BAUM HEDLUND ARISTEI GOLDMAN PC
CONSUMER ATTORNEYS

Washington, D.C. Office
2101 L Street, N.W.
Suite 800
Washington, D.C. 20037-1526
Office (202) 466-0513
Fax (202) 466-0527

10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
Office (310) 207-3233
Fax (310) 820-7444
www.baumhedlundlaw.com

Philadelphia Office
1500 Market Street
12th Floor East Tower
Philadelphia, PA 19102-2100
Office (215) 665-5659
Fax (215) 569-8228

December 20, 2019

VIA U.S. CERTIFIED MAIL

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 - 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 on behalf of our client, Dr. Jay D. Amsterdam, Professor of Psychiatry (Emeritus) at the University of Pennsylvania who previously lodged a formal scientific misconduct complaint with your office on July 8, 2011 (Exhibit 1) and June 25, 2012 (Exhibit 2).

In response to Dr. Amsterdam's filing of the initial July 8, 2011 complaint of scientific misconduct, the University of Pennsylvania (herein after referred to as Penn) undertook a perfunctory and incomplete investigation of Dr. Amsterdam's allegations of scientific misconduct against Dr. Dwight, L Evans *et al.*, whereby Penn declined to examine vital evidence that would have supported Dr. Amsterdam's allegations. At the time of Penn's investigation, several good faith attempts were made by this office on behalf of our client to avail the University of this evidence, all of which were ignored. As a result of the incomplete investigation, Penn exonerated all of the named respondents of wrong doing and whitewashed away Dr. Amsterdam's complaint.

A letter from Dr. Wright (of the Office of Research Integrity) to Dr. Amsterdam dated February 7, 2013, indicated Dr. Wright's agreement with Penn's findings that the alleged research misconduct was merely that of ghostwriting and that plagiarism had not occurred. This determination enabled Penn to exonerate fraudulent misconduct committed by GlaxoSmithKline (hereinafter referred to as GSK), Scientific Therapeutics Information, Inc. (hereinafter referred to as STI) and the named respondents of Dr. Amsterdam's misconduct complaint (which alleged that plagiarism had indeed occurred and served the purpose of GSK in misrepresenting the results of the paroxetine 352 article published in *The American Journal of Psychiatry*).

The published 352 article[1] falsely concluded that paroxetine therapy is effective in bipolar depression without any meaningful manic or other side effects, when, in reality, the published results were manipulated and manufactured by GSK and STI employees.[2][3] *See* Exhibit 3.

As a result, the paroxetine 352 article in the *American Journal of Psychiatry* has been widely cited in the scientific literature as a seminal trial of antidepressant therapy in bipolar depression.

Recently, however, in June 2019, new evidence has come to light supporting Dr. Amsterdam's allegations of scientific misconduct. This evidence appeared on the Drug Industry Document Archive (DIDA) website of the University of California, San Francisco. The majority of the evidence was produced by STI as part of paroxetine litigation from *In Re: Paxil, C.P. Ct. PA (On-Drug)*:
https://www.industrydocuments.ucsf.edu/drug/collections /paxil-litigation-documents/j..

These documents contain vital evidence supporting Dr. Amsterdam's allegations of scientific misconduct that were not previously examined by Penn (or your office).

As a result of this recent internet posting and its subsequent publication (Exhibit 3), we now respectfully request that the Office of Research Integrity of the HHS formally re-open our client's case (#2012-33) for the purpose of undertaking a complete and transparent examination of all available evidence, by Penn and your office.

Because the research performed in the paroxetine 352 study was conducted on behalf of the U.S taxpayer via NIMH funding , we respectfully request that the misconduct case be re-opened in order to correct the scientific record about errors of fact and judgment in Penn's prior adjudication of this case.

The newly available documents reveal that:

1. The academic respondents in this case (i.e., Drs. Evans, Guylai, Nemeroff, Sachs, and Bowden) appear to have misled (either directly or indirectly) the Penn ORI Inquiry Committee and the Office of Research Integrity as to the extent of their involvement in the paroxetine 352 study. (*see* Exhibits 2 and 3). They further appear to have misled Penn and ORI investigators as to the extent of their true involvement in the drafting of the 352 manuscript (*see* Exhibit 3). Moreover, the respondents misled *The American Journal of Psychiatry,* their respective universities, and U.S. taxpayers as to the extent of their

[1] Nemeroff CB, Evans DL, Gyulai L, Sachs GS, Bowden CL, Gergel IP, Oakes R, Pitts CD. Double-blind, placebo-controlled comparison of imipramine and paroxetine in the treatment of bipolar depression. American Journal of Psychiatry, 2001,158(6), 906-912.
[2] Amsterdam JD, McHenry, LB.The paroxetine 352 bipolar trial: A study in medical ghostwriting. *International Journal of Risk & Safety in Medicine*, 2012, 24, 221–231
[3] Amsterdam JD, McHenry LB: The Paroxetine 352 Bipolar Study Revisited: Deconstruction of Corporate and Academic Misconduct, Journal of Scientific Practice and Integrity, 2019, 1(1), 1-12.

conflict-of-interest with GSK or the extent of their involvement in the conduct of the paroxetine 352 study (*see* Exhibit 3).

2. The newly available evidence strongly suggests that the respondents named in Dr. Amsterdam's complaint are guilty of misappropriation of intellectual property, i.e., claiming authorship on a scientific article for which they did little, if any, work necessary to merit authorship (*see* Exhibit 3). Prior claims to the contrary by Penn and your office were based upon an incomplete review of the evidence. However, the newly available STI documents provide conclusive evidence supporting Dr. Amsterdam's complaint of scientific misconduct (*see* Exhibit 3).

3. The newly available evidence indicates that the paroxetine 352 manuscript was entirely written and produced by paid employees of GSK and STI (without any assistance or input from the named respondents) (*see* Exhibit 3). Furthermore, the newly available documents portray a detailed picture of how GSK and STI employees manipulated the results of the paroxetine 352 study (including sample size estimates, statistical outcome results, and safety data) that favored paroxetine, and that were unwarranted, and potentially dangerous to patients (*see* Exhibit 3).

4. The newly available evidence reveals a clear cut conflict-of-interest and corruption of journal editorial oversight by *the* editors of *The American Journal of Psychiatry*, whereby the plagiarized and seriously flawed 352 manuscript (which had been rejected for publication by independent peer reviewers) was surreptitiously and corruptly "pulled over the line" for publication by the journal editor (who was a friend of the lead author on the 352 manuscript, and who was also a recipient of multiple GSK payments for prior and current work on GSK-related projects) (*see* Exhibit 3).

Pursuant to an assertion that Dr. Amsterdam's request to re-open his misconduct complaint may have exceeded the statute of limitations for such an undertaking, we would assert that the newly available STI documents have only recently become available in June of 2019; and were previously unexamined by Penn or your office as part of our client's original ORI complaint. We would further assert that the Amsterdam complaint continues to meet 'the exception clause' for the statute of limitations , as the published paroxetine 352 article has been widely viewed as an influential study that is cited more than 500 times since its publication (including its citation in the influential consensus statement by the ISBD "Taskforce on antidepressant use in bipolar disorders" - Pacchiarotti I, Bond DJ, Baldessarini, RJ,*et al*., The International Society for Bipolar Disorders (ISBD) Task Force report on antidepressant use in bipolar disorders. *American Journal of Psychiatry,* 170(11):1249-1262, 2013).

Finally, the newly available STI documents clearly indicate the presence of fabrication and falsification of results in the paroxetine 352 article (*see* Exhibit 3).

In summary, given the newly available evidence pertaining to Dr. Amsterdam's misconduct complaint, we respectfully request that you re-open Dr. Amsterdam's case for further investigation

and adjudication, and you reconsider your prior erroneous conclusions about this important case. We continue to assert the importance of performing a complete and transparent investigation of all available evidence (including the newly available STI documents) and hope that you will comply with this request.

Sincerely,

Michael L. Baum, Esq.

Enclosures

cc: Dr. Jay D. Amsterdam (*via Electronic Mail with Enclosures)*
Sean V. Burke, Esq.,
Associate General Counsel, Univ. of Pennsylvania (*via Electronic Mail with Enclosures)*
Senator Charles Grassley (*via U.S. Mail without Enclosures)*
J. Larry Jameson, MD, PhD, Dean, Perelman School of Medicine (*via Electronic Mail without Enclosures)*
Amy Gutmann, PhD, President, University of Pennsylvania (*via Electronic Mail without Enclosures)*