

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

June 24, 2010

## **Via Electronic Transmission**

The Honorable Francis S. Collins, MD, PhD  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

RE: Proposed Rule on the Responsibility of Applications for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought

Dear Director Collins:

Since 2008, I have been examining the practice of medical ghostwriting, which involves pharmaceutical or device companies hiring medical education, marketing or communications companies to draft articles that are presented to prominent physicians and scientists to sign on as authors. The physicians and scientists sign on even if they may not be intimately familiar with the underlying data or provided limited input on the article. The objectives of that practice are to raise the credibility of the findings and conclusions and increase the likelihood that the articles, which tend to put the companies' products in a positive light, will be published in important medical journals.

As Ranking Member of the Senate Committee on Finance (Committee), my concern with the practice has been the lack of transparency regarding the companies' role in developing the articles and providing financial support for the education, communications or marketing companies that draft the manuscripts that are then presented to physicians and scientists to sign on as authors. Moreover, reliance on the ghostwritten articles by others in the medical community may lead physicians to prescribe treatments that are more costly or even harmful to their patients.

Enclosed is a report I am releasing today that presents my Committee staff's findings to date on medical ghostwriting. Over the last two years, I have written to two pharmaceutical companies, a medical publishing company, a medical communications company, ten medical schools, and eight medical journals regarding this issue. In addition, my staff has reviewed court documents and publications and interviewed researchers, attorneys examining conflicts of interest and/or the practice of medical ghostwriting.

In August 2009, I also wrote to the National Institutes of Health (NIH) to inquire about the agency's policies on ghostwriting. My staff found that the NIH does not have explicit policies on the disclosure of industry financing of ghostwritten articles. Like the medical schools and journals, however, the NIH can and should play a role in promoting greater transparency and ensuring adequate disclosure and accountability in the development and authorship of medical literature.

Therefore, I urge the NIH take into consideration the findings outlined in this report in finalizing its *Proposed Rule on the Responsibility of Applications for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought* (Proposed Rule). In particular, the NIH ought to ensure that the final rule defines the term "significant financial interest" to include pharmaceutical and device company financing and/or other material contribution or support to develop medical literature, including but not limited to conceiving and designing the underlying paper, collecting and/or analyzing the data, and drafting, reviewing and/or revising the manuscript. The term should also include pharmaceutical and device company payments to any NIH-supported researcher for writing, editing or contributing to an article published in a medical journal or other medical or research publication.

In addition, NIH should require institutions that receive NIH grants to maintain up-to-date, written and enforced policies on (1) the authorship of articles, such as those established by the International Committee of Medical Journal Editors, and (2) the disclosure of any financial or material support, contribution or other item or service of value provided by a drug or device company to any articles written by or attributed to the institution, including any faculty member or researcher affiliated with the institution, that are published in a medical journal or other publication.

The NIH should also consider requiring that articles based on research funded, all or in part by NIH, including intramural and extramural research, are published in a medical journal or other publication that has written, enforced policies on the authorship and the disclosure of any financial or material support, contribution or other item or service of value provided by a drug or device company with respect to such articles.

Thank you for your attention to this important matter. Should you have any questions regarding this letter or the enclosed report, please contact Emilia DiSanto or Angela Choy of my Committee staff at (202) 224-4515.

Sincerely,



Charles E. Grassley  
Ranking Member

Enclosure