

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

August 11, 2009

Via Electronic Transmission

Raynard S. Kington, M.D., Ph.D.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Acting Director Kington:

As a senior member of the United States Senate and the Ranking Member of the Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the National Institutes of Health (NIH/Agency). In this capacity, I must ensure that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the public funding provided for medical studies. This research often forms the basis for action taken by the Medicare and Medicaid programs.

First, let me thank you for your service as Acting Director at NIH and your attention to conflicts of interest issues. Over the last several years, I have been examining ghostwriting, a practice in which drug and device companies hire medical communications and education companies to draft journal articles and then have "independent" academics sign onto them as the lead author.

I was troubled by a recent article in *The New York Times* discussing Wyeth's hiring of DesignWrite-to ghostwrite articles that are favorable to the Wyeth's hormone therapy product, Premarin.¹ *The New York Times* released several documents for this story and I have attached them to this letter. [Attachment A]

In December, I wrote to DesignWrite and Wyeth to inquire about their policies and procedures with respect to ghostwriting and the manuscripts that DesignWrite prepared on hormone therapy products at Wyeth's request. My inquiries to date have uncovered troubling information regarding the practice. [Attachment B] In one email, DesignWrite's Vice President for Scientific Affairs described the company's process of ghostwriting for Wyeth:

¹ Singer, Natasha "Medical Papers by Ghostwriters Pushed Therapy," *The New York Times*, August 5, 2009.

The first step is to choose the target journal best suited to the manuscript's content, thus avoiding the possibility of manuscript rejection. We will then analyze the data and write the manuscript, recruit a suitable well-recognized expert to lend his/her name as author of the document, and secure his/her approval of its content. After the client has reviewed and released the manuscript for submission, DesignWrite will see it through the necessary production stages-creating camera-ready figures and tables and the text according to the journal guidelines-and submit the package (manuscript, art, cover letter, and any required forms and checklists) to the appropriate journal editor. Any revisions requested by the journal will be handled by DesignWrite in conjunction with the client and the author. Should the journal reject the manuscript, DesignWrite will restyle it for submission to another journal within 10 working days. [Attachment C]

Furthermore, my staff examined a list of several publications DesignWrite ghostwrote for Wyeth. I am attaching those documents to this letter. [Attachment D] I would also like to bring to NIH's attention that several researchers who apparently signed onto these ghostwritten publications are researchers who receive NIH grants. These investigators include Dr. Michelle Warren, Professor of Medicine at Columbia University; Dr. Rogerio Lobo, Professor at Columbia University; Dr. William Cefalu, Professor at LSU Pennington; Dr. Lisa Shulman Associate Professor at the University of Maryland; and Dr. Lori Mosca, Associate Professor of Medicine at Columbia University. [Attachment E]

At this time, I have not drawn any conclusions about the extent of these professors' interactions with DesignWrite. However, I am asking that you look into this matter and ensure that taxpayer dollars for biomedical research are being spent properly.

Accordingly, I request that NIH respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with the appropriate answer.

- 1) What is the current NIH policy on ghostwriting with regards to NIH researchers? Please provide a copy of such policy.
- 2) What is the current NIH policy on ghostwriting with regards to NIH grantee institutions? Please provide a copy of such policy.
- 3) What is the current NIH policy on ghostwriting with regards to primary investigators of NIH grants? Please provide a copy of such policy.
- 4) Has NIH received any complaints about individual grantee institutions, primary investigators and/or NIH researchers regarding possible ghostwriting and if so how has NIH handled these complaints?

- 5) What is the current NIH policy regarding primary investigators found to have violated medical ethics and/or have medical licenses that have been suspended or revoked? Please provide a copy of such policy.

I thank you again for your continued cooperation. If you have any questions please contact my Committee staff, Paul Thacker or Brian Downey at (202) 224-4515. All formal correspondence should be sent electronically in PDF searchable format to Brian_Downey@finance-rep.senate.gov by no later than August 25, 2009.

Sincerely,



Charles E. Grassley
Ranking Member

cc: The Honorable Daniel R. Levinson
Inspector General
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