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## **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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National Institutes of Health Bethesda, Maryland 20892

Mr. Paul Thacker Investigator Project On Government Oversight 1100 G Street, NW, Suite 900 Washington, DC 20005-3806

Dear Mr. Thacker:

Thank you for your letter of November 29, 2010, in which you express your concern about financial conflicts of interest and ghostwriting in academia, particularly in medical schools.

I want to state clearly that the National Institutes of Health (NIH) does not condone the practice of ghostwriting, particularly situations in which investigators may have accepted payment from private entities in return for allowing their names to be used as authors on publications in which they had very limited input. In fact, NIH's Intramural Research Program has authorship guidelines that are comparable to those described in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, which were developed by the Internal Committee of Medical Journal Editors.

While the NIH extramural policy governing NIH grantees does not use the term ghostwriting, Federal regulations and policies relating to Public Health Service (PHS)-supported research could be applicable to ghostwriting, depending on the specific circumstances of a particular case. For example, a case of ghostwriting involving NIH-funded researchers may be appropriate for consideration as a case of plagiarism; i.e., the appropriation of another person's ideas, processes, results, or words without giving appropriate credit; or fabrication, i.e., making up data or results and recording or reporting them. Such a case would be handled by the Office of Research Integrity (ORI) of the Department of Health and Human Services (HHS), which investigates research misconduct as defined in the PHS's 42 C.F.R. Parts 50 and 93, *Policies on Research Misconduct and the Final Rule*. If ORI makes a finding of research misconduct, the NIH may take appropriate enforcement action(s), which could include modification of the terms of the award, suspension, termination, withholding of support, temporary withholding of payment, conversion from an advance payment method to a reimbursement method, or debarment, among other options.

The NIH believes that ghostwriting should be addressed when scientific articles citing extramural Federal funding are submitted to journals for publication. Current policy requires all HHS grantees to acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. However, it does not require that all parties who contribute to a publication, including those that contribute financially, be acknowledged. The NIH is considering how best to address the issue of ghostwriting in the development and authorship of medical literature arising from Federal research funding.

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