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March 30, 2020

Elisabeth Handley, M.P.A.
Director, Office of Research Integrity
U.S. Department of Health and Human Services
Office of Research Integrity
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RE: ORI 2012-33 - Complaint of Scientific Misconduct against Dwight L. Evans,
Laszlo Gyulai, Charles B. Nemeroff, Gary S. Sachs, and Charles L.
Bowden

Dear Ms Handley:

I am writing to you pursuant to a March 3, 2020 letter to your office from Sean V. Burke, Esq., counsel for the University of Pennsylvania, pertaining to my December 20, 2019 correspondence to you regarding newly-available evidentiary documents related to the above-referenced research misconduct case. These Scientific Therapeutics Information, Inc. (STI) documents appeared on the internet in June 2019 and revealed the presence of heretofore unknown acts of grave research misconduct that occurred during the course of the GlaxoSmithKline (GSK) paroxetine 352 bipolar depression trial, which was chiefly supported by a grant from the National Institute of Mental Health (MH-51761).

The newly-posted STI documents were not available to the ORI in 2013 at the time Dr. Wright of the ORI provided his February 7, 2013 letter of adjudication to our client, Dr. Amsterdam.

As my December 20, 2019 letter to you asserted, these new STI documents clearly provide documentary evidence that our client's original allegations of research misconduct far exceeded the mere presence of ghostwriting. The STI documents provide a detailed web of data manipulation, data suppression, and deliberate deception by the above-referenced respondents, as well as GSK and STI paid employees – as originally alleged by our client.

You may recall that our client, Dr. Amsterdam, was Professor of Psychiatry at the Perelman School of Medicine of the University of Pennsylvania in July of 2011, when he originally filed the initial July 8, 2011 complaint of scientific misconduct. Subsequent to this filing, it appears that the University of Pennsylvania (herein after referred to as Penn) undertook an incomplete investigation of Dr. Amsterdam's allegations of scientific misconduct against Dr. Dwight, L Evans *et al.*

At the time of Penn's investigation in 2011, several good faith attempts were made by this office to avail Penn of the STI evidence, but it was never clear to us that this information was properly considered. As a result, Penn publicly exonerated all of the named respondents of wrongdoing and whitewashed away Dr. Amsterdam's complaint of research misconduct.

It now appears that Penn and Mr. Burke are asserting the position that all relevant, factual evidence pertaining to the paroxetine 352 misconduct allegations was examined by Penn and the ORI, and that the STI documents pertaining to this case (which we have now provided to Penn and to the ORI) do not provide any new, factual information. With that erroneous assumption, Penn and Mr. Burke believe our client's request to re-open his case, despite this additional available evidence, should be declined by your office.

Pursuant to Mr. Burke's March 3, 2020 request to your office to deny our request to re-open the above-referenced case, we would respectfully provide the following additional information:

1. At the outset, Mr. Burke has misrepresented our client, Professor Amsterdam, as being merely "*a former University of Pennsylvania faculty member.*" In fact, Dr. Amsterdam has been on the Penn faculty continuously since 1977 and continues to be an active Emeritus Professor of Psychiatry on the faculty of the Perelman School of Medicine at the University of Pennsylvania to this very day. Although Dr. Amsterdam's academic title is now that of an Emeritus Professor, Dr. Amsterdam continues to be an active member of the senior and emeritus faculty at Penn, and is still an active psychopharmacology researcher at Penn who continues to widely publish his scientific findings.

2. Mr. Burke's March 3, 2020 letter asserts that: "*Mr. Baum's letter substantially misrepresents the investigation undertaken by the University of Pennsylvania into the original complaint....*" of research misconduct alleged by Dr. Amsterdam. Mr. Burke's assertion is false. Dr. Amsterdam's attorneys have most definitely not misrepresented anything at all related to the conduct of his allegations in the above-referenced case.

3. In his March 3, 2020 letter, Mr. Burke asserts that Penn's 2011 investigation of Dr. Amsterdam's allegations of research misconduct were fully and adequately investigated by the Penn inquiry committee, "*which did indeed take into account information from GlaxoSmithKline reflecting the use of professional writers during the drafting of the-June 2001 paroxetine paper.*"

While Mr. Burke does correctly assert that Penn's original inquiry committee "*did take into account information from GlaxoSmithKline reflecting the use of professional writers during the drafting of the-June 2001 paroxetine paper....*", he now fails to indicate to the ORI that the Penn

inquiry committee failed to verify the review of the STI documents despite repeated efforts by this office to assist Penn in 2011. While it appears that Mr. Burke may want to imply that the STI documents in question were indeed part of the cache of GSK documents provided to Penn by GSK in 2011, it still appears that the STI documents in question were not a part of the documents provided to Penn by GSK (see section 5 below). Hence, it still appears neither Penn nor ORI reviewed the inculpatory STI documents.

As we indicated in our December 20, 2019 letter, the STI documents clearly show that the fraud and misconduct that was alleged by our client went far beyond that of mere ghostwriting. To characterize ghostwriting in the facilitation of fraud as a “collaboration,” as Mr. Burke asserts, euphemistically disguises the reality of the situation.

It now appears that Penn is trying to have it both ways; i.e., Penn publicly insists that there were no ghostwriters involved in the production of the paroxetine 352 article, while at the same time, indicating to the ORI that there was, indeed, ghostwriting involved in the production and misrepresentation of the paroxetine 352 study report – but that this ghostwriting represented the complete extent of the research misconduct allegations. In other words, there is an explicit contradiction in Penn’s attempt to defend the named authors on the paroxetine 352 article, while simultaneously asserting that ghostwriters did and did not write the 352 article.

As a result of this sleight-of-hand, Penn’s defense on ghostwriting has been the subject of comedy in various published and posted articles (See for example: <https://www.madinamerica.com/2012/03/the-george-constanza-excuse-for-medical-ghostwriting/>) It should also be noted, as revealed in the newly posted STI documents, that one of the ghostwriters of the 352 article is Ms. Sally Laden, the most infamous of ghostwriters who has been exposed in numerous scandals relating to the publications of fraudulent clinical trial reports, including GSK’s paroxetine study 329.

As Dr. Amsterdam’s original research misconduct allegations stated, and as our recent (December 20, 2019) letter to the ORI reiterated, Penn is attempting to present conflicting findings in order to absolve the University and its professors from the appearance of wrongdoing; while presenting the opposite to the ORI, because, in the past, the ORI did not regard ghostwriting as research misconduct.

The academic respondents all denied that ghostwriters were involved in the production of the paroxetine 352 manuscript. Moreover, in his testimony to Penn’s inquiry committee, and in public statements made by Penn on his behalf, Dr. Evans (who was then Chairman of the Department of Psychiatry at Penn) asserted that there were no ghostwriters involved in the production of the 352 manuscript.

However, as the new STI documents clearly demonstrate, this testimony by Evans to the Penn inquiry committee was clearly misleading and false (and was therefore also misleading to the ORI). This misrepresentation by Evans and Penn is now made plain by the contents of the STI documents

– which show that Evans did, indeed, correspond with the STI ghostwriters, and that this correspondence was conducted on the Penn email server (a fact that was known to Penn in 2011).

4. In his March 3, 2020 letter, Mr. Burke asserts that “*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.*” Mr. Burke engages in a sleight-of-hand with the ORI by doubling down on Penn’s assertion that, since ghostwriting and the misrepresentation of scientific data were acceptable to Penn back in 2001, that it was also defensible by Penn in 2011 to 2020, when Penn regards ghost writing as a form of plagiarism (or research misconduct). Our client continues to assert that the practice of scientific misconduct in the form of data manipulation, data misrepresentation and outcome deception whether performed by industry-paid ghostwriters, industry-paid employees, or university academics is a form of research misconduct regardless of when it occurred.

5. In his March 3, 2020 letter, Mr. Burke states: “*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.*”

It remains unclear exactly what documents were examined by Penn’s inquiry committee. In correspondence between this office and Mr. Burke after 2011, our client sought to obtain verification of the STI documents that may have been in Penn’s possession (and which the Penn inquiry committee may have examined in 2011). To this end, a letter was sent from this office to Mr. Burke on January 13, 2016 specifically requesting that Mr. Burke “*provide us with a complete listing of the Bates-labeled STI documents that were provided to the University by GSK pursuant to the above-referenced ORI inquiry in order for us, and the University, to determine finally whether or not the Bates-numbered confidential GSK and STI documents contained in the University’s possession are the same sealed GSK and STI documents in our firm’s possession.*”

By way of this undertaking, we sought to verify whether or not the STI documents that may have been in Penn’s possession in 2011 were the same as the STI documents in our possession that were produced as part of *In Re: Paxil, C.P. Ct. PA (On-Drug)* and concern the production of the report of paroxetine study 352.

A follow up letter of inquiry was again sent to Mr. Burke on March 8, 2016, pursuant to Penn’s failure to respond to our prior request for Penn’s validation of the Bates numbers that were on the STI documents in Penn’s possession. (See attached letter to Mr. Burke March 8, 2016 regarding his failure to respond.) On March 29, 2016, Mr. Burke opaquely replied: “*all relevant documents in [Penn’s] possession, subject to a confidentiality agreement [with GSK]... were shared with the inquiry committee*” (See attached letter from Mr. Burke, March 29, 2016).

Mr. Burke's most recent, March 3, 2020 letter to the ORI merely reaffirms his prior assertion that Penn “*did indeed take into account information from GlaxoSmithKline*”; but he fails to be clear as to whether this did include the actual STI documents described above. Thus, Penn’s failure to be clear and the failure to identify the STI documents by Bates numbers remains a substantial issue as

to whether or not Penn's 2011 inquiry into our client's misconduct allegations was complete and fully transparent.

The STI documents, now available in the public domain, and included by our client in our letter to ORI of December 20, 2019, clearly demonstrate that a substantial web of scientific misconduct had occurred that was characterized by data manipulation, data suppression, and other forms of research misconduct during the paroxetine 352 study.

For Mr. Burke to assert that our client has provided to the ORI and to Penn "*no new, material factual information in this case, nor actually has there ever been a material factual issue*" strains the limits of credulity. In this regard, the newly published STI documents and their release into the public domain can no longer be ignored by Penn or the ORI.

From the foregoing information, it now appears that the STI documents were not part of Penn's inquiry into Dr. Amsterdam's original allegations of scientific misconduct. In the absence of verification by Penn that their GSK-produced STI documents have the same Bates numbers that appear on the newly published STI documents, it appears that the evidence of research misconduct contained within the newly publicized STI documents were not part of Penn's 2011 inquiry into Dr. Amsterdam's allegations, and in turn, were not conveyed to the ORI for its final review and adjudication in 2013.

In summary, We respectfully request that you reject Mr. Burke's (i.e., Penn's) attempt to prevent the public examination of the newly available STI documentary evidence of research misconduct in the paroxetine 352 case and that you permit the above-reference misconduct case to be reopened for a complete and transparent investigation by an impartial inquiry committee that has no prior conflicts-of-interest.

Sincerely,



Michael L. Baum, Esq.

cc: Sean Burke, Esq. (via email)
Jay D. Amsterdam, M.D. (via email)