up to now, *extramural* investigators have been required to disclose certain financial interests – but only to their own institutions. The institution is allowed to keep this information private, and that's what most medical schools and other academic institutions do. However, under the rule proposed by NIH in May 2010 – if it is finalized – these financial interests must be disclosed in a publicly accessible database.

There are published stories about shocking violations in the *extramural* program similar to those that preceded the drastic reform of the *intramural* program in August 2005. We believe that most and perhaps all of these violations would have been prevented if the NIH's proposed requirement for public disclosure had been in place.

The leaders of NIH have invested considerable thought in drafting the proposed rule for a publicly accessible database. We have heard that OMB is considering a weakening or elimination of the database proposed by NIH. If OMB prevails on this point, the result is predictable.<sup>2</sup>

In their article in *JAMA* cited above, Dr. Collins and Dr. Rockey wrote that  
for the good of the research enterprise and for our nation as a whole, it is imperative to take collective steps now to usher in a new era of clarity and transparency in the management of FCOI.

The idea of a public database was proposed by the NIH under Dr. Collins's leadership. The requirement for public disclosure by federally funded medical researchers is a natural part of the Obama administration's commitment to transparency in order to ensure the public trust. If the creation of the public database is permitted by OMB, it will be a milestone in the NIH's program of research at medical schools and universities – an advance of which the President and Dr. Collins can be proud.

We urge you to ensure that the OMB, in its evaluation of the proposed rule for dealing with conflicts of interest, leaves the part of the rule on a public database untouched.

Sincerely,



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Executive Director  
Project On Government Oversight



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<sup>2</sup> For a recent example of what can happen and probably would happen in the absence of a federal requirement for public disclosure, see the articles, published on July 2 by the *Boston Globe*, *San Francisco Chronicle*, and others. These articles describe disciplinary action that Massachusetts General Hospital took against Dr. Joseph Biederman, Professor of Psychiatry, for failing to report large payments he received from drug companies. Dr. Biederman might have disclosed these payments appropriately if he had been required to disclose them not only to the MGH for its internal evaluation, but in a database mandated by the federal government for examination by members of the public.