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May 29, 2012

Via Electronic Transmission

The Honorable Francis S. Collins, PhD, MD
Director
National Institutes of Health
U.S. Department of Health and Human Services
One Center Drive
Bethesda, MD 20892

Dear Director Collins:

Recently, the National Institutes of Health (NIH) awarded Dr. Charles B. Nemeroff a grant worth roughly \$400,000 per year for a five year period.¹ Please explain how the NIH arrived at this decision to award Dr. Nemeroff despite past ethical problems. Although NIH has recently revamped its conflict of interest guidelines, this decision risks sending the wrong message to physicians seeking or performing federally funded research.²

As you're aware, since 2008, I have worked to achieve public disclosure of financial relationships between physicians and the drug, device, and biologic industries. In the summer of 2008, I uncovered extensive evidence of close financial relationships between certain physicians and industry, including physicians employed at universities who received federal funds. The evidence indicated that universities did not properly manage their physicians' financial conflicts of interest, so I called on NIH to strengthen this process.

A prime example in failing to fully disclose industry income was illustrated by one of the nation's most influential psychiatrist's, Dr. Charles B. Nemeroff, Chair of Emory University's Psychiatry Department. In 2008, documents indicated that Dr. Nemeroff failed to disclose nearly \$1.2 million in consulting arrangements.³ At that time, Dr. Nemeroff was leading a NIH grant worth \$9 million, for the study of depression. The undisclosed income came from the drug maker GlaxoSmithKline, manufacturer of the depression drug Paxil. Due to Dr. Nemeroff's

¹ Jocelyn Kaiser. "Sanctioned Psychiatrist Gets First NIH Grant in 3 Years." *Science*. May 22, 2012.
<http://news.sciencemag.org/scienceinsider/2012/05/sanctioned-psychiatrist-gets.html>

² Katherine Hobson. "New NIH Conflict-of-Interest Rules: Better Than the Old Rules?" *The Wall Street Journal*. August 23, 2011. <http://blogs.wsj.com/health/2011/08/23/new-nih-conflict-of-interest-rules-better-than-the-old-rules/>

³ Gardiner Harris. "Top Psychiatrist Didn't Report Drug Makers Pay." *The New York Times*. October 3, 2008.
<http://www.nytimes.com/2008/10/04/health/policy/04drug.html?pagewanted=all>

failure to disclose these financial relationships, the NIH suspended his grant in August 2008.⁴ Dr. Nemeroff would eventually leave Emory University before being hired by the Miller School of Medicine at the University of Miami.

My concern surrounding Dr. Nemeroff and the NIH led me to write the Department of Health and Human Services Office of Inspector General (HHS OIG) on February 24, 2009 regarding NIH's lack of oversight on conflicts of interest by external institutions that receive NIH funding. The letter focused on Dr. Nemeroff's relationships and cited multiple allegations including:

- Potential violation of NIH conflict of interest rules,
- Possible violation of Institutional Review Board (IRB) protocols,
- Failure to report IRB violations to the Office of Human Subject Research Protection,
- Possible violations of Federal Contracting Rules regarding Commitment of Time for NIH grants and possible misleading information provided to the NIH.⁵

The HHS OIG's Office of Investigations is reportedly working with the U.S. Department of Justice (DOJ). Although HHS OIG has concluded its investigation, it is waiting for DOJ to decide whether to take action before releasing the OIG report.⁶ So, there has been no final resolution by DOJ or public finding by HHS OIG related to the investigation of Dr. Nemeroff. Yet, NIH awarded him another grant.

On November 29, 2010, *The New York Times* reported that, according to documents, GlaxoSmithKline helped to ghostwrite a textbook purportedly authored by Dr. Nemeroff and Dr. Alan Schatzberg.⁷ After reading this "textbook," a psychiatrist named Dr. Daniel Carlat referred to it as "an advertisement for Paxil."⁸

Further, the Office of Management and Budget (OMB) did not include a specific provision to the HHS conflict of interest rules that would have required universities to disclose financial relationships between researchers and industry to be posted on publicly available websites. I wrote to OMB on August 4, 2011, regarding this decision.⁹ OMB responded without providing the documents I requested and explained that the public could be forced to submit written requests before institutions would be required to disclose potential conflicts of interest. OMB stated that "under the final rule, investigators are required to report significant financial

⁴ Jocelyn Kaiser. "NIH Suspends Grant to Emory University." *Science*. October 18, 2008.

<http://news.sciencemag.org/sciencenow/2008/10/14-01.html>

⁵ Letter from Senator Grassley to U.S. Department of Health and Human Services Office of Inspector General. February 24, 2009.

⁶ Letter from HHS OIG to Senator Grassley. June 17, 2010.

⁷ Duff Wilson, "Drug Maker Hired Writing Company for Doctors' Book, Documents Say," *The New York Times*, November 29, 2010. <http://www.nytimes.com/2010/11/30/business/30drug.html>

⁸ Daniel Carlat, "Nemeroff and Schatzberg's 'Textbook' Pushed Paxil," Carlat Psychiatry Blog, December 3, 2010. <http://carlatpsychiatry.blogspot.com/2010/12/nemeroff-and-schatzbergs-textbook.html>

⁹ "Grassley Urges Agency Not to Weaken Federal Health Research Transparency Rule." August 4, 2011. http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=36314

interests to their institutions. Institutions must make identified financial conflicts of interest publicly accessible and may do so in one of two ways: (1) via a public web site or (2) by providing the information in writing upon request.”¹⁰ OMB should have supported the policy that every institution post financial conflicts of interest on a public website.

It’s troubling that NIH continues to provide limited federal dollars to individuals who have previously had grant funding suspended for failure to disclose conflicts of interest and even more troubling that the Administration chose not to require full, open, and public disclosure of financial interests on a public website. Accordingly, I ask that you respond to my request for answers to the following questions, providing all related documents:

- 1) Provide all internal documents including emails surrounding the approval of the grant to Dr. Nemeroff.
- 2) Was NIH aware that Dr. Nemeroff was under federal investigation? If so, why did NIH decide to award this grant anyway?
- 3) Did anyone discuss the matter of Dr. Nemeroff’s grant application with the HHS OIG and/or DOJ? If yes, please provide records. If not, why not?
- 4) Who were the peer reviewers’ for Dr. Nemeroff’s grant? Were they made aware of Dr. Nemeroff’s potential conflicts of interest? If not, why not? Provide pertinent documents.
- 5) Were the peer reviewers’ aware that Dr. Nemeroff was under federal investigation? If not, why not? Provide pertinent documents.
- 6) Does the NIH have safeguards and procedures that would detect and deny grant applicants who have been convicted of a felony? Provide pertinent documents.

Thank you in advance for your prompt attention to these matters. I would appreciate receiving a response by no later than June 12, 2012. Should you have any questions, please contact Brian Downey or Erika Smith of my staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member

CC: Dr. Donna E. Shalala
President
University of Miami

¹⁰ Letter from the Office of Management and Budget to Senator Grassley, August 30, 2011.