

Renn Medicine

Office of the General Counsel

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March 3, 2020

Elisabeth Handley, M.P.A.
Director, Office of Research Integrity
U.S. Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

Re: ORI 2012-33

Dear Ms. Handley:

This office represents The Trustees of the University of Pennsylvania, and I am writing in response to the December 20, 2019, letter to you from Michael L. Baum, Esquire, an attorney representing Dr. Jay D. Amsterdam, the original complainant in the above-referenced case, and a former University of Pennsylvania faculty member.

Mr. Baum's letter substantially misrepresents the investigation undertaken by the University of Pennsylvania into the original complaint, which did indeed take into account information from GlaxoSmithKline reflecting the use of professional writers during the drafting of the June 2001 paroxetine paper. Critically, however, the University concluded that the use of a "ghostwriter" did not constitute plagiarism or any other form of research misconduct as it was defined at the time the article in question went to publication. In this finding ORI concurred, as indicated by the response ORI provided to Dr. Amsterdam's attorneys (see Letter from Wright to Amsterdam of 2/7/13, a copy of which is attached hereto as Exhibit A). Specifically, Dr. Donald Wright, writing as director, stated as follows:

ORI finds that the use of a ghostwriter does not meet ORI's definition of plagiarism. ORI's working definition of plagiarism, as explained on its website, is the "theft or misappropriation of intellectual property . . . [or] the substantial unattributed textual copying of another's work." There is no assertion of theft or misappropriation in this case and the facts indicate that the authors, including both the alleged ghostwriters and the named authors, were collaborators. Neither the professional writers nor the authors objected to the collaboration. Furthermore, it is clear from the record that the named authors each made substantial

contributions to the underlying research and/or the processes of drafting and reviewing each article. . . . ORI also finds that the use of a ghostwriter was not a "practice that seriously deviat[ed] from those that are commonly accepted within the scientific community" at the time that the article was written and published. ORI concurs with the University of Pennsylvania's description that ghostwriting was not an uncommon or unethical practice in the late 1990s and early 2000s and, therefore, that it was not a practice that seriously deviated from those commonly accepted within the scientific community.

In sum, and contrary to Mr. Baum's claims, there is no new, material factual information in this case, nor actually has there ever been a material factual issue. The University recognized that the authors collaborated with professional writers when drafting the paper, and the University concluded that such collaboration in 2001 did not constitute research misconduct. The complainant however insists on an alternative interpretation of the facts – one which ORI has explicitly rejected – and disingenuously seeks reconsideration of this alternative interpretation by claiming there are new relevant facts.

We respectfully request that you reject this attempt to reargue an issue decided long ago, and respectfully submit that the matter is and should remain closed. Nevertheless, if any further background would be helpful, please do not hesitate to contact the undersigned.

Sean V. Burke/epe

Sincerely,

Sean V. Burke

SVB/lpe Enclosures

cc: Michael L. Baum, Esq.