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United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

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August 4, 2011

Via Electronic Transmission

The Honorable Jacob J. Lew
Director
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20503

Dear Director Lew:

I write to you today regarding public disclosure of financial relationships between physicians and the drug, device and biologic industries. For the past three years I have worked to shine light on these relationships, including with the help of Senator Kohl in securing the passage of the Physician Payment Sunshine Act of 2009 (PPSA).

Before the passage of PPSA, in summer of 2008, I began releasing the results of my oversight work that demonstrated that universities are not and have not managed their professors' financial conflicts of interest and that change is needed at the National Institutes of Health (NIH). Specifically, I found:

- The Chair of the Psychiatry Department at Emory University failed to report hundreds of thousands of dollars in payments from a pharmaceutical company while researching that same company's drugs with an NIH grant. The Health and Human Services Office of the Inspector General (HHS OIG) is now investigating the matter.
- The Chair of the Psychiatry Department at Stanford University received an NIH grant to study a drug while partially owning a company that was seeking FDA approval of said drug. He was later removed from the grant.
- Three psychiatrists at Harvard University failed to report almost a million dollars each in outside income while heading up several NIH grants. Harvard released a report on the matter, and a briefing has been scheduled with my office.

I am concerned about recent reports that the Office of Management and Budget (OMB) may be attempting to weaken conflicts of interest rules proposed in May 2010 by the Department of Health and Human Services (HHS).

According to an article in *Nature*, OMB has removed the requirement for a publicly available website that would publish the conflicts of interests of researchers funded by taxpayers.¹

I am troubled that taxpayers cannot learn about the outside income of the researchers whom the taxpayers are funding, and this flies in the face of President Obama's call for more transparency in the government. The public's business should be public. The consequences of a lack of transparency include doctors' possibly using taxpayer-funded grants to leverage their own financial interests, to the detriment of consumers. Transparency is a backstop against such practices. I urge OMB to follow through and approve a rule that includes a publicly available website. OMB is the final arbiter of this decision. Any weakening of publicly available information requires careful scrutiny.

In order to understand why OMB appears to have concluded that weakening the HHS proposed conflict of interest rule is appropriate, I would appreciate your response to the following requests for documents:

- 1) Please provide all records relating to communications, including emails, with OMB staff regarding the Department of Health and Human Services' proposed conflicts of interest rule from May 1, 2010, to the present.
- 2) Please provide all records, including calendar entries, relating to meetings with Administrator Cass Sunstein, OMB Office of Information and Regulatory Affairs, from May 1, 2010, to the present.

I request that OMB respond to my request by no later than August 25, 2011. Thank you for your attention to this important matter. Should you have any questions regarding this letter, please contact Brian Downey of my Committee Staff at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

cc: The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services

The Honorable Francis S. Collins
Director
National Institutes of Health
U.S. Department of Health and Human Services

¹ Meredith Wadman. August 1, 2011. *Nature*. <http://www.nature.com/news/2011/110801/full/476017a.html>