



JAN 14 2010

The Honorable Charles E. Grassley  
United States Senate  
Washington, DC 20510

Dear Senator Grassley:

Thank you for your letter dated October 26, 2009, in which you expressed concern regarding an article in the October 25, 2009, issue of the *The Chronicle of Higher Education* (CHE) that discussed consulting fees received by scientists funded by the National Institutes of Health (NIH). In your letter, you expressed concern with one particular investigator, Dr. Christie M. Ballantyne of Baylor College of Medicine (BCM), and BCM's failure to report the conflict to the NIH in compliance with the Federal Financial Conflict of Interest (FCOI) regulation (42 CFR Part 50 Subpart F). You asked that the NIH review the information and provide a briefing to your staff regarding these allegations. On December 1, 2009, Dr. Sally Rockey, NIH Deputy Director for Extramural Research, met with your staff to discuss the NIH's preliminary findings.

Upon receipt of your letter, the NIH contacted the grantee institutions mentioned in the CHE article and asked for specific information to determine for the period from 2007 to the present if: (1) significant financial interests<sup>1</sup>, including any from Merck & Company and/or the Schering-Plough Corporation (Merck), were appropriately disclosed to the institution by the named investigators<sup>2</sup>; (2) the institution reviewed investigator disclosures to determine whether a financial conflict-of-interest existed; and (3) any identified conflict was appropriately managed, reduced, or eliminated and reported to the NIH.

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<sup>1</sup> *Significant Financial Interest* means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include: (1) Salary, royalties, or other remuneration from the applicant institution; (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program; (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) Income from service on advisory committees or review panels for public or nonprofit entities; (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

<sup>2</sup> Christie M. Ballantyne, M.D. at BCM, Antonio M. Gotto, Jr., M.D., D.Phil at Weill Medical College of Cornell University; Sergio Fazio, M.D., Ph.D. at Vanderbilt University; and Ishwarlal Jialal, M.D., Ph.D. at the University of California, Davis. Note: Dr. Michael H. Davidson of the University of Chicago did not have any NIH grant support.

Based upon the information received to date, Weill Medical College of Cornell University and Vanderbilt University reported that the investigators disclosed their financial interests from Merck and both institutions determined that the interests were not related to NIH-supported research. Therefore, those institutions did not identify any financial conflicts of interest to report to the NIH. We are, however, continuing to engage in further communication with one grantee (University of California, Davis) to obtain additional information.

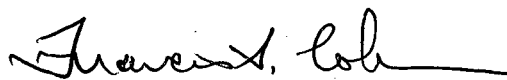
As we discussed with your staff during our December meeting, the response received from BCM, while confirming the required disclosure by the investigator, raised serious concerns regarding BCM's compliance with the FCOI regulation. As a result, the NIH has imposed special award conditions on all BCM grant awards until BCM can assure the NIH that the detected deficiencies noted in their response have been appropriately addressed and BCM can demonstrate compliance with the FCOI regulation to the NIH's satisfaction.

Because of the NIH's concerns about the potential effect of BCM's non-compliance on NIH-funded research, we also asked BCM to conduct a retrospective review of investigator financial disclosures for active NIH grant awards (including subawards), for the period of 2004 to the present, to ensure that investigator financial interests were disclosed, reviewed and, where FCOIs were identified, managed appropriately. In addition, we asked BCM to provide us with their FCOI policy and any procedural documents.

We will continue to work closely and diligently with these institutions to complete our review and to address any deficiencies related to the institution's compliance with the FCOI regulation to ensure objectivity in NIH-funded research and that investigator conflicts do not bias the design, conduct, or reporting of NIH-supported research. As you know, we are in the process of developing proposed changes to the current regulation to enhance oversight of FCOIs.

I appreciate your interest in NIH and look forward to working with you.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins", with a long horizontal flourish extending to the right.

Francis S. Collins, M.D., Ph.D.  
Director