

Jay D. Amsterdam: The Paroxetine 352 Bipolar Study Ethical Conduct

**5. Attachment G (Letter to the Office of Research Integrity –
Lawyer's letter excerpt)**

According to a letter written by Dr. Francis Collins, Director of the NIH, ghostwriting that involves a federal grant may be cause for an investigation of plagiarism. Dr. Collins stated in his letter, which was published on POGO's website: [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. (Attachment G.)

Attachment G

Letter from Francis S. Collins to Paull Thacker.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 17 2011

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/or 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.

As you are aware, the NIH, on behalf of HHS and the PHS, is engaged in the rulemaking process to revise the regulations governing investigator financial conflict-of-interest (42 CFR Part 50 Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* and 45 CFR Part 94, *Responsible Prospective Contractors*). Because of its potential to create conflicts-of-interest that could bias or otherwise inappropriately influence NIH-supported research, "paid authorship" was specifically included in the proposed revisions to the regulations. By including "paid authorship" in the definition of "Significant Financial Interest" in the proposed rule, the NIH is sending a clear message to institutions and investigators alike that we support the principles of transparency and accountability in research and that institutions and investigators engaging in such activity may be subject to more rigorous disclosure and reporting. The proposed rule may be accessed at <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480af37ce>.

The NIH is committed to preserving the public trust in the objectivity of NTH-supported research, and we strongly believe that all research should be conducted with the highest scientific and ethical standards. Thus, we have proposed substantial changes to the existing financial conflict-of-interest regulations to increase accountability and transparency, which are vital to managing the essential relationships between Government, NIH-funded research institutions, and the private sector.

Thank you again for your interest in the NIH and our programs. I am also sending this response to Ms. Brian.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Francis S. Collins". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

September 2, 2021