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Jay D. Amsterdam: The paroxetine 352 bipolar study

Ethical conduct

1. Email exchange between Jay D. Amsterdam and Thomas A. Ban

Dear Tom:

Thank you for your nice email, and for your suggestions regarding the INHN posting of the paroxetine 352 documents

Pursuant to your suggestions (below), please allow me to respond to each numbered item (below), with my responses embedded beneath each numbered suggestion:

Many thanks for agreeing to post these vital historical documents about an ongoing, if terribly unfortunate, aspect of our field on the INHN historical website.

Yours most kindly,

Jay

Dear Jay,

Thank you very much for sending me the impressive documentation of your "paroxetine" project. My suggestion is that we should post for our "historical record":

Your letter to the Office of Research Integrity

There have been several letters from my attorney to the ORI that include (a) my original July 8, 2011 research misconduct complaint (containing all of the Penn email and other related documents). I already sent this to you as attachment #1. Although not sent to you, I would be happy to provide the actual attachment evidence documents contained in the July 8, 2011 complaint.

The reply of the Office of Research Integrity to you with their findings of the Inquiry

Regrettably, the letter to me from the ORI in response to my July 8, 2011 and June 25, 2012 research misconduct complaints has been designated by the ORI as ‘confidential; and my attorneys have advised me against posting any document designated as ‘confidential”. On the other hand, in lieu of your requested ORI letter to me, I do have a non-designated letter from my attorney to the ORI discussing their findings of my research misconduct complaints, that are not designated as confidential. I would be happy to see if I could obtain clearance from my attorney to post this letter in lieu of the ORI letter to me.

Your letter to the University (if there was a letter) related to 1:

Regrettably, the letter from the University to me containing the University's investigatory findings of my misconduct complaints against their professors, is also designated as "confidential." As a result of Penn's designation of confidentiality, my lawyer wrote the June 25, 2012 (2nd research misconduct) letter to the ORI, in which he noted most of the findings in the University's letter to me. This 2nd research misconduct letter of June 25, 2012 was already sent to you as attachment #2. Thus, it contains a point by point rebuttal of the University's findings (or cover up).

The reply of the University to your letter or the document in which they let you know the result of their inquiry.

Regrettably, all University documents were designated as 'confidential' and, thus, I have been advised by my attorney not to post these documents. However, my point by point response to the University's finding are contained in my June 25, 2012 letter to the ORI (see #3 above). However, I do have other letters to the ORI (by my attorney) that describe in exquisite detail the shortcomings of the University's investigation (or their obfuscation thereof) that are not designated as confidential, and which would be of historical interest to INHN readers (one of which I sent to you as attachment #3). I would be happy to see if I can obtain clearance to post these letters on the INHN website.

5. Documentation of misappropriation (1 piece)

Are you suggesting that I select only one (1 of the inculpatory STI documents that I sent to you that demonstrates "misappropriation"; or, are you suggesting that I provide you with some other evidence of "misappropriation"? I'm not exactly certain of what you mean by "misappropriation." Can you give me an example of what you mean?

Documentation of falsification (1 piece)

Are you suggesting that I select only one (1 of the inculpatory STI documents that I sent to you that demonstrates "falsification"? I'm not exactly certain of what you mean by "falsification." Falsification of what? Can you give me an example of what you mean?

Documentation of corruption (1 piece)

It may be difficult for me to select only one (1) item from the STI documents to demonstrate corruption; given that the numerous examples of the corruption demonstrated within the STI documents that I provided to you range from the corruption of ghost writing of the Am J Psychiatry article, to plagiarism by the academic authors (who were not involved in either the writing of the article or in the conduct of the research study), to the corruption of the editor of the American Journal of Psychiatry in publishing the rejected manuscript, to the cover up by the University of the wrong doing of their professors, to the corruption of the academic authors and the Universities lying to the ORI investigators and the public about there being no ghost writers involved in the production of the published article (while email documentation clearly shows evidence of this

practice on the University email servers, etc, etc, etc. Put simply, there was so much corruption involved in this case, that I'm not sure which of the STI documents I would pick first! They all show inculpatory evidence. Finally, please be aware that there were other STI-related documentary evidence of grave research misconduct, that were not provided to you because they had a 'confidential' designation affixed to them. But from what has been provided to you for the historical record of our field, strains the limits of academic and professional ethics – to put it simply. Please advise.

Items 5, 6 and 7 could be summarizing essays that would set the stage for an active exchange.

Kindest regards,

Tom

August 5, 2021

2. Letter to the Office of Research Integrity – Lawyer's letter

Your letter to the Office of Research Integrity

> There have been several letters from my attorney to the ORI that include (a) my original July 8, 2011, research misconduct complaint (containing all of the Penn email and other related documents). I already sent this to you as attachment #1. Although not sent to you, I would be happy to provide the actual attachment evidence documents contained in the July 8, 2011 complaint.
>
> The letter to the Office of Research Integrity was written and sent by my lawyer It includes my Timeline for publication of Paxil Bipolar Study 352 without my knowledge

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July 8, 2011

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U.S. Department of Health and Human Services
Office of Research Integrity
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Re: Complaint of Scientific Misconduct against Dwight 1. Evans, Laszlo Gyulai; Charles Nemeroff, Gary S. Sachs and Charles 1. Bowden

Dear Dr. Wright:

On behalf of Dr. Jay D. Amsterdam, Professor of Psychiatry at the University of Pennsylvania, a charge of research misconduct is hereby submitted against Dr. Dwight L. Evans, Professor of Psychiatry and Chairman of the Department of Psychiatry at the University of Pennsylvania, Dr. Laszlo Gyulai, Associate Professor of Psychiatry at the University of Pennsylvania, Dr. Charles B. Nemeroff, Professor of Psychiatry and Chairman of the Department of Psychiatry at the University of Miami, Dr. Gary S. Sachs, Professor of Psychiatry at Harvard University, and Dr. Charles L. Bowden, Professor of Psychiatry and Chairman of the Department of Psychiatry at the University of Texas.

Dr. Amsterdam believes the individuals named above engaged in scientific misconduct by allowing their names to be appended to a manuscript that was drafted by a "medical communications company" (Scientific Therapeutics Information, "STI") hired by SmithKline Beecham (now known as GlaxoSmithKline, "GSK"), and which Dr. Amsterdam contends misrepresented information from a scientific research study (Paroxetine Study 352), which was funded by GSK and NIH. The manuscript (hereinafter "Study 352") was eventually published in the American Journal of Psychiatry (158:906-912; June 2001) suggesting that Paxil may be beneficial in the treatment of bipolar depression, without acknowledging the medical communication company's contribution or the extent of GSK's involvement. The published manuscript was biased in its conclusions, made unsubstantiated efficacy claims and downplayed the adverse event profile of Paxil. (Attachment A.) Since its publication, study 352 has been cited in hundreds of medical journal articles, textbooks and practice guidelines up to 2011. (See, e.g., Attachment B and C.) Although Dr. Amsterdam was a Co-Principal Investigator of

the study and possibly enrolled the largest number of patients, he was excluded from the final data review, analysis and publication. (See Attachment D.)

Dr. Amsterdam only recently became aware that two of the lead authors of Study 352, including his direct supervisor, were linked to ghostwriting through a letter from the Project On Government Oversight (POGO) to NIH Director Francis Collins in November 2010, posted on POGO's website at http://www.pogo.org/pogofileslletters/ public-health/ph-iis-20101129.html. Like the examples contained in POGO's letter to NIH, Dr. Amsterdam believes the manuscript published in the American Journal of Psychiatry was ghostwritten by STI, which was hired by GSK and paid with GSK funds, and that the individuals above lent their names as "authors" to the manuscript.

Based upon evidence presented in this complaint and the documents attached hereto, it appears that most, if not all, of the" guest authors" were determined by GSK in conjunction with the "medical communications" firm, STI. STI has had a longstanding history of ghostwriting scientific and medical articles and textbooks which have been attributed to prominently known academics - a practice that has been the subject of mounting criticism. See, for example, an editorial in the Journal of the American Medical Association regarding ghostwriting in relation to Merck's promotion and sales of VIOXX. (Attachment E.)

The acknowledgement section of the published manuscript states that Study 352 was conducted and published with support from NIMH grant MH-51761. (Attachment A.) According to a recent search of the NIH Reporter database, NIMH grant MH-51761 was part of an "infrastructure support" and "core-patient recruitment and assessment" project for NIH-funded clinical research trials. (Attachment F.) In this case, it was used to support the recruitment and assessment of research subjects for participation in this GSK-sponsored and GSK-funded clinical trial of Paxil for the treatment of patients with bipolar type I major depression.

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.)

Moreover, according to a report on ghostwriting by Senator Charles Grassley (dated June 24, 2010), the University of Pennsylvania considers ghostwriting to be equivalent to plagiarism.[1]

While this incident took place some time ago (i.e., 2001), the manuscript has been cited hundreds of times up through 2011 according to an internet search on Google Scholar. (Attachment B.) In fact, Dr. Gyulai cited the paper again in a study he published in 2007 in the New England Journal of Medicine (Attachment H) and Dr. Sachs cited the paper in 2011 in the Journal of Clinical Psychiatry. (See Attachment C, Record 1.)

Moreover, the purported "findings" of Study 352 and the published results from other studies and articles that have cited this study have been used to support the design and implementation of at least two other NIMH-funded grants to study the efficacy and safety of antidepressant drugs (like Paxil) in bipolar depression. See, e.g., MH080097, Prevention of Relapse and Recurrence of Bipolar Depression and MH060353, Treatment of Bipolar Type II Major Depression.

Dr. Amsterdam submits this complaint in the hopes that ORI will conduct an investigation, impose appropriate penalties to correct the past publication of Study 352' s results, to prevent similar conduct from happening again, and hopefully prevent further use of this paper to support the dangerous prescription of Paxil to patients diagnosed with bipolar depression.

Pursuant to 42 C.F.R. Part 50.103(d)(13), Dr. Amsterdam should receive full and complete protection from retaliation and/ or defamation by either the University of Pennsylvania or any other parties involved in the production and publication of Study 352. Dr. Amsterdam requests the protections described in ORI's "Handling Misconduct - Whistleblowers." (Attachment I.)

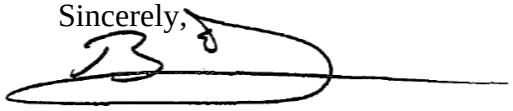
To ensure that this complaint is taken seriously, and to alert interested parties, we are providing copies of this correspondence to Senator Charles Grassley, Senator Herb Kohl, and the Chairman and Ranking members of the House Energy and Commerce, and the House Committee on Oversight and Government Reform.

In the following pages, we will layout Dr. Amsterdam's complaint in more detail.

[1] See: http://grassley.senate.gov / aboutjupload/Senator-Grassley-Report.pdf

Thank you for your time and interest in this important matter. Please apprise me of any further help I may offer to you.

Sincerely,



Bijan Esfandiari, Esq.

BE:gb

cc:

Dr. Jay Amsterdam
Senator Charles Grassley
Senator Herb Kohl
Sincerely, c::239
Bijan Esfandiari, Esq.
Chairman, House Energy and Commerce, Fred Upton
Ranking Member, House Energy and Commerce, Henry Waxman
Chairman, House Committee on Oversight and Govt. Reform, Darrell E. Issa
Ranking Member, House Committee on Oversight and Govt. Reform, Elijah Cummings

DR. AMSTERDAM'S TIMELINE RE PUBLICATION OF PAXIL BIPOLAR STUDY 352 WITHOUT HIS KNOWLEDGE

In the mid-1990's, Dr. Amsterdam became a Co-Principal Investigator on a clinical trial, Paroxetine Study 352, comparing the antidepressant drugs imipramine (Tofranil®) and paroxetine (Paxil®) for the treatment of bipolar type I major depression (or manic depression). The trial was sponsored, in part, by GlaxoSmithKline which sells paroxetine under the brand names Paxil® in the US and Seroxat in other countries.

Dr. Amsterdam recruited one of the largest, if not the largest, patient samples into a study that comprised 18 other investigative-sites.

In early 2001, Dr. Amsterdam became aware that Dr. Dwight Evans and Dr. Laszlo Gyulai were attempting to publish data from the above referenced study. Although Dr. Amsterdam was a Co-Principal Investigator of Study 352 and enrolled one of the largest numbers of patients, he was excluded from the final data review, analysis and publication. (Attachment J, K, L and D.)

Dr. Amsterdam contacted his immediate supervisor and department chairman, Dr. Dwight L. Evans about the matter. In a March 22,2001 email to Dr. Amsterdam, Dr. Evans stated that he had discussed the issue with Dr. Karl Rickels who was also a

professor in the Department of Psychiatry at the University of Pennsylvania and Dr. Gyulai's direct supervisor. Dr. Evans assured Dr. Amsterdam that Dr. Rickels would be reviewing the matter and, once accomplished, he trusted there would be "an equitable outcome." (Attachment M.)

Dr. Amsterdam sent a follow-up email to Dr. Rickels on April 1, 2001 asking him what he had found during his investigation. Dr. Amsterdam explained to Dr. Rickels that, if he (Dr. Rickels) felt uncomfortable dealing with the matter, that he should let Dr. Amsterdam know so that he (Dr. Amsterdam) could "take up the issue with others at the University and/or the American Journal of Psychiatry." (Attachment J.) The American Journal of Psychiatry accepted the manuscript for publication in January 2001 (Attachment A at p. 911) and the study was eventually published in the June 2001 edition of the journal. Id.

On April 3, 2001, Dr. Rickels sent Dr. Amsterdam a letter discussing what he had learned during his investigation. (Attachment K.) In that letter, Dr. Rickels noted, among other things, the following information:

(1) Dr. Amsterdam was co-investigator of the trial;
(2) Dr. Amsterdam had enrolled more patients in the trial than Dr. Gyulai;
(3) The ghostwriting firm, STI, had chosen Dr. Gyulai as the paper's first author;
(4) GSK had decided to replace Dr. Gyulai as first author with Dr. Charles Nemeroff; and
(5) Academic investigators in the trial never reviewed or even saw the submitted manuscript.

On May 1, 2001, Dr. Amsterdam sent Drs. Evans and Rickels another email to explain that he was unsatisfied with the response and, since the last letter, there has been only "radio silence." As he wrote, "Am I to assume that it is okay in this department for a junior faculty member to abscond with data from a full professor and publish it without any ramifications?" (Attachment N.)

The following day, Dr. Rickels emailed Dr. Amsterdam and explained that Dr. Evans had tasked him (Dr. Rickels) with trying "to bring about a resolution." (Attachment O.)

On May 11, 2001, Dr. Amsterdam emailed Dr. Rickels and explained that he considered data that he (Dr. Amsterdam) accumulated in his research unit from the study "were misappropriated from me and used and published without my knowledge and without regard to the significant contribution that I made to this study." Dr. Amsterdam complained that the "theft and publication of [his] data should not go unnoticed and

uncensured." He proposed that Dr. Gyulai write a letter of apology and be censured in order to ensure "this situation does not happen again." (Attachment P.)

Ten days later, Dr. Rickels emailed Dr. Amsterdam stating that he had shared Dr. Amsterdam's comments with Dr. Evans and, once he received a reply from Dr. Evans, he (Dr. Rickels) would like to meet with Dr. Amsterdam to discuss the topic. (Attachment Q.)

On Jun 13,2001, Dr. Amsterdam again emailed Dr. Rickels to complain that there had been no resolution of the matter. Dr. Amsterdam wrote: "Before I contact either University officials or the editorial board of [the American Journal of Psychiatry] regarding this egregious behavior, I await your last efforts at resolution of this problem./I (Attachment R)

That same day, Dr. Rickels responded that Dr. Gyulai had been ill and that Dr. Amsterdam would be contacted soon. (Attachment S.)

On June 29, 2001, Dr. Amsterdam received a formal letter from Dr. Rickels stating that Dr. Gyulai had returned part-time from sick leave and he intended to speak with Dr. Gyulai concerning "this unfortunate situation ... today." (Attachment T.)

On July 5, 2001, Dr. Gyulai sent a letter of apology to Dr. Amsterdam. In that letter, Dr. Gyulai explained that control of the paper had been taken away from him and that GSK published the paper without circulating the draft to all the participants and only allowed him (Dr. Gyulai) to see a near-final draft "when only minor changes could be done." (Attachment L.)

Four days later, Dr. Amsterdam sent an email to Dr. Rickels stating that the apology was not sufficient in light of the "deliberate misappropriation and publication of [his] data" without his knowledge. Dr. Amsterdam was insistent that some sort of reprimand was necessary to ensure "plagiarism" of a colleague's data never happens again. (Attachment U.)

The following day, July 20, 2001, Dr. Rickels sent Dr. Amsterdam a letter stating "it is unfortunate that [GSK] did not circulate the manuscript to you and I regret that Dr. Gyulai did not share it with you. Once again, as Dr. Gyulai's Program Director, I have expressed my belief that he should have done so." (Attachment V.)

TIMELINESS OF COMPLAINT

According to Office of Research Integrity (ORI) guidelines, rules governing research misconduct only apply if such conduct occurred within six years, unless "the respondent continues or renews any incident of alleged research misconduct that occurred

outside the six-year limit through the citation, republication or other use for the potential benefit of the research record that is the subject of the allegation."

With respect to this condition, although the data were published in an NIH-supported study in 2001, Dr. Gyulai cited this study just four years ago, in a study published in 2007 in the New England Journal of Medicine. (Attachment H, at page 3.) This is well within the six-year window for filing a complaint of research misconduct. Moreover, the report that appeared under Dr. Evans', Dr. Gyulai's and the other authors' names has had an ongoing influence on the scientific field as evidenced by its citation in hundreds of medical journal articles, textbooks and practice guidelines, up through and including 2011. (See Attachment B and C.)

EVIDENCE OF POTENTIAL GHOSTWRITING / ALLEGED PLAGIARISM

In defense of Dr. Gyulai, Dr. Rickels sent Dr. Amsterdam a letter on April 3, 2001, explaining that the "medical communications" firm, STI, had chosen Dr. Gyulai as the paper's first author. (Attachment K.)

At the time, Dr. Amsterdam was not aware of STI's involvement in ghostwriting scientific studies on behalf of prominent academics (including Dr. Evans and the other individuals named in this complaint) to promote sales of pharmaceutical agents. However, such behavior is now well understood. For instance, the Journal of the American Medical Association published an editorial in April 2008, excoriating Merck & Co. Inc. for using STI to publish a ghostwritten article in 2002 in JAMA to push sales of VIOXX. (Attachment E.) According to this editorial:

> Perhaps some editors, investigators, reviewers, and readers would see little or no harm in this failed disclosure because all other disclosures were made. However, if there was nothing to hide, why were the names (and affiliations) of the individuals who actually wrote at least the first draft of the manuscript omitted?

Indeed, although the spectral fingerprints of STI are readily apparent, STI's involvement was not disclosed in the manuscript draft or the final published article that appeared in the American Journal of Psychiatry. (Attachment A and D.)

As it turned out, Dr. Amsterdam discovered that his own supervisor, Dr. Dwight L. Evans, to whom Dr. Amsterdam had been complaining, published a scientific editorial in the prestigious journal Biological Psychiatry in 2003 that was ghostwritten by the very same "medical communications" firm that ghostwrote the 2001 American Journal of Psychiatry article (i.e., STI). Dr. Amsterdam discovered this while reviewing a letter that

the Project On Government Oversight sent to NIH Director Frances Collins in November of 2010.[2]

According to documents, Sally Laden of STI ghostwrote the 2003 editorial for Biological Psychiatry for Dr. Dwight L. Evans and Dr. Dennis Charney. Dr. Charney was then an employee at the NIH Intramural Program and he is now Dean of Research at the Mt. Sinai School of Medicine in -New-YorK. (See e.g., Attachment Wand http://www.pogo.org/pogo-files/letters/public-health/ph-iis-20101129.html.)

In an email to a GSK employee, Ms. Laden wrote, "Is there a problem with my invoice for writing Dwight Evans' editorial for the [Depression and Bipolar Support Alliance], s comorbidity issue to Biological Psychiatry?" [See Attachment W] When the editorial was published, Drs. Evans and Charney "acknowledge[d] Sally K. Laden for editorial support." (Attachment X.)

In conclusion, it is ironic and troubling that Dr. Amsterdam brought his allegations of research misconduct to his direct supervisor and chairman, Dr. Evans, and his complaint was not only ignored by Dr. Evans (who simply handed it off to Dr. Rickels to resolve), but Dr. Evans himself was involved in the ghostwritten Study 352 article by STI and then, two years later, an editorial was also ghostwritten for him by STI.

DR. AMSTERDAM'S CRITICISMS OF THE PUBLISHED PAXIL BIPOLAR STUDY 352

First, the study failed to recruit a sufficient patient sample size to adequately test the primary efficacy outcome measure. The primary efficacy outcome measure failed to show superiority of either antidepressant drug treatment compared to placebo. This important information was not reported in the manuscript. The authors then relied on post hoc analyses of subsets of the data to find a favorable result for the antidepressant Paxil. Specifically, this result was accomplished by sub-dividing patient cohorts for each treatment into sub-groups of "high" (Le., ~8.0 mEqjL) versus "low" (Le., <8.0 mEqjL) baseline serum lithium levels after the primary data analyses were found to be . negative. This post hoc data presentation was then presented as the primary study finding, and gave the false impression that one group of patients with low lithium levels (who may be unable to tolerate higher lithium levels) showed superior benefit with Paxil versus placebo (compared to imipramine versus placebo).

Moreover, patients with "low" lithium levels were presented as being a distinct patient group who were somehow different from patients in the "high" lithium level group. In fact, this was a disingenuous distinction because all of the patients in the study had what were considered to be adequate and clinically therapeutic lithium levels, or they would have been discontinued from the trial. Moreover, this sub-division of treatment

[2] See: http://www.pogo.org/pogo-files/letters/public-health/ph-iis-20101129.html

cohorts into "high" versus "low" lithium level groups was not clinically meaningful and these data were added to the manuscript to produce a favorable outcome finding for promoting Paxil (in a study that was otherwise negative in its findings and that recruited an insufficient patient sample size to accurately test the null hypothesis for the primary efficacy measures).

Second, the published manuscript downplayed a well-known (and potentially dangerous) adverse event profile of Paxil. For example, the manuscript did not report any mania ratings (e.g., Young Mania Rating Scale), although the results section did hote that end-point mania analyses were performed. The manuscript portrayed Paxil as being safe and producing no manic symptoms or manic episodes (in either the entire Paxil-treated patient group or in the "high" or "low" lithium level sub-groups), a finding which was not supported by available clinical or research evidence in 2001 (or ubsequent to that date). As a result, the stated findings suggest that Paxil is a safe and well tolerated alternative to imipramine (the other antidepressant used in the study) which appeared to cause manic symptoms in both the "high" and "low" lithium level patient subgroups. Thus, these purported findings ran completely counter to almost all available clinical and research findings up to 2001 (and subsequent to that date), and suggested a treatment approach for bipolar depression (i.e., Paxil) which contradicted
much of the available clinical and research evidence, as well as most published practice guidelines for treating bipolar type I depression.

Third, the results in the published manuscript emphasized a substantial side effect profile for imipramine while minimizing and down-playing the side effect profile of Paxil. For example, the manuscript emphasized a substantial rate of sexual side effects for imipramine (an antidepressant drug not particularly known to produce this side effect), while down-playing the sexual side effect profile of Paxil, and suggested that there were no sexual side effects encountered with Paxil in the study. This was a grossly misleading fact which was further emphasized by the authors citing the medical literature indicting only imipramine side effects while simultaneously omitting citations from the medical literature that accurately report the incidence of Paxil sexual side effects. In this regard, the published manuscript stated that "patients treated with imipramine reported a higher incidence of abnormal ejaculation (18.8%) and impotence (25.0%) than did patients receiving paroxetine (0.0% and 6.3%, respectively) or placebo (5.0% and 0.0%, respectively)". Moreover, in the discussion section of the published manuscript, this "finding" is further supported by literature citing the high sexual side effect rate with imipramine while providing no citations for Paxil-induced side effects – even though Paxil's sexual side effects were well known at the time of publication. In fact, the side effect bias favoring Paxil was so supportive and contrary to the available medical literature in 2001 that it would be reasonable for a reader to wonder whether SmithKline Beecham, Inc. actually provided the side effect citations to the" authors" for publication in the published manuscript.

Alarmingly, despite the foregoing enumerated deficiencies, Study 352 and its published results have been relied upon as justification for prescribing Paxil to patients diagnosed with bipolar depression, a practice with little benefit, per the above, and substantial risk of stimulating a manic reaction with an increased risk of suicide and other dangerous adverse reactions.

*****

August 12, 2021

3. Attachments A, B, C and D (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

Dr. Amsterdam believes the individuals named above engaged in scientific misconduct by allowing their names to be appended to a manuscript that was drafted by a "medical communications company" (Scientific Therapeutics Information, "STI") hired by SmithKline Beecham (now known as GlaxoSmithKline, "GSK"), and which Dr. Amsterdam contends misrepresented information from a scientific research study (Paroxetine Study 352), which was funded by GSK and NIH. The manuscript (hereinafter "Study 352") was eventually published in the American Journal of Psychiatry (158:906-912; June 2001) suggesting that Paxil may be beneficial in the treatment of bipolar depression, without acknowledging the medical communication company's contribution or the extent of GSK's involvement. The published manuscript was biased in its conclusions, made unsubstantiated efficacy claims and downplayed the adverse event profile of Paxil. (Attachment A.) Since its publication, study 352 has been cited in hundreds of medical journal articles, textbooks and practice guidelines up to 2011. (See, e.g., Attachment B and C.) Although Dr. Amsterdam was a Co-Principal Investigator of the study and possibly enrolled the largest number of patients, he was excluded from the final data review, analysis and publication. (See Attachment D.)

Attachment A

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):906-12.

Attachment B

Google scholar search of citations for 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):906-12.

Attachment C

ICI Website of knowledge. 2 pages, 183 references for 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):906-12.

Attachment D

Final ghostwritten draft of Nemeroff et al. manuscript for publication in the Am. J. Psychiatry.

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. (Final draft of paper in Attachment A in Dr. Amsterdam's possession).

August 19, 2021

Attachments E and F (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

Dr. Amsterdam only recently became aware that two of the lead authors of Study 352, including his direct supervisor, were linked to ghostwriting through a letter from the Project On Government Oversight (POGO) to NIH Director Francis Collins in November 2010, posted on POGO's website at http://www.pogo.org/pogofileslletters/public-health/ph-iis-20101129.html. Like the examples contained in POGO's letter to NIH, Dr. Amsterdam believes the manuscript published in the American Journal of Psychiatry was ghostwritten by STI, which was hired by GSK and paid with GSK funds, and that the individuals above lent their names as "authors" to the manuscript.

Based upon evidence presented in this complaint and the documents attached hereto, it appears that most, if not all, of the" guest authors" were determined by GSK in conjunction with the "medical communications" firm, STI. STI has had a longstanding history of ghostwriting scientific and medical articles and textbooks which have been attributed to prominently known academics - a practice that has been the subject of mounting criticism. See, for example, an editorial in the Journal of the American Medical

Association regarding ghostwriting in relation to Merck's promotion and sales of VIOXX. (Attachment E.)

Project Number	Sub #	Project Title	Principal Investigator	Organization	FY	Admin IC
5R24MH051761-05	9002	CORE-NEUROENDOCRINOLOGY, NEUROCHEMISTRY, AND BRAIN IMAGING	BONSALL, ROBERT W.	EMORY UNIVERSITY	1998	NIMH
5R24MHQ51761-04	9002	CORE-NEUROENDOCRINOLOGY, NEUROCHEMISTRY, AND BRAIN IMAGING	BONSALL, ROBERT W.	EMORY UNIVERSITY	1997	NIMH
5R24MH0517B1-03	9002	CORE-NEUROENDOCRINOLOGY, NEUROCHEMISTRY, AND BRAIN IMAGING	BONSALL, ROBERT W		1996	NIMH
5R24MH051761-05	9001	CORE-PATIENT RECRUITMENT AND ASSESSMENT	GOODMAN, SHERRYL	EMORY UNIVERSITY	1998	NIMH
5R24MH351761-04	9001	CORE-PATIENT RECRUITMENT AND ASSESSMENT	GOODMAN, SHERRYL	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-03	9001	CORE-PATIENT RECRUITMENT AND ASSESSMENT	GOODMAN, SHERRYL		1996	NIMH
5R24MH051761-05	9004	CORE-EXPERIMENTAL DESIGN AND BIOSTATISTICS	MARSTELLER, FREDERICK A	EMORY UNIVERSITY	1998	NIMH
5R24MH051761-04	9004	CORE-EXPERIMENTAL DESIGN AND BIOSTATISTICS	MARSTELLER, FREDERICK A	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-03	9004	CORE-EXPERIMENTAL DESIGN AND BIOSTATISTICS	MARSTELLER, FREDERICK A		1996	NIMH
5R24MH051761-05	9003	CORE-BIOLOGICAL TISSUES AND FLUIDS	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1998	NIMH
5R24MH051761-05		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1998	NIMH
5R24MH051761-04	9003	CORE-BIOLOGICAL TISSUES AND FLUIDS	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-04		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1997	NIMH
3R24MH051761-04S1		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-03	9003	CORE-BIOLOGICAL TISSUES AND FLUIDS	NEMEROFF, CHARLES B		1996	NIMH
5R24MH051761-03		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1996	NIMH
5R24MH051761-02		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1995	NIMH
1R24MH051761-Q1A1		INFRASTRUCTURE SUPPORT PROGRAM	NEMEROFF, CHARLES B	EMORY UNIVERSITY	1994	NIMH
5R24MH051761-04S1	9001	CORE-PATIENT RECRUITMENT AND ASSESSMENT	Unavailable	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-04S1	9002	CORE-NEUROENDOCRINOLOGY, NEUROCHEMISTRY, AND BRAIN IMAGING	Unavailable	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-04S1	9003	CORE-BIOLOGICAL TISSUES AND FLUIDS	Unavailable	EMORY UNIVERSITY	1997	NIMH
5R24MH051761-04S1	9004	CORE-EXPERIMENTAL DESIGN AND BIOSTATISTICS	Unavailable	EMORY UNIVERSITY	1997	NIMH
Page Last Updated on March 8, 2011. This site is best viewed with internet Explorer (6.0 or higher) or Mozilla Firefox (2.0).						

The acknowledgement section of the published manuscript states that Study 352 was conducted and published with support from NIMH grant MH-51761. (Attachment A.) According to a recent search of the NIH Reporter database, NIMH grant MH-51761 was part of an "infrastructure support" and "core-patient recruitment and assessment" project for NIH-funded clinical research trials. (Attachment F.) In this case, it was used to support the recruitment and assessment of research subjects for participation in this GSK-sponsored and GSK-funded clinical trial of Paxil for the treatment of patients with bipolar type I major depression.

Attachment E

Catherine D. DeAngelis and Phil B. Fontanarosa: Impugning the integrity of medical science. The adverse effect of industry interest. Editorial. JAMA 2008;299:1833-5.

Attachment F

NIH RePORTER - NIH Portfolio Online Search Results. 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. Am J Psychiatry 2001;158(6):906-12.

U.S. Department of Health and Human Services

Home > RePORTER > Search Results

Search Results - NIH RePORTER-NIH Research Portfolio Online ...

There were 22 results matching your search criteria.

August 26, 2021

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.

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://wwvv.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,

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

September 2, 2021

6. Attachments H and I (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

Moreover, according to a report on ghostwriting by Senator Charles Grassley (dated June 24, 2010), the University of Pennsylvania considers ghostwriting to be equivalent to plagiarism.

While this incident took place some time ago (i.e., 2001), the manuscript has been cited hundreds of times up through 2011 according to an internet search on Google Scholar. (Attachment B.) In fact, Dr. Gyulai cited the paper again in a study he published in 2007 in the New England Journal of Medicine (Attachment H) and Dr. Sachs cited the paper in 2011 in the Journal of Clinical Psychiatry. (See Attachment C, Record 1.)

Moreover, the purported "findings" of Study 352 and the published results from other studies and articles that have cited this study have been used to support the design and implementation of at least two other NIMH-funded grants to study the efficacy and safety of antidepressant drugs (like Paxil) in bipolar depression. See, e.g., MH080097, Prevention of Relapse and Recurrence of Bipolar Depression and MH060353, Treatment of Bipolar Type II Major Depression.

Dr. Amsterdam submits this complaint in the hopes that ORI will conduct an investigation, impose appropriate penalties to correct the past publication of Study 352' s results, to prevent similar conduct from happening again, and hopefully prevent further use of this paper to support the dangerous prescription of Paxil to patients diagnosed with bipolar depression.

Pursuant to 42 C.F.R. Part 50.103(d)(13), Dr. Amsterdam should receive full and complete protection from retaliation and/ or defamation by either the University of Pennsylvania or any other parties involved in the production and publication of Study 352. Dr. Amsterdam requests the protections described in ORr's "Handling Misconduct - Whistleblowers." (Attachment I.)

To ensure that this complaint is taken seriously, and to alert interested parties, we are providing copies of this correspondence to Senator Charles Grassley, Senator Herb Kohl, and the Chairman and Ranking members of the House Energy and Commerce, and the House Committee on Oversight and Government Reform.

ATTACHMENT H

Sachs GS, Nierenberg AA, Calabrese JR, Marangell LB, Wisniewski SR, Gyulai L, Friedman ES, Bowden CL, Fossey MD, Ostacher MJ, Ketter TA, Patel J, Hauser P, Rapport D, Martinez JM, Allen MH, Miklowitz DJ, Otto MW, Dennehy EB, Thase ME.

Effectiveness of Adjunctive Antidepressant Treatment for Bipolar Depression. N Engl J Med 2007;356(17):1711-22.

ATTACHMENT I

Office of Research Integrity. Handling Misconduct – Whistleblowers. ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research. November 20, 1995. http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml.

September 9, 2021

7. Attachment J (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

"DR. AMSTERDAM'S TIMELINE RE PUBLICATION OF PAXIL BIPOLAR STUDY 352 WITHOUT HIS KNOWLEDGE"

In the mid-1990s, Dr. Amsterdam became a Co-Principal Investigator on a clinical trial, Paroxetine Study 352, comparing the antidepressant drugs imipramine (Tofranil®) and paroxetine (Paxil®) for the treatment of bipolar type I major depression (or manic depression).

The trial was sponsored, in part, by GlaxoSmithKline which sells paroxetine under the brand names Paxil® in the US and Seroxat in other countries. Dr. Amsterdam recruited one of the largest, if not the largest, patient samples into a study that comprised 18 other investigative-sites.

In early 2001, Dr. Amsterdam became aware that Dr. Dwight Evans and Dr. Laszlo Gyulai were attempting to publish data from the above referenced study. Although Dr. Amsterdam was a Co-Principal Investigator of Study 352 and enrolled one of the largest numbers of patients, he was excluded from the final data review, analysis and publication. (Attachment J, K, L and D.)

ATTACHMENT J

Dr. Karl Rickels, 11:03 AM 4/2/01 -0400, SKB Bipolar study

To: Dr. Karl Rickels
From: "Dr. Jay D. Amsterdam" < jamsterd@mail.med.upenn.edu>
Subject: SKB Bipolar study
Cc: dlevans@mail.med.upenn.edu
Bcc:

Attached:

Karl,

It has been about 5 or 6 weeks since I brought to your attention the troubling issue of investigator contribution and authorship on manuscripts from the SKB BP I study. You will recall that at least one manuscript from this study is in press to the Am J Psych, and other manuscripts may also have been submitted to other journals. Again, it is my feeling that as a major investigator in this nineteen-site study, I should have been provided with data for review and consideration for authorship on these manuscripts. As we discussed, it was agreed upon in 1995 by you, me and Dr. Gyulai that if I would have a major input into this study at the Penn site and serve as a major contributor to the study, then I should have input into data analysis and authorship. In our discussion several weeks ago you indicated your recollection of this agreement, and your understanding of the situation and its potential ramifications and that you would look into the matter. As I have not heard from you regarding this potentially troubling situation I thought that I would take the liberty of reminding you of it. As one of the articles is no doubt close to publication, I felt it necessary to speak with Dr. Evans. I did this several weeks ago regarding the situation and he indicated to me that he would speak to you about it.

As I previously indicated to you it is not my intention to put you in a difficult situation, and that if you feel uncomfortable helping out in this matter, please let me know so that I can take up the issue with others at the University and/or the American Journal of Psychiatry.

I look forward to hearing from you at your earliest convenience, and I thank you for your assistance in this matter.

Regards,
Jay

September 16, 2021

8. Attachment K (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

"DR. AMSTERDAM'S TIMELINE RE PUBLICATION OF PAXIL BIPOLAR STUDY 352 WITHOUT HIS KNOWLEDGE"

In the mid-1990s, Dr. Amsterdam became a Co-Principal Investigator on a clinical trial, Paroxetine Study 352, comparing the antidepressant drugs imipramine (Tofranil®) and paroxetine (Paxil®) for the treatment of bipolar type I major depression (or manic depression).

The trial was sponsored, in part, by GlaxoSmithKline which sells paroxetine under the brand names Paxil® in the US and Seroxat in other countries. Dr. Amsterdam

recruited one of the largest, if not the largest, patient samples into a study that comprised 18 other investigative-sites.

In early 2001, Dr. Amsterdam became aware that Dr. Dwight Evans and Dr. Laszlo Gyulai were attempting to publish data from the above referenced study. Although Dr. Amsterdam was a Co-Principal Investigator of Study 352 and enrolled one of the largest numbers of patients, he was excluded from the final data review, analysis and publication. (Attachment J, K, L and D.)

ATTACHMENT K

April 3, 2001

Jay D. Amsterdam, M.D.
Department Psychiatry
University of Pennsylvania
3600 Market Street, 8th Floor
Philadelphia, PA 19104-2649

RE: Bipolar Paper Authorship

Dear Jay,

After you talked to Dwight Evans about the bipolar paper authorship problem, he called me to look into this matter. I did so and on March 29, 2001, I emailed Dwight what I could learn. I reported to him on the following points:

1. Dr. Gyulai was contacted to be the PI for the Penn Site in 1994.
2. In 1995, I suggested that Dr. Gyulai ask Dr. Amsterdam whether he could help him with the project as Dr. Gyulai had problems enrolling patients. Dr. Amsterdam at that time was short in research funds and thus his participation could benefit both Dr. Gyulai and Dr. Amsterdam. Dr. Gyulai would enroll more patients and Dr. Amsterdam would receive more income for his unit. At this time, Dr. Amsterdam became a co-investigator.

3. Penn enrolled 19 patients into the randomized part of the study, with Dr. Amsterdam enrolling 12 patients and Dr. Gyulai enrolling 7 patients.
4. On April 8, 1997, Dr. Gyulai was asked by Grace Johnson of STI to serve as first author of the paper and to review and comment on the enclosed draft #2. On May 14, 1997, Ms. Johnson forwarded a diskette containing draft #2. On December 3, 1997, Dr. Gyulai mailed to Dr. Gergel a revised draft of the paper.
5. As you know, at some later date, SKB decided to replace Dr. Gyulai with Charlie Nemeroff as first author.
6. All participants in the study, including Dr. Amsterdam, are acknowledged in the paper.
7. However, apparently these participants never had a chance to review or even just see the manuscript.
8. Probably one of the reasons Dr. Gyulai did not communicate with Dr. Amsterdam regarding the paper are the existing interpersonal conflicts between Dr. Gyulai and Dr. Amsterdam.
9. Dr. Gyulai recently communicated with SKB and requested permission to write a second paper as first author based on the same data. He proposed that this paper deal with an analysis of all HAM-D subscales and a 2 X 2 factorial analysis (2 treatment x high vs low Lithium levels). Dr. Gyulai expressed the hope that Dr. Amsterdam would be allowed by SKB to join him as one of several authors in this second publication.
10. Dr. Gyulai told me, but I have no independent confirmation, that he suggested to SKB that Dr. Amsterdam should be considered as an author for the first paper. This was turned down on the reasonable basis that only one author per site could be considered. In fact, several sites were not even considered for authorship.

I thought you might be interested in what I have learned.

Sincerely,

Karl Rickels, M.D.

KR:tch

September 23, 2021

9. Attachment L (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

"DR. AMSTERDAM'S TIMELINE RE PUBLICATION OF PAXIL BIPOLAR STUDY 352 WITHOUT HIS KNOWLEDGE"

In the mid-1990s, Dr. Amsterdam became a Co-Principal Investigator on a clinical trial, Paroxetine Study 352, comparing the antidepressant drugs imipramine (Tofranil®) and paroxetine (Paxil®) for the treatment of bipolar type I major depression (or manic depression).

The trial was sponsored, in part, by GlaxoSmithKline which sells paroxetine under the brand names Paxil® in the US and Seroxat in other countries. Dr. Amsterdam recruited one of the largest, if not the largest, patient samples into a study that comprised 18 other investigative-sites.

In early 2001, Dr. Amsterdam became aware that Dr. Dwight Evans and Dr. Laszlo Gyulai were attempting to publish data from the above referenced study. Although Dr. Amsterdam was a Co-Principal Investigator of Study 352 and enrolled one of the largest numbers of patients, he was excluded from the final data review, analysis and publication. (Attachment J, K, L and D.)

ATTACHMENT L

UNIVERSITY OF
PENNSYLVANIA
MEDICAL CENTER

Jay D. Amsterdam, M.D.
Professor, Director,
Depression Research Unit,
Mood and Anxiety Disorders Section
Department of Psychiatry
University of Pennsylvania

7/5/01

Dear Jay,

I regret that there appears to be some misunderstanding about the publication of the data of the SKB PAR- 29060/352 study, which was conducted between 1994 and 1996 and I sincerely apologize for it. I understand that you feel that I took your data collected in this study and that I was unfairly one of the authors of the paper from the project, which appeared in the Am. J. Psychiatry.

I was the primary investigator of the Penn site and, as you know, I worked on early drafts of the paper. I did not determine authorship, and as you know, the paper was taken away from me as first author during the writing process. However, I regret that I did not discuss

the issue of authorship with you. I agree with you that SKB should have circulated the paper to all participants. I only saw the final draft shortly before it was submitted when only minor changes could be done.

I hope that this clarifies some of the misunderstandings and makes it possible for us to work in a collaborative fashion. I am truly sorry about the whole matter and would be happy to personally meet with you and discuss these issues as colleague to colleague.

I remain sincerely yours,

Laszlo Gyulai, M.D.

cc: Dr. Dwight L. Evans
Dr. Karl Rickels

September 30, 2021

Samuel Gershon's comment on collating document

This document is a careful and detailed report on gross improprieties in the marketing and advertising of this whole series of compounds.

This massive project illustrates the distortion of data at every level of its presentation for the purpose of marketing. Its use at scientific meetings to aid in the promotion of sales and biases the educational process to both students and practitioners. One should add at this point that the ultimate victim of these distortions is the patient. I wish to stress the importance of Amsterdam and his colleagues in collating all this careful evidence and preparing it for a broader audience.

Also, INHN is to be commended for undertaking the massive task of preparing this material and presenting it in a meticulous format for the readers to appreciate.

I would like this opportunity to inform readers that materials are gradually also being presented in INHN on a serious controversy, currently ongoing, dealing with the reporting and evaluation of a "new" potential "anti-Alzheimer's drug" and the current disputes appearing in the newspapers.
This, I guess, may become another example of the episode reported above.

September 9, 2021

Jay Amsterdam's reply to Samuel Gershon's comment

Thank you so much for posting your recent commentary on the Paroxetine 352 ethical misconduct case.

In my experience, this type of overt collegial support for endeavors to correct this type of academic and corporate misconduct has been rare and far between (especially since the passing of Barney Carroll and Mickey Nardo). Your willingness to bravely speak out on this egregious conduct in our field has given me some measure of comfort and hope.

As the collated Paroxetine 352 INHN postings have revealed, the best that the field could offer was weakly expressed in the letter by Dr. Frances Collins, paraphrased, (a la Claude Rains in Casablanca): *I'm shocked, shocked to see that ghostwriting is going on at the NIMH and in academia!* And even this disingenuous acknowledgement by Collins that there might be a "ghost in the garden," pales to the silence of so many of our academic colleagues who, like so many current politicians, are fearful of being "primaried" by Big Pharma (out of easy money) if they were to speak truth to power.

So, thanks for your ongoing support in this collaborative INHN endeavor to correct the record on ghostwriting and plagiarism in academia. I hope that you will be willing to contribute future supporting posts, as the primary source documents of personal emails and letters begin to make their INHN appearance.

Reference:

Attachment G (Letter to the Office of Research Integrity – Lawyer's letter excerpt) (Jay D. Amsterdam: The Paroxetine 352 Bipolar Study Ethical Conduct). inhn.org.archives. September 2, 2021.

November 25, 2021

Mark Kramer's comment on Samuel Gershon's comment

My truly good friend, Jay Amsterdam ("Prof. Jay" – my affectionate nickname for him) informed me that Dr. Gershon had commented on Jay's post. That was encouraging to Professor Jay. I get it! He's given all of us an embarrassment: incontrovertibly factual data which grandly documents the actual words and methods by which high level professionals from industry and academia – connected grandly to our ranks – have colluded to pollute the integrity of our field.

Of course, Jay is disappointed that responses to his disclosures have not been met with more interest and even activism from members of this devoted body. After all, I understand it's bulletins reach into organizations such as ACNP. I think P.J. must feel that the silence has been deafening in our ranks. Why isn't there an outcry from every quarter? Why aren't those who perpetrated these crimes against academia, industry and big publishing, outcast – made to pay in some way?

I felt Jay's email to me had a quality of shaming me. But I'm tired. I previously told him I was moving on from our field: that his fight was no longer my fight.

Besides, I said almost everything I wanted to about corruption (academic, corporate, anti- pharmacology cottage industries) in a long paper that I authored in response to honorable pioneer Dr. Barry Blackwell (Kramer 2016). I don't know that Barry liked it too much. The paper was really to set my mind as straight as possible on the issues. It's a shame that Don Klein expected more from me. I politely agreed with him that it could have been better. But then again that brilliant man was annoyed with a lot of things (may he rest in peace]. In the end, I really could not devise a strategy that would fix our fallen Humpty Dumpty – the one I once so loved dearly on the shaky wall.

And frankly, I told Jay as a friend that he would be so much better off, after he documented what he did, to try to advance the field further scientifically. I was concerned that his salutary efforts would be used against the field, such that really sick patients who

might have benefited from a TCA for example, would be turned towards only those practicing in competing non-medical mental health industries.

To me, my friend Jay, despite the incredible efforts he's made (keep in mind with drastically failing, vision) coupled with the suffering he's endured in academia (despite being an impressively capable and productive clinical researcher), sounds at times like a looped jazz phrase: it's great the first time your hear it, it gets clarified second time, the third time it might be taken as a polyrhythmic variation, but the fourth time you just want to hear something else. I love David Healy for his ability to write clearly, his history telling, but I'm sick of his phrases too. f*** it!

Medicines trend to work better than placebo in clinical practice and in clinical trials. I learned this (a little more than anecdotally) from serial systematic placebo-controlled N of 1 experiments as a resident and I don't see why some guys don't understand that, if you don't. Withholding psychopharmaceutical drugs routinely for certain patients is immoral. Medicine is art as well as science; there likely will always be harms.

And it's true that jazz players, like some psychopharmacologists, do loop their phrases because they don't yet know what else to do. LOL – perhaps micro-dosed mushrooms will help.

I just can't, and don't want to, do anymore in this field. I've been with Jay from the very beginning of his current efforts. I respect him very much. I tried at times to help, but the wind is out of my sails for this kind of thing. It's actually out of my sails for psychopharmacology. I will die happily knowing that we documented what we know in the *Journal of Affective Disorders* about substance P (neurokinin type 1 receptor) antagonist antidepressants (multiple huge clinical replications, means by which Merck and Co. likely dropped the ball/ why they were not commercialized) (Rupniak and Kramer 2017) and that's all I can do.

My disappointment is so heavy with our field, that it's painful to think of it, especially its lack of etiological science, not to mention it's now clear underlayment of corruption. Some etiological mechanisms eluding us might be in relationship to regional BBB endothelial dysfunction (involving gilia and inflammatory protein dynamics). I don't think much of psychopharmacology has much to do with neuronal circuitry at all (Auld and Robitaille 2003). But that's just what's left of my reeling analytical mind going a bit off axis

Playing advanced jazz piano is what brings me and others peace, discovery, and great enjoyment. This has always been my first love anyway. It is so now – especially in these last years of life.

So, when P.J. let me know about Sam's response I just dictated a sloppy response into my phone which revealed my cocky position. I inadvertently copied Tom Ban on it about where I stand so I was encouraged just to submit what I dictated. Okay here goes nothing. Maybe this will stir the pot a little for Jay's efforts, maybe it won't. By way of this, I allow my response requested to be bundled in with other responses to Jay. I think what I say is crude and freely associative ... but real.

---

professor j, thanks for copying me on this.
a few sayings

1] No good deed goes unpunished.

2] He who pays the piper calls the tune.

So, P.J. what's the plan?

Meanwhile my own crusade is getting rid of privatized water in my State. The suckers want to raise water rates 18%. The company's gross profit margin before taxes is 35% which equals highly profitable. They only pay a million dollars in taxes in most years, and yet their net profits were ~$1.3 billion. So, out of every water bill a household pays in Pennsylvania now the company receives 1/3 of it in profit for shareholders and executives – who, by the way, make up to $24 million a year. The hourly rate of their average employee is $20 per hour. So, forget trickle down.

Wherever you turn Jay there's injustice and there's corruption. You can't tell me that AQUA water company did not get into Pennsylvania by greasing the wheels of Governors and the State Senates?

Problem: it's humanity Jay – that’s the problem. It's really worse now because of huge income disparity. What drives people like Nemeroff, Evans, Keller, Montgomery et al. to do what they do (did) as KOLs shills? What happened to them? They undertook

useful science early on, but why did they morph into something so unethical and so immoral? Is it fear? Need for control? It's not just money because they have enough, but apparently, they don't think so. So, then, it's power. But to what end?

You've done your work, Jay. I don't think that there's any more to be done unless you have a plan. Maybe I would join a plan, but I don't have one and will not invest the time to draw one up. It's not like we have a cohesive set of principles in our governing bodies in the US. We're a polarized mess.

Case in point: If people can't see that they ought to be vaccinated they're nuts (clinical diagnosis: "Mark Kramer's personal DSM version-1"). Also denying that there was an insurrection on Jan. 6th and that Trump and those Republican b****** who support his brand is a f****** freak show (code that for the DSM!).

The thing to be more worried about than old pharmacologists reading all these documents you've provided, is a knock on your door asking if you're Jewish. Smell the gas boychick!

There's nothing to be done, Jay – enjoy your life, love the lovable ones, drink wine, listen to good music... (www.mark-kramer.com).

I think most people realize there's nothing to be done, that's why you're hearing silence. Or maybe they don't want to hurt their relationships with KOLs, no matter the cost to their integrity.

Also, understand, as I'm sure you do, that most people, as they get older, have bandwidth limited to taking care of their own health and the health of their loved ones. My own Don Quixote seems to have left town – not entirely, but at least he'll try to get the water bills down.

Reference:

Auld DS, Robitaille R. Glial Cells and Neurotransmission: An inclusive view of synaptic function. Neuron 2003;40(2):389-400.

Kramer MS. Commentary. Innovation, propaganda, and jail time. Barry Blackwell: Corporate Corruption in the Psychopharmaceutical Industry. inhn.org.controversies. October 13, 2016.

Rupniak NMJ, Kramer MS. NK1 receptor antagonists for depression: Why a validated concept was abandoned. J Affect Disord 2017;223:121-5.

November 11, 2021

Barry Blackwell's comment on Mark Kramer's comment

I share Mark's kindly admiration for Jay's detailed documentation of overt, even blatant, corruption in the pharmaceutical industry abetted by well-known credentialled, once respected, academic psychopharmacologists, now also overlooked or ignored by professional organizations at the highest level of professional and national accountability.

I also share Mark's end of career frustration and tedium concerning issues deeply rooted in contemporary flaws within our social and political institutions. Income disparity bolstered by greed and addiction to unsightly wealth, absence of political compromise and balanced legislation, growing authoritarianism, threats of violence and false allegations of voter fraud, even doubts about the integrity and flexibility of the Constitution. Accompanied by a persistent, life-threatening viral pandemic, teetering on the brink of control.

Mark takes refuge in music, I turn to poetry, perhaps each of us clings to hope that "this too shall pass." Meanwhile INHN and our website still exist, Tom Ban remains at the helm so there is space and time to share our concerns and hopes.

November 18, 2021

Jay Amsterdam's comment on Barry Blackwell's comment on Mark Kramer's comment on Sam Gershon's comment on Jay Amsterdam's project on the ethical conduct in the paroxetine 352 study

Dear Barry:

Thank you for the kind and generous words that you have posted on the INHN web-site from November 18, 2021 regarding the primary source historical documents pertaining to the corruption and cover up of the GSK paroxetine study 352 bipolar trial by academic key opinion leaders (KOLs and their protective academic institutions.

I certainly appreciate your views about posting this historical , "*detailed documentation of overt, even blatant, corruption in the pharmaceutical industry abetted by well-known credentialled, once respected, academic psychopharmacologists, now also overlooked or ignored by professional organizations at the highest level of professional and national accountability"*. On the other hand, your expression of shared career resignation with that of Professor (aka: Maestro) Mark ,Kramer in his November 11, 2021 INHN commentary sits less well with me. This difference in sentiment between us, may be the result of my having been witness to the actual corruption and misconduct in the 352 study by (then) trusted colleagues and university administrators.

Despite this difference of opinion, the frustration that you and Mark have expressed is certainly understandable and is, moreover, nothing new to any of us.

To this end, I refer you back to the historical email thread (below) between yourself, Maestro Kramer, and this writer from November 23, 2018 to November 26, 2018. Beyond the prescient words expressed in these email correspondence,. I would also note the presence of Barney Carroll (who was part of the email thread),but who was also prematurely taken from our midst by his untimely death in 2018.

(*Note* - If you are a purist, then start reading the email thread from the bottom up. Otherwise, enjoy the prior historical commentary from the bottom down).

With kindest regards,

Jay

December 27, 2021

From: Barry Blackwell <blackwellbarry@hotmail.com>
Sent: Friday, January 26, 2018 12:01 PM
To: J Amsterdam <enopath@aol.com>
Subject: Re: The seedy underbelly of academic psychiatry

Jay,

I appreciate all you have done and continue to do. Mark (maestro) Kramer's reply was also helpful. Closeted inside INHN with minimal or no resources Tom and I do our level best as do you and others. Our ethical malaise is understandable given the wealth and political influence of Big Pharma and the greed, income disparity, Congressional gridlock and Presidential ineptitude we live under. Perhaps we should take comfort in the fact we lived and worked in better times. If my attachments were read by any of your mailing list I do hope they elicited even the tiniest twinge of guilt, but doubt it.

Best,

Barry

From: J Amsterdam <enopath@aol.com>
Sent: Friday, January 26, 2018 9:45 AM
To: 'Mark Kramer'; 'Barry Blackwell'
Cc: tomban@bell.net
Subject: RE: The seedy underbelly of academic psychiatry

Dear Maestro & Barry:

Do you think that your little email thread (below) can be made public, and sent to everyone in the academic and psychopharmacologic world that either of you have ever known in your entire lives? After all, both of you have had a lifetime of the political nuances of Pharma industry, academia, and admin to put names to this issue. I believe that it’s called a grass-roots effort; made direct to the players and stake holders. Alas,

my list of professional email recipients is quite limited. I sent our latest Psychiatria Polska blockbuster out to virtually everyone that I know. To date, I have received only a handful of comments (mostly congratulations) from the 'usual suspects' (i.e., Barry, Barney, Sam, Mark, and my Old Testiment religion professor from my college days). What is more telling to me is the folks who did not respond to receipt of the article! I would have been interested in seeing who responded with a "I'm shocked, shocked to learn that fraud is going on …."

Nevertheless, I am confident that the rest of the email recipients did read my email to them and, most also read the article. Of that I am certain. The fact that 97% of them are on the academic-Pharma payroll does not diminish their deep-seated embarrassment (as they read the article and cast their glance in the mirror). If I could have located Karl Rickels' and Joe Mendels' email addresses, I would have also included them. I can remember sitting across from Karl in his office, back in 1984, getting lectured by him (as he was my mentor) about the necessities of writing my own research articles! He said that he never had Pharma involved in the writing of his papers. At that time in my career, I didn't even know what Rickels was talking about. Of course I wrote my own research papers. Who would'a thought that, even back in the early 80s, Pharma had KOLs who were on the take. Boy was I naïve! A similar conversation was held with Mendels 4 years earlier (before he was tossed out of Penn for misappropriation of federal funds). At the time, I did not understand what these two early Pharma poster boys were telling me. Of course I wrote my own research papers (as I had thought all my colleagues had done). It wasn't until 2007 (when Barney and Bob started sending me emails about their outing of Nemeroff) that I began to understand that many of my, heretofore, academic role models (as a young researcher) were engaged in ongoing plagiarism and Pharma corruption. Imagine my disgust.

Maestro, your feelings of resignation over the current academic-industrial cabal is palpable. And, you are correct, Maestro, I do have a fire in my belly to expose these miscreants (like I have quietly done since I blew the whistle on one of my research mentors for stealing federal grant money for personal use). I would also remind you that David did not go up against Goliath at the command of God; but rather, he did so out of a sense of moral compass (and carried the 'spirit of God within him'). I shudder to recall the number of folks who, since 2010, have told me that I am like David going up against the Pharma Goliath, or I am like Don Quixote fighting windmills at Penn, or I am like a punch-drunk fighter getting battered without reason, etc. Well, that is true, I am all of these characters. However, I would rather be my kind of fool than theirs. Barney once advised me not to go back to the grind of academia, as it would deprive me of the time to continue the fight to "hammer the bastards". He was right! Anyway, someone has to do the work. If there was no David, then where would we be?

So far, I have done my part to bring the issue into public scrutiny. I have previously brought the issue up to multiple members of Congress, and even to the President's desk. Although I am mindful of the 8 second attention span of my colleagues and the futility expressed by the Maestro of hoping the public will read more than 1 page of a document (much less 50 pages), I attach for your illumination (should you have the patience and attention span to read them) some of my past attempts at fighting windmills. Feel free to re-send them out to everyone in the whole world that you have ever known, even those with an 8-secondd attention span.

With much affection,

JD

From: Mark Kramer [mailto:mark-kramer@verizon.net]
Sent: Friday, January 26, 2018 2:11 AM
To: 'Barry Blackwell' <blackwellbarry@hotmail.com>
Cc: tomban@bell.net; 'J Amsterdam' <enopath@aol.com>
Subject: RE: The seedy underbelly of academic psychiatry

Yes, Barry.

Your point is well-taken about many of us being mired in ethical lassitude. Your call to action through INHN, and then through your personal note, engaged my attention enough to call it to action. I then shaped a short paragraph which will be sent to appropriate D.C. jurisdictive representatives. However, doing so, expecting reform, is just short of an Abilify resistant delusion. I now newly feel a petition would be equally non-productive.

Those of us who do not profit materially or psychologically from today's inglorious medical climate, yet who also deeply care about mitigating harms inflicted on science and humanity by highly organized multinational Goliaths, would need to be in line for divine intervention, as was David.

So, I am just not complaining anymore.

Just 2-3 years ago – when in quixotic persona – I might have been moved to orchestrate face to face meeting(s) on the issues with DC representatives I had known. Alas, they've fled amidst authentic scandals.

As I see it, only Professor Jay has the youth and raw fire in his belly to engage the DC crooks face-to-face. If he should ever flex his network to gain a face to face, I will be happy to prepare some slides and drive us there or take a train with my dear buddy. Sadly, for me such an outing would only be to enjoy camaraderie, as well as to uncork the medicinally needed wine in DC after the meeting(s.)

Over just the last year I've grown weary with our world. It's not just the recent loss of my life-long wife and friend. I see daily that "truth" is manufactured willy-nilly; lies are sold for profit legally without remorse. Bribery-lobbying is authorized and corporations (the journals, pharma, academic centers, device manufacturers, and natural resource distributors) are now international cabals. We live in a time when availability of water and air to developing nations is conditioned on profits by the World Bank. Such a steadily organizing World Order cannot be penetrated by slingshots and stones. $$ Multibillion fines have not slowed it down. Racism and tribalism provide cover for its nameless leaders – those without country or creed - only aligned with greed. (I agree with your writings on that.)

Until now, for over 20 years I'd only been a lone crusader in our academic wilderness hoping to bring a groundbreaking psychopharmacologic principle into the world. Yet nearly no one in INHN, or any institution I know, or those in numerous informal discussion groups I've engaged, aside from Barney, and some neuropeptide experts (Leeman, Hokfelt, Douglas) had been interested enough to pose significant scientific questions or observations. Even after my colleague and I recently spelled out in J.A.D. the reasons as to why our preclinical and clinical findings (the latter replicated in thousands of patients) had not been commercialized, the silence has been deafening – Just as Professor J had predicted.

That is when I understood that anachronism exemplifies our profession's science. I've become sadly informed that the INHN is not as current as I initially hoped it could be. I could not have known. When will it realize that neuropeptide systems are our next chapter? Who, if not the INHN, will record this chapter of new psychopharm history? And even if we should prepare the story for the INHN, the sad truth is that it would only be a trifling % of members who will engage enough to relish, debate, and thus further the potential import?

I have to say I am now as sad and cynical as Professor Sam.

Dispirited to my core at age 72, with a FH forecasting just a few years left, my only remaining idea is just to live it out with equanimity, but Nero-like: exclusively play or listen to celestial music as our city continues to burn and I prepare to meet my maker. Music, after all, is concerned more with inspiration than ethical lassitude. I should have enlisted the cabal to sell my music as their soundtrack. But no. Conscience is like that.

Good work is yours and the INHN's, nevertheless. And thank you for being one of a handful that actually read my diatribe in response to yours.

Be well, Barry.

Mark

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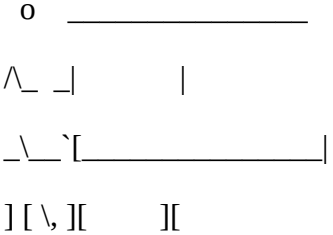

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From: Barry Blackwell [mailto:blackwellbarry@hotmail.com]
Sent: Thursday, January 25, 2018 8:46 AM
To: Mark Kramer <mark-kramer@verizon.net>
Cc: tomban@bell.net
Subject: Re: The seedy underbelly of academic psychiatry

Mark - thanks for your reply and comments. I am weary of reading laments about the Big Pharma status quo when no attempt is made to address or reverse it. For example I would hope that any right minded person who knows the truth would at least have attempted to alert their legislative representatives of the political causes and implications of this disaster. Even if they can't be bothered to respond. If you have any other ideas about how to influence the situation please let me know. We seem to be mired in ethical lassitude.

Barry

From: Mark Kramer <mark-kramer@verizon.net>
Sent: Wednesday, January 24, 2018 12:26 PM
To: 'Barry Blackwell'; 'J Amsterdam'; 'samuel gershon'; 'Bernard Carroll'
Cc: 'Edward Shorter'; 'Max Fink'; 'Tom Ban'; 'martin b.kassell'; 'Dubin, William R.'; 'Rob DeRubeis'; 'LORENZO LORENZO-LUACES'; 'Lorenzo Lorenzo-Luaces Valencia'; 'Hollon, Steven D'; 'Parker, Gordon'; DrSAger@lawyerstress.com; 'Michael Feinberg'; 'edward. tobe@comcast. net'; pumariega-andres@cooperhealth.edu; 'Trudo Lemmens'; 'don klein'; 'Erick Turner'; 'Robert T. Rubin'; 'James Williams'; 'Martin Rosenberg'; 'Susan Molchan'; jcoynester@gmail.com; 'Coyne, James'; pdoshi@bmj.com; 'Paul Grof'; 'Paul Thacker'; 'Allen Frances'; 'Ari Albala, M.D.'; 'Beck, Aaron'; 'Thase, Michael'; 'Boghos I. Yerevanian M. D.'; 'Carey, Ben'; 'Cagande, Consuelo'; giovanniandrea.fava@unibo.it; 'Mark H. Pollack'; 'Meir Steiner'; 'Fava, Maurizio,M.D.'; 'Nierenberg, Andrew A., M.D.'; 'Nassir Ghaemi'; 'Neil Dubin'; David.Healy54@googlemail.com; 'Ed Silverman'; 'Fournier, Jay'; 'Frye Mark'; 'Hagop S. Akiskal, MD'; 'Ira D Glick'; 'Irl Extein MD'; 'Sobanko, Joseph'; john_zajecka@rush.edu; jws6@columbia.edu; 'Kenneth'; 'Lewis Judd'; 'Jan Fawcett'; 'The Neurocritic'; 'Neuro Skeptic'; 'Paul Andrews'; 'Zachary Cohen'; 'Pacchiarotti Isabella'; 'Paula Clayton'; 'Peter Doshi'; 'Philip Gold'; 'Preston, Samuel H'; 'Baldessarini Ross J'; 'Ranga Krishnan'; rshelton@uab.edu; 'Suppes Trisha'; 'Sona Dimidjian'; tketter@stanford.edu; 'Tondo Leonardo'; 'wallyfletcher'; 'Walter A. Brown, MD'; 'Nolen, WA'; 'William E. Bunney Jr.'; leemonmchenry@gmail.com; 'Jureidini, Jon (Health)'; 'Robert Whitaker'; 'Carey, Ben'; 'martin b.kassell'
Subject: RE: The seedy underbelly of academic psychiatry

Dear Barry et al,

Attributed to ongoing digital barrage, Microsoft claims that our average attention span is now only 8 seconds (down 33% over a few years) ; now 1 second shorter than that of a goldfish.

If emails are ignored after 48 hours of sending, then they will likely never be opened or processed further. Thus proactive follow up to outreach emails are required after 48 hours. The more that people that are exposed to the communication, the more they may take note and act on it.

I assumed that professionals in our niche would have very long attention spans and not require e-mail re-prompts to get them to pay attention to their important issues. Mine was a faulty idea. And I do not think this happens because most of the cc list here is on the pharma payroll.

The issue is exactly the same today in the field of music. “Piano Jazz” is a narrow niche of once hungry adherents. Emails or social media announcements to that audience, even if accompanied by free samples, are similarly disregarded on the first round. Even major brands have to show the same ad 20 times in a single day, on the same channel to have impact.

So, you asked for ideas.

The idea is that even our most important considerations (corruption of health data) have to be marketed in the same manner as “pet rocks.” We might expect more of each other, but Kripes, there is now ample evidence that self-absorption is endemic.

No need to respond.

Best, Mark

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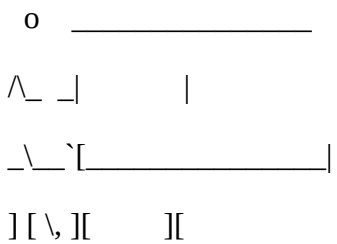

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From: Barry Blackwell [mailto:blackwellbarry@hotmail.com]
Sent: Wednesday, January 24, 2018 12:06 PM
To: J Amsterdam <enopath@aol.com>; 'samuel gershon' <samuelgershon258@gmail.com>; 'Bernard Carroll' <bcarroll40@comcast.net>
Cc: 'Edward Shorter' <edwardshorter@gmail.com>; 'Mark Kramer' <mark-kramer@verizon.net>; 'Max Fink' <Max.Fink@stonybrookmedicine.edu>; 'Tom Ban' <tomban@bell.net>; 'martin b.kassell' <mbkmd@yahoo.com>; 'Dubin, William R.' <William.Dubin@tuhs.temple.edu>; 'Rob DeRubeis' <derubeis@psych.upenn.edu>; 'LORENZO LORENZO-LUACES' <lorenzl@sas.upenn.edu>; 'Lorenzo Lorenzo-Luaces Valencia' <lllv1989@gmail.com>; 'Hollon, Steven D' <steven.d.hollon@Vanderbilt.Edu>; 'Parker, Gordon' <g.parker@unsw.edu.au>; DrSAger@lawyerstress.com; 'Michael Feinberg' <mfeinberg@dca.net>; 'edward. tobe@comcast. net' <edward.tobe@comcast.net>; pumariega-andres@cooperhealth.edu; 'Trudo Lemmens' <trudo.lemmens@utoronto.ca>; 'don klein' <donaldk737@aol.com>; 'Erick Turner' <turnere@ohsu.edu>; 'Robert T. Rubin' <rtrubin@yahoo.com>; 'James Williams' <jwilli77@cox.net>; 'Martin Rosenberg' <mrosenbe@camden.rutgers.edu>; 'Susan Molchan' <susan_molchan@verizon.net>; jcoynester@gmail.com; 'Coyne, James' <jcoyne@pennmedicine.upenn.edu>; pdoshi@bmj.com; 'Paul Grof' <paulgrof75@gmail.com>; 'Paul Thacker' <thackerpd@gmail.com>; 'Allen Frances' <allenfrancesmd@gmail.com>; 'Ari Albala, M.D.' <arialbala@gmail.com>; 'Beck, Aaron' <abeck@pennmedicine.upenn.edu>; 'Thase, Michael' <thase@pennmedicine.upenn.edu>; 'Boghos I. Yerevanian M. D.' <byerevanian@gmail.com>; 'Carey, Ben' <bencarey@nytimes.com>; 'Cagande, Consuelo' <Cagande-Consuelo@CooperHealth.edu>; giovanniandrea.fava@unibo.it; 'Mark H. Pollack' <Mark_Pollack@rush.edu>; 'Meir Steiner' <mst@mcmaster.ca>;

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Subject: Re: The seedy underbelly of academic psychiatry

Jay, congratulations on success in publishing your article on Corporate Corruption of Clinical Trials. An earlier draft you shared with me as part of an extended exchange on INHN after publication of my essay on Corporate Corruption in the Psychopharmacological Industry, a review based on 9 books published in the previous decade on this topic. Attached to this e-mail is both the original essay and a subsequent posting which summarizes exchanges between six leaders in the field expressing a consensus about the problem and pessimism about what might be done professionally or politically to reverse it. Following publication of my essay and the responses our Central Office sent a letter to all 74 US members of INHN inviting them to contact their Congressmen and Senators. 25 members opened the e-mail, only 9 downloaded it and nobody responded. I personally sent the essay to both Wisconsin Senators, Two Democratic congressmen and to Paul Ryan Speaker of the House. In addition I sent copies to the White House Scientific Office and the Attorney General of Ohio who was conducting a lawsuit against the manufacturers of opioids. Nobody responded.

I have taken the liberty of attaching the relevant documents to this reply in the hope that somebody amongst the colleague on your mailing list might have ideas they are willing to share.

Best Wishes,

Barry.

From: J Amsterdam <enopath@aol.com>
Sent: Wednesday, January 24, 2018 9:21 AM
To: 'samuel gershon'; 'Bernard Carroll'
Cc: 'Edward Shorter'; 'Mark Kramer'; 'Max Fink'; 'Barry Blackwell'; 'Tom Ban'; 'martin b.kassell'; 'Dubin, William R.'; 'Rob DeRubeis'; 'LORENZO LORENZO-LUACES'; 'Lorenzo Lorenzo-Luaces Valencia'; 'Hollon, Steven D'; 'Parker, Gordon'; DrSAger@lawyerstress.com; 'Michael Feinberg'; 'edward. tobe@comcast. net'; pumariega-andres@cooperhealth.edu; 'Trudo Lemmens'; 'don klein'; 'Erick Turner'; 'Robert T. Rubin'; 'James Williams'; 'Martin Rosenberg'; 'Susan Molchan'; jcoynester@gmail.com; 'Coyne, James'; pdoshi@bmj.com; 'Paul Grof'; 'Paul Thacker'; 'Allen Frances'; 'Ari Albala, M.D.'; 'Beck, Aaron'; 'Thase, Michael'; 'Boghos I. Yerevanian M. D.'; 'Carey, Ben'; 'Cagande, Consuelo'; giovanniandrea.fava@unibo.it; 'Mark H. Pollack'; 'Meir Steiner'; 'Fava, Maurizio,M.D.'; 'Nierenberg, Andrew A., M.D.'; 'Nassir Ghaemi'; 'Neil Dubin'; David.Healy54@googlemail.com; 'Ed Silverman'; 'Fournier, Jay'; 'Frye Mark'; 'Hagop S. Akiskal, MD'; 'Ira D Glick'; 'Irl Extein MD'; 'Sobanko, Joseph'; john_zajecka@rush.edu; jws6@columbia.edu; 'Kenneth'; 'Lewis Judd'; 'Jan Fawcett'; 'The Neurocritic'; 'Neuro Skeptic'; 'Paul Andrews'; 'Zachary Cohen'; 'Pacchiarotti Isabella'; 'Paula Clayton'; 'Peter Doshi'; 'Philip Gold'; 'Preston, Samuel H'; 'Baldessarini Ross J'; 'Ranga Krishnan'; rshelton@uab.edu; 'Suppes Trisha'; 'Sona Dimidjian'; tketter@stanford.edu; 'Tondo Leonardo'; 'wallyfletcher'; 'Walter A. Brown, MD'; 'Nolen, WA'; 'William E. Bunney Jr.'; leemonmchenry@gmail.com; 'Jureidini, Jon (Health)'; 'Robert Whitaker'; 'Carey, Ben'; mbkmd@yahoo.com
Subject: RE: The seedy underbelly of academic psychiatry

Dear Sam:

Thanks so much for your nice email. I certainly agree with your demoralization concerning the negative effects of the academic-industrial complex on medical research writ large, and on our beloved field of psychopharmacology, in particular.

I believe that we can all lament over the commercialization of clinical trials research and the scientific publication of it. It is a sad state of affairs when 'doctored' data get prominent billing in top notch, peer-reviewed scientific journals (for hyped 'positive' results and commercial gain; while the deconstruction of the falsified data cannot get any consideration for publication in the same scientific journals that published the falsified data. And, as for retraction of the bogus data, well… don't hold your breath waiting for the American Journal of Psychiatry to acquiesce to what should be done for the benefit of science and our patients.

As to the point (below) that Barney tweeted regarding the inability to publish peer-reviewed scientific articles within the US exposing research misconduct in main stream journals, I attach a short piece originally published by the late Dr. John ('Mickey') Nardo in his blog: 1 Boring Old Man. This short piece describes the 'publication journey' that we endured in order to successfully publish our deconstruction article on the CIT-MD-18 trial . I hope that you find it illuminating.

With all good wishes,

Jay

From: samuel gershon [mailto:samuelgershon258@gmail.com]
Sent: Tuesday, January 23, 2018 11:49 PM
To: Bernard Carroll <bcarroll40@comcast.net>
Cc: J Amsterdam <enopath@aol.com>; Edward Shorter <edwardshorter@gmail.com>; Mark Kramer <mark-kramer@verizon.net>; Max Fink <Max.Fink@stonybrookmedicine.edu>; Barry Blackwell <blackwellbarry@hotmail.com>; Tom Ban <tomban@bell.net>; martin b.kassell <mbkmd@yahoo.com>; Dubin, William R. <William.Dubin@tuhs.temple.edu>; Rob DeRubeis <derubeis@psych.upenn.edu>; LORENZO LORENZO-LUACES <lorenzl@sas.upenn.edu>; Lorenzo Lorenzo-Luaces Valencia <lllv1989@gmail.com>; Hollon, Steven D <steven.d.hollon@Vanderbilt.Edu>; Parker, Gordon <g.parker@unsw.edu.au>; DrSAger@lawyerstress.com; Michael Feinberg <mfeinberg@dca.net>; edward. tobe@comcast. net <edward.tobe@comcast.net>; (pumariega-andres@cooperhealth.edu) <pumariega-andres@cooperhealth.edu>; Trudo Lemmens <trudo.lemmens@utoronto.ca>; don klein <donaldk737@aol.com>; Erick Turner <turnere@ohsu.edu>; Robert T. Rubin <rtrubin@yahoo.com>; James Williams <jwilli77@cox.net>; Martin Rosenberg <mrosenbe@camden.rutgers.edu>; Susan Molchan <susan_molchan@verizon.net>; jcoynester@gmail.com; Coyne, James <jcoyne@pennmedicine.upenn.edu>; pdoshi@bmj.com; Paul Grof

<paulgrof75@gmail.com>; Paul Thacker <thackerpd@gmail.com>; Allen Frances <allenfrancesmd@gmail.com>; Ari Albala, M.D. <arialbala@gmail.com>; Beck, Aaron <abeck@pennmedicine.upenn.edu>; Thase, Michael <thase@pennmedicine.upenn.edu>; Boghos I. Yerevanian M. D. <byerevanian@gmail.com>; Carey, Ben <bencarey@nytimes.com>; Cagande, Consuelo <Cagande-Consuelo@CooperHealth.edu>; giovanniandrea.fava@unibo.it; Mark H. Pollack <Mark_Pollack@rush.edu>; Meir Steiner <mst@mcmaster.ca>; Fava, Maurizio,M.D. <MFAVA@mgh.harvard.edu>; Nierenberg, Andrew A., M.D. <ANIERENBERG@mgh.harvard.edu>; Nassir Ghaemi <nghaemi@tuftsmedicalcenter.org>; Neil Dubin <neildubinmd@zoomtown.com>; David.Healy54@googlemail.com; Ed Silverman <ed.silverman@statnews.com>; Fournier, Jay <fournierjc@upmc.edu>; Frye Mark <mfrye@mayo.edu>; Hagop S. Akiskal, MD <hakiskal@ucsd.edu>; Ira D Glick <iraglick@stanford.edu>; Irl Extein MD <irlex@aol.com>; Sobanko, Joseph <Joseph.Sobanko@uphs.upenn.edu>; john_zajecka@rush.edu; jws6@columbia.edu; Kenneth <kweiss@comcast.net>; Lewis Judd <ljudd@ucsd.edu>; Jan Fawcett <jfawcett@salud.unm.edu>; The Neurocritic <neurocritic@gmail.com>; Neuro Skeptic <neuroskeptic@googlemail.com>; Paul Andrews <pandrews@psychology.mcmaster.ca>; Zachary Cohen <zachary.d.cohen@gmail.com>; Pacchiarotti Isabella <pacchiar@clinic.ub.es>; Paula Clayton <pjcpsych@aol.com>; Peter Doshi <pdoshi@rx.umaryland.edu>; Philip Gold <philipgold@mail.nih.gov>; Preston, Samuel H <spreston@pop.upenn.edu>; Baldessarini Ross J <rbaldessarini@mclean.harvard.edu>; Ranga Krishnan <Ranga_Krishnan@rush.edu>; rshelton@uab.edu; Suppes Trisha <tsuppes@stanford.edu>; Sona Dimidjian <sona.dimidjian@colorado.edu>; tketter@stanford.edu; Tondo Leonardo <leonardot@aol.com>; wallyfletcher <wallyfletcher48@gmail.com>; Walter A. Brown, MD <walter_brown@brown.edu>; Nolen, WA <w.a.nolen@umcg.nl>; William E. Bunney Jr. <webunney@uci.edu>; (leemonmchenry@gmail.com) <leemonmchenry@gmail.com>; Jureidini, Jon (Health) <Jon.Jureidini@sa.gov.au>
Subject: Re: The seedy underbelly of academic psychiatry

this is a remarkable discovery,., we I think were all aware of these issues but this dramatic presentation of the facts in this format,., deserves a revival of discussion and explication on a broader scale,.,Part of the problem is of course money———many journals won't pay anything toward the cost of running the journal office and the editors necessary expenses,., the institution often find this as an access to drug company support,., and investigators can use crummy papers published in crummy and also not so crummy journals to flush out their CV ,s and then we have the relatively new trilogy,. of pay-to-play,. pay -to- review,. and pay -to-write,., SAM

On Jan 23, 2018, at 9:09 PM, Bernard Carroll <bcarroll40@comcast.net> wrote:

Good work Jay and Leemon and Jon. I Tweeted a link to the on-line open access article. Barney.

https://twitter.com/bcarroll40/status/955985103020204032

Dr. Bernard Carroll

Behavioral Research Consulting

100 Del Mesa Carmel

Carmel, CA 93923.

Phone: 831-626-1467

E-mail: bcarroll40@comcast.net

From: J Amsterdam [mailto:enopath@aol.com]
Sent: Tuesday, January 23, 2018 12:18 PM
To: 'Bernard Carroll' <bcarroll40@comcast.net>; 'samuel gershon' <samuelgershon258@gmail.com>; 'Edward Shorter' <edwardshorter@gmail.com>; 'Mark Kramer' <mark-kramer@verizon.net>; 'Max Fink' <Max.Fink@stonybrookmedicine.edu>; 'Barry Blackwell' <blackwellbarry@hotmail.com>; 'Tom Ban' <tomban@bell.net>; mbkmd@yahoo.com; 'Dubin, William R.' <William.Dubin@tuhs.temple.edu>; 'Rob DeRubeis' <derubeis@psych.upenn.edu>; lorenzl@sas.upenn.edu; lllv1989@gmail.com; 'Hollon, Steven D' <steven.d.hollon@Vanderbilt.Edu>; 'Parker, Gordon' <g.parker@unsw.edu.au>; DrSAger@lawyerstress.com; 'Michael Feinberg' <mfeinberg@dca.net>; edward. tobe@comcast. net <edward.tobe@comcast.net>; pumariega-andres@cooperhealth.edu; 'Trudo Lemmens' <trudo.lemmens@utoronto.ca>; 'Klein, Donald F.' <donaldk737@aol.com>; turnere@ohsu.edu; 'Robert T. Rubin' <rtrubin@yahoo.com>; 'James Williams' <jwilli77@cox.net>; 'Martin Rosenberg' <mrosenbe@camden.rutgers.edu>; 'Susan Molchan' <susan_molchan@verizon.net>; jcoynester@gmail.com; Coyne, James <jcoyne@pennmedicine.upenn.edu>; pdoshi@bmj.com; 'Paul Grof' <paulgrof75@gmail.com>; 'Paul Thacker' <thackerpd@gmail.com>; allenfrancesmd@gmail.com; 'Ari Albala, M.D.' <arialbala@gmail.com>; Beck, Aaron

<abeck@pennmedicine.upenn.edu>; Thase, Michael <thase@pennmedicine.upenn.edu>; 'Boghos I. Yerevanian M. D.' <byerevanian@gmail.com>; 'Carey, Ben' <bencarey@nytimes.com>; 'Cagande, Consuelo' <Cagande-Consuelo@CooperHealth.edu>; giovanniandrea.fava@unibo.it; 'Mark H. Pollack' <Mark_Pollack@rush.edu>; 'Meir Steiner' <mst@mcmaster.ca>; 'Fava, Maurizio,M.D.' <MFAVA@mgh.harvard.edu>; ANIERENBERG@mgh.harvard.edu; 'Nassir Ghaemi' <nghaemi@tuftsmedicalcenter.org>; 'Neil Dubin' <neildubinmd@zoomtown.com>; David.Healy54@googlemail.com; 'Ed Silverman' <ed.silverman@statnews.com>; 'Fournier, Jay' <fournierjc@upmc.edu>; 'Frye Mark' <mfrye@mayo.edu>; 'Hagop S. Akiskal, MD' <hakiskal@ucsd.edu>; 'Ira D Glick' <iraglick@stanford.edu>; 'Irl Extein MD' <irlex@aol.com>; 'Sobanko, Joseph' <Joseph.Sobanko@uphs.upenn.edu>; john_zajecka@rush.edu; jws6@columbia.edu; 'Kenneth' <kweiss@comcast.net>; 'Lewis Judd' <ljudd@ucsd.edu>; jfawcett@salud.unm.edu; neurocritic@gmail.com; neuroskeptic@googlemail.com; 'Paul Andrews' <pandrews@psychology.mcmaster.ca>; 'Zachary Cohen' <zachary.d.cohen@gmail.com>; 'Pacchiarotti Isabella' <pacchiar@clinic.ub.es>; 'Paula Clayton' <pjcpsych@aol.com>; 'Peter Doshi' <pdoshi@rx.umaryland.edu>; Philip Gold <philipgold@mail.nih.gov>; 'Preston, Samuel H' <spreston@pop.upenn.edu>; 'Baldessarini Ross J' <rbaldessarini@mclean.harvard.edu>; 'Ranga Krishnan' <Ranga_Krishnan@rush.edu>; rshelton@uab.edu; 'Suppes Trisha' <tsuppes@stanford.edu>; 'Sona Dimidjian' <sona.dimidjian@colorado.edu>; tketter@stanford.edu; 'Tondo Leonardo' <leonardot@aol.com>; 'wallyfletcher' <wallyfletcher48@gmail.com>; 'Walter A. Brown, MD' <walter_brown@brown.edu>; w.a.nolen@umcg.nl; 'William E. Bunney Jr.' <webunney@uci.edu>
Cc: leemonmchenry@gmail.com; 'Jureidini, Jon (Health)' <Jon.Jureidini@sa.gov.au>
Subject: The seedy underbelly of academic psychiatry

Dear Friends & Colleagues:

Please find attached an article, just published today, that describes the somewhat seedy underbelly of the academic-industrial complex. It contains additional information to that previously noted in some of our earlier publications. I hope that you enjoy it. Moreover, I would commend each of you to widely distribute the article to every colleague you have ever met in the entire world, so that this sort of unacademic behavior and research misconduct is more widely appreciated and, hopefully, less often practiced.

Finally, before you give any further thought as to why we selected the present publication venue, please note that, heretofore, the publication of an article of this sort has never been accepted for publication in a peer-reviewed psychiatric journal . Thus,

the appearance of this article represents the first published, forensic deconstruction of research misconduct in a peer-reviewed medical journal. I commend the editorial staff at the Psychiatria Polska for showing the moral compass and ethical back bone to publish such an article.

My very best wishes,

Jay

Jay D. Amsterdam, MD

May 19, 2022

10. Attachment M (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

"DR. AMSTERDAM'S TIMELINE RE PUBLICATION OF PAXIL BIPOLAR STUDY 352 WITHOUT HIS KNOWLEDGE"

Dr. Amsterdam contacted his immediate supervisor and department chairman, Dr. Dwight L. Evans about the matter. In a March 22,2001 email to Dr. Amsterdam, Dr. Evans stated that he had discussed the issue with Dr. Karl Rickels who was also a professor in the Department of Psychiatry at the University of Pennsylvania and Dr. Gyulai's direct supervisor. Dr. Evans assured Dr. Amsterdam that Dr. Rickels would be reviewing the matter and, once accomplished, he trusted there would be "an equitable outcome." (Attachment M.)

ATTACHMENT M

Sender: psych@mail.med.upenn.edu

Mailer: QUALCOMM Windows Eudora Light Version 3.0.3 (32)

Date: Thu, 22 Mar 2001 04:31:18 -0500

To: jamsterd@mail.med.upenn.edu

From: "Dr. Dwight L. Evans, MD" <psych@mail.med.upenn.edu>

Subject: SKB Study

Cc: krickels@mail.med.upenn.edu

Dear Jay,

I have discussed the SKB study at length with Karl Rickels. He will review and look into the entire matter as it relates to the work that you did here at Penn. Once this is accomplished, I trust there will be an equitable outcome.

Dwight

Dwight L. Evans, MD

Ruth Meltzer Professor and Chairman

Department of Psychiatry

University of Pennsylvania Health System

3 Blockley Hall

Philadelphia, PA 19104

215-662-2818

215-662-6911 Fax

Email: psych@mail.med.upenn.edu

October 7, 2021

11. Attachment N (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On May 1, 2001, Dr. Amsterdam sent Drs. Evans and Rickels another email to explain that he was unsatisfied with the response and, since the last letter, there has been only "radio silence." As he wrote, "Am I to assume that it is okay in this department for a junior

faculty member to abscond with data from a full professor and publish it without any ramifications?" (Attachment N.)

Attachment N

To: "Dr. Dwight L. Evans, MD" <psych@mail.med.upenn.edu>
From: "Dr. Jay D. Amsterdam" <jamsterd@mail.med.upenn.edu>
Subject: SKB study publication
Cc:
Bcc:
Attached:

Hi Dwight,

To date there has been only "radio silence" regarding the matter of the Am J Psychiatry publication. Am I to assume that it is okay in this department for a junior faculty member to abscond with data from a full professor and publish it without any ramifications? As you can see from Karl's review of this matter, my estimate of the situation was accurate and it appears as though the "high enroller in the entire 19 site SKB study" (me) was purposefully omitted from data review, analysis and publication. What do you suggest that I do at this point? I would appreciate your continued advice on this exceedingly troubling matter. I look forward to your suggestions at your convenience.

Best, as always,

Jay

October 14, 2021

12. Attachment O (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On May 1, 2001, Dr. Amsterdam sent Drs. Evans and Rickels another email to explain that he was unsatisfied with the response and, since the last letter, there has been only "radio silence." As he wrote, "Am I to assume that it is okay in this department for a junior

faculty member to abscond with data from a full professor and publish it without any ramifications?" (Attachment N.)

The following day, Dr. Rickels emailed Dr. Amsterdam and explained that Dr. Evans had tasked him (Dr. Rickels) with trying "to bring about a resolution." (Attachment O.)

Attachment O

Sender: krickels@mail.med.upenn.edu
Mailer: QUALCOMM Windows Eudora Pro Version 4.2.2
Date: Wed, 02 May 2001 11 :23:55 -0400
To: jamsterd@mail.med.upenn.edu
From: "Dr. Karl Rickels" <krickels@mail.med.upenn.edu>
Subject: SKB study publication
Cc: "Dr. Dwight L. Evans, MD" <psych@mail.med.upenn.edu>

Dear Jay,

Dwight shared your email to him and asked me "to bring about a resolution". It would be helpful if you could let me know by email what steps you would like me or Dwight to take in this matter. After I receive your suggestions, I would be happy to come over to your office for any further clarification.

Best regards,

Karl
****
Karl Rickels, M.D.
Professor of Psychiatry
University of Pennsylvania
Department of Psychiatry
Mood and Anxiety Disorders Section
3535 Market Street
Suite 670
Philadelphia, PA 19104-3309

Telephone: 215-746-6417
Fax: 215-746-6551
email: krickels@mail.med.b1penn.edu

October 21, 2021

13. Attachment P (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On May 11, 2001, Dr. Amsterdam emailed Dr. Rickels and explained that he considered data that he (Dr. Amsterdam) accumulated in his research unit from the study "were misappropriated from me and used and published without my knowledge and without regard to the significant contribution that I made to this study." Dr. Amsterdam complained that the "theft and publication of [his] data should not go unnoticed and uncensured." He proposed that Dr. Gyulai write a letter of apology and be censured in order to ensure "this situation does not happen again." (Attachment P.)

Attachment P

To: Dr. Karl Rickels
From: "Dr. Jay D. Amsterdam" <jamsterd@mail.med.upenn.edu>
Subject: SKB Paxil BP study publication
Cc:
Bee:
Attached:

Dear Karl,

Thank you for your nice email in response to my note to Dr. Evans. I have given a great deal of thought as to how to resolve this extremely troubling matter. As per your investigation there is little doubt that these data were misappropriated from me and used and published without my knowledge and without regard to the significant contribution that I made to this study.

It is certainly not my intention to embarrass any of the authors who will eventually receive all the accolades when this paper comes to print. However, I am sure you will agree that there is little doubt that I was systematically slighted by Dr. Gyulai. His statement to you that he contacted SKB about having my name included as an author does not, unfortunately, comport with what knowledgeable persons at SKB report.

I think that it is important to maintain the highest academic and collegial relationship at an institution such as Penn. Thus, the theft and publication of a professor's data by a junior faculty member should not go unnoticed and uncensured. Therefore, in an effort to assure that this situation does not happen again, I would propose the following:

1. Dr. Gyulai write a letter of apology to me acknowledging his wrong doing and that he will not do this again in the future.
2. That Dr. Gyulai receive a letter of censure from the chairman (copied to me) admonishing him not to engage in this sort of behavior in the future.
3. That Dr. Gyulai receive a letter of censure from you, his section chief (copied to me) admonishing him not to engage in this sort of behavior in the future.

I think that this would resolve the immediate problem in a private, but useful, fashion; and will not result in any embarrassment to people who were uninvolved with the Penn site and unaware of Dr. Gyulai's behavior. It will also serve as a warning that our academic freedom is paramount and should not be compromised by petty, personal vein glory.

I would be happy to discuss these suggestions with you at your convenience.

As ever,

Jay

October 28, 2021

14. Attachment Q (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On May 11, 2001, Dr. Amsterdam emailed Dr. Rickels and explained that he considered data that he (Dr. Amsterdam) accumulated in his research unit from the study "were misappropriated from me and used and published without my knowledge and without regard to the significant contribution that I made to this study." Dr. Amsterdam complained that the "theft and publication of [his] data should not go unnoticed and uncensured." He proposed that Dr. Gyulai write a letter of apology and be censured in order to ensure "this situation does not happen again." (Attachment P.)

Ten days later, Dr. Rickels emailed Dr. Amsterdam stating that he had shared Dr. Amsterdam's comments with Dr. Evans and, once he received a reply from Dr. Evans, he (Dr. Rickels) would like to meet with Dr. Amsterdam to discuss the topic. (Attachment Q.)

Attachment Q

X-Sender: krickels@mail.med.upenn.edu
X-Mailer: QUALCOMM Windows Eudora Pro Version 4.2.2
Date: Mon, 21 May 2001 10:37:12 -0400
To: jamsterd@mail.med.upenn.edu
From: "Dr. Karl Rickels" <krickels@mail.med.upenn.edu>
Subject: SKB Publication
Cc: dlevans@mail.med.upenn.edu

Dear Jay,

I have shared your comments RE: SKB Publication, with Dr. Evans. Once I hear a response from him, I would like to get together with you on this topic.

Sincerely,

Karl

****

Karl Rickels, M.D.
Professor of Psychiatry
University of Pennsylvania
Department of Psychiatry
Mood and Anxiety Disorders Section
3535 Market Street
Suite 670
Philadelphia, PA 19104-3309

Telephone: 215-746-6417
Fax: 215-746-6551
email: krickels@mail.med.upenn.edu

November 4, 2021

15. Attachment R (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On June 13, 2001, Dr. Amsterdam again emailed Dr. Rickels to complain that there had been no resolution of the matter. Dr. Amsterdam wrote: "Before I contact either University officials or the editorial board of [the American Journal of Psychiatry] regarding this egregious behavior, I await your last efforts at resolution of this problem." (Attachment R)

Attachment R

To: krickels@mail.med.upenn.edu
From: "Dr. Jay D. Amsterdam" <jamsterd@mail.med.upenn.edu>
Subject: Am. J Psych paper
Cc:
Bcc:
Attached:

Dear Karl:

Months of inactivity and languishing over the issue of the upcoming SKB bipolar study, from which I have been excluded as a principal author, have produced no resolution (satisfactory or otherwise).

The article containing the data stolen from me has now appeared in print in the Am. J Psych 158: 906-912, 2001.

I suppose that the inactivity that I have seen indicates that I must now proceed at other levels regarding the "unacademic" and "un-collegial" behavior of Dr. Gyulai. Before I contact either University officials or the editorial board of Am J. Psych regarding this egregious behavior, I await your last efforts at resolution of this problem.

Jay

November 11, 2021

16. Attachment S (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On Jun 13,2001, Dr. Amsterdam again emailed Dr. Rickels to complain that there had been no resolution of the matter. Dr. Amsterdam wrote: "Before I contact either University officials or the editorial board of [the American Journal of Psychiatry] regarding this egregious behavior, I await your last efforts at resolution of this problem. (Attachment R)

That same day, Dr. Rickels responded that Dr. Gyulai had been ill and that Dr. Amsterdam would be contacted soon. (Attachment S.)

Attachment S

X-Sender: krickels@maiLmed.upenn.edu
X-Mailer: QUALCOMM Windows Eudora Pro Version 4.2.2
Date: Wed, 13 Jun 200116:01:59 -0400
To: "Dr. Jay D. Amsterdam" <jamsterd@maiLmed.upenn.edu>
From: "Dr. Karl Rickels" <krickels@mail.med.upenn.edu>
Subject: Re: Am. J Psych paper
Cc: "Dr. Dwight L. Evans, MO" <psych@maiLmed.upenn.edu>

Dear Jay,

Sorry I have not responded earlier. Dr. Gyulai had a serious operation and is recuperating at home. I will definitely get back to you once Dr. Gyulai is returned to work.

Regards,

Karl

At 12:04 PM 6/13/01 -0400, you wrote:

Dear Karl:

Months of inactivity and languishing over the issue of the upcoming SKB bipolar study, from which I have been excluded as a principal author, have produced no resolution (satisfactory or otherwise).

The article containing the data stolen from me has now appeared in print in the Am. J Psych 158: 906-912, 2001.

I suppose that the inactivity that I have seen indicates that I must now proceed at other levels regarding the "unacademic" and "un-collegial" behavior of Dr. Gyulai. Before I contact either University officials or the editorial board of Am J. Psych regarding this egregious behavior, I await your last efforts at resolution of this problem.

Jay

Jay D. Amsterdam, M.D.
Depression Research Unit
3600 Market Street, 8th floor
Philadelphia, PA 19104-2649
ph 215.662.3462
fax 215.662.6443
email: jamsterd@mail.med.upenn.edu

****

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Telephone: 215-746-6417
Fax: 215-746-6551
email: krickels@mail.med.upenn.edu

November 18, 2021

17. Attachment T (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On June 29, 2001, Dr. Amsterdam received a formal letter from Dr. Rickels stating that Dr. Gyulai had returned part-time from sick leave and he intended to speak with Dr. Gyulai concerning "this unfortunate situation ... today." (Attachment T.)

Attachment T

UNIVERSITY OF PENNSYLVANIA

MEDICAL CENTER

Karl Rickels, M.D.
Stuart and Emily B. H. Mudd Professor

University of Pennsylvania School of Medicine Hospital of the University of Pennsylvania

Chief, Mood and Anxiety Disorders Section Department of Psychiatry

June 29, 2001

Jay D. Amsterdam, M.D.
Professor, Director,
Depression Research Unit,
Mood and Anxiety Disorders Section Department of Psychiatry University of Pennsylvania

RE:SKB PAR-29060/
352
Dear Jay,

Laszlo Gyulai has now returned part-time from his sick leave, and I want to assure you that I will discuss this unfortunate situation with him today. I am sorry that this situation has developed this far, and I can assure you that the problem is of concern to me. I hope, sincerely, that this matter can be resolved between you and Laszlo in a collegiate matter.

Best regards,

Karl Rickels, M.D.

cc: Dwight L. Evans, M.D.
Laszlo Gyulai, M.D.

KR:tch

3535 Market Street • Suite 670 • Philadelphia, PA 19104-3309 ¦ Tel: 215-746-6417 • Fax: 215-746-6551 • Email: krickels@mail.med.upenn.edu

November 25, 2021

18. Attachment U (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On July 5, 2001, Dr. Gyulai sent a letter of apology to Dr. Amsterdam. In that letter, Dr. Gyulai explained that control of the paper had been taken away from him and that GSK published the paper without circulating the draft to all the participants and only allowed him (Dr. Gyulai) to see a near-final draft "when only minor changes could be done." (Attachment L.)

Fourteen days later, Dr. Amsterdam sent an email to Dr. Rickels stating that the apology was not sufficient in light of the "deliberate misappropriation and publication of [his] data" without his knowledge. Dr. Amsterdam was insistent that some sort of reprimand was necessary to ensure "plagiarism" of a colleague's data never happens again. (Attachment U.)

Attachment U

e-mail sent 07/19/01

Dear Karl:

As you know, Dr. Gyulai sent me a letter on 7/05/01 regarding the SmithKline data and publication issue. I would like to inform you (as his Section Chief) that his letter is certainly NOT acceptable as an apology to me for his deliberate misappropriation and publication of my data.

This matter was certainly NOT a "misunderstanding" on my part; nor was Dr. Gyulai the "primary investigator of the Penn site..." In fact, if Dr. Gyulai would simply read the Penn IRB- approved consent form for this study, he would clearly see that Dr. Amsterdam was listed as the "Co-Principal Investigator" on this study (not to mention the highest patient enroller in the study).

Additionally, this study was NOT conducted at only one Penn site, but *was* conducted primarily from bipolar patients recruited from the *Depression Research Unit* under my direction!

Finally, I have no idea of whether Dr. Gyulai ever wrote (or did not write) several drafts of the manuscript, or whether "the paper was taken away ..." from him, because Dr. Gyulai sequestered ALL available data and drafts of ALL manuscripts and NEVER communicated any information to me (the Co-PI) regarding any of these issues.

Thus, if you (as Dr. Gyulai's Section Chief) feel that his "apology" is sufficient to assuage this degree of uncollegial and unethical culpability in this matter, and neither you nor the Chairman feel that a letter of reprimand admonishing Dr. Gyulai NEVER to

plagiarize a colleague's data ever again, is appropriate, then I will certainly take this troubling matter further.

Please feel free to communicate your feelings to me regarding this issue in the *very near future* at your convenience.

Respectfully,

Jay

December 2, 2021

19. Attachment V (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

On July 5, 2001, Dr. Gyulai sent a letter of apology to Dr. Amsterdam. In that letter, Dr. Gyulai explained that control of the paper had been taken away from him and that GSK published the paper without circulating the draft to all the participants and only allowed him (Dr. Gyulai) to see a near-final draft "when only minor changes could be done." (Attachment L.)

Fourteen days later, Dr. Amsterdam sent an email to Dr. Rickels stating that the apology was not sufficient in light of the "deliberate misappropriation and publication of [his] data" without his knowledge. Dr. Amsterdam was insistent that some sort of reprimand was necessary to ensure "plagiarism" of a colleague's data never happens again. (Attachment U.)

The following day, July 20, 2001, Dr. Rickels sent Dr. Amsterdam a letter stating "it is unfortunate that [GSK] did not circulate the manuscript to you and I regret that Dr. Gyulai did not share it with you. Once again, as Dr. Gyulai's Program Director, I have expressed my belief that he should have done so." (Attachment V.)

Attachment V

UNIVERSITY OF PENNSYLVANIA MEDICAL CENTER

University of Pennsylvania School of Medicine Hospital of the University of Pennsylvania

Karl Rickels, M.D.
Stuart and Emily B. H. Mudd Professor
Chief, Mood and Anxiety Disorders Section Department of Psychiatry

July 20, 2001

Jay Amsterdam, M.D.
Director Depression Research Unit 3535 Market Street, Suite 3039 Philadelphia, PA 19104

Dear Jay:

I am responding to your recent e-mail regarding the SmithKline bipolar paper. I trust you know that I really want to resolve this situation. As I indicated to you before, I regret that Dr. Gyulai did not discuss the issue of authorship of the paper with you.
I do want to indicate my understanding of how the study was conducted here at Penn

. From my perspective, Dr. Gyulai was the principal investigator here at the Penn site. When it became clear that Dr. Gyulai was not recruiting at a rapid enough pace for the successful conduct of the study, I suggested that he discuss asking you to be involved with the study to increase the enrollment. From my memory, this occurred at a time when your program was in need of increased clinical trial activity and you were appropriately financially compensated for your work. I agree that you were very successful in recruiting subjects, but I do not believe Dr. Gyulai intended "deliberate misappropriation and publication',' of data.

Again, I regret that Dr. Gyulai did not discuss the authorship with you, and as Dr. Gyulai's Program Director, I made this very clear to him.

I also agree that it is unfortunate that Smith-Kline Beecham did not circulate the manuscript to you and I regret that Dr. Gyulai did not share it with you. Once again, as Dr. Gyulai's Program Director, I have expressed my belief that he should have done so.

I would be happy to sit and discuss this with you further, and I would be happy to involve Dr. Gyulai in this discussion with you if you'd like.

Sincerely,

Karl Rickels, M.D.
cc: Dwight L. Evans, M.D. Laszlo Gyulai, M.D.

December 9, 2021

20. Attachment W (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

EVIDENCE OF POTENTIAL GHOSTWRITING / ALLEGED PLAGIARISM

According to documents, Sally Laden of STI ghostwrote the 2003 editorial for Biological Psychiatry for Dr. Dwight L. Evans and Dr. Dennis Charney. Dr. Charney was then an employee at the NIH Intramural Program and he is now Dean of Research at the Mt. Sinai School of Medicine in New York. (See e.g., Attachment W and http://www.pogo.org/pogo-files/letters/public-health/ph-iis-20101129.html.)

Attachment W

From:
Sally Laden < sally.laden@cox.net>
To:
eric.m.dube@gsk.com

Subject:

Proposal for 2 review articles

Date:

07/28/2003 09:40:30 (GMT-05:00)

Dear Eric:

Thank you for thinking of me for the Safety in Breast Feeding and the Tolerability of Paxil CR review articles. A proposal for both is attached. Please review and contact me with questions. As we discussed on Friday, X am not able to start work on these papers until September, but if we decide to move forward, I will reserve that month for these projects.

Two other questions:

1) Lydia Lewisfrom the DBSA asked me to be the writer for their upcoming dual diagnosis consensus meeting this November. She mentioned that Scott committed GSK to funding the writing costs for the consensus statement. Lydiais asking if GSK will be able to paying me directly rather than offering the DBSA a grant for the cost of the writing. I am having problems connecting with Scott. If you see him in the near future, would you inquire about this? I would submit the proposal directly to GSK and bill GSK directly.
(Thanks)

2) Is there a problem with my invoice for writing Dwight Evans, editorial for the DBSA, scomorbidity issue to Biological Psychiatry? I submitted it over a month ago and was wondering about the status. If the payment cycle >30 days, so be it. I was just wondering.

Thanks again Eric. I look forward to working with you again.

Sally Laden MSE Communications

898 Cahill Court Cheshire, CT06410
T 203 y271-1047 F 203 y271-1054 E sally.laden@cox.net - New business proposals.doc
Attachments: New business proposals.doc;embedded picture.bmp

Produced By GSK In In Re Paxil, C.P.Ct.PA (Pregnancy)

PAR07032165D
PAR070321650

December 16, 2021

21. Attachment X (Letter to the Office of Research Integrity – Lawyer's letter excerpt)

EVIDENCE OF POTENTIAL GHOSTWRITING / ALLEGED PLAGIARISM

In an email to a GSK employee, Ms. Laden wrote, "Is there a problem with my invoice for writing Dwight Evans' editorial for the [Depression and Bipolar Support Alliance], s comorbidity issue to Biological Psychiatry?" [See Attachment W] When the editorial was published, Drs. Evans and Charney "acknowledge[d] Sally K. Laden for editorial support." (Attachment X.)

Attachment X

Editorial

Mood Disorders and Medical Illness: A Major Public Health Problem

Despite efficacious and widely available antidepressants and psychotherapeutic interventions, the psychosocial and medical burden of depression is increasing. In fact, the World Health Organization projects that depression will continue to be prevalent, and by the year 2020, will remain a leading cause of disability, second only to cardiovascular disease (Michaud et al 2001). Although we do not know with certainty why rates and disability associated with depression are increasing, it is likely that this mood disorder continues to be remarkably under-recognized and under-treated. Depression frequently occurs in the context of chronic medical illness, and it is only relatively recently that the research community has turned its attention to the relationship between depression and chronic medical conditions. However, there is much work yet to be done. The recently released Institute of Medicine report (2003) acknowledged depression as one of a number of chronic conditions that requires priority action, but did not address the importance of

comorbid depression and medical illness.

The relationship between depression and medical illnesses is complex. A chronically ill patient who also is clinically depressed may experience enhanced morbidity, a poorer prognosis, and even increased mortality from the medical diagnosis. Simply put, depression makes everything worse. But the association with depression goes beyond the effects of comorbidity on the course and outcome of a medical illness. A burgeoning body of evidence has now demonstrated that the relationship between depression and certain medical illnesses may indeed be bidirectional in nature. Depression may be both a cause and a consequence of some medical illnesses, such as cardiovascular disease, stroke, HIV/AIDS, cancer, and epilepsy.

In recognition of the need to increase awareness about this topic and improve the quality of life for persons with depression, the Depression and Bipolar Support Alliance, the world's largest patient advocacy organization, convened a two-day, multidisciplinary consensus conference on November 12, 2002 in Washington, DC. Nearly 50 experts in the fields of psychiatry, cardiology, immunology, oncology, neurology, endocrinology, internal medicine, family medicine, federal health care agency policy and research, and patient advocacy participated in this process. Formal presentations centered around the perspectives and goals of the National Institutes of Health and the Food and Drug Administration, the personal and societal burden of depression and medical illness, and the epidemiology, mechanisms, diagnosis, treatment, and prognosis of depression in the context of cardiovascular disease, cancer, HIV/AIDS, stroke, neurologic diseases, diabetes, osteoporosis, obesity, and chronic pain. Workgroups met to discuss specific issues related to these topics and on the second day, workgroup leaders presented their findings and facilitated open discussions from the group.

Burden of Mood Disorders and Medical Illness

The functional impairment associated with depression contributes significantly to the economic burden of chronic medical illness. Depression also is becoming recognized as a cause of increased morbidity and mortality in chronic medical illness. As reviewed by Katon (2003), medical costs for patients with major depression are approximately 50% higher than the costs of chronic medical illness alone. In addition, Katon (2003) underscores the equally important, but often less appreciated, effects of depression on adverse health behaviors, such as smoking, unhealthy diet, sedentary lifestyle, and poor adherence to medical regimens (e.g., cardiac rehabilitation). The findings from a number of studies have established that major depression is associated with significant functional impairment, lost work productivity, occupational disability, and increased health care resource utilization, and that effective treatment restores functioning. Simon (2003) reviews these data in the context of evidence from recent cross-sectional, longitudinal, and treatment studies of depressed patients with and without arthritis, chronic obstructive pulmonary disease, diabetes, or heart disease. This emerging body of evidence demonstrates that depression significantly increases the burden of functional impairment in medical illness, and that treatment reduces disability and health service costs. The effect of other mood disorders, such as dysthymia or bipolar disorder, on the burden of chronic medical illness is remarkably understudied.

Cardiovascular Disease

It is now recognized that major depression and bipolar disorder are associated with increased rates of death from coronary heart disease (CHD), and that major depression or depressive symptoms increase the risk of incident CHD (Musselman et al 1998). As reviewed by Rudisch and Nemeroff (2003), as many as 27% of patients with CHD have major depression, but a substantially larger number of cardiac patients have subsyndromal depressive symptoms. Depression is a particularly lethal development for patients with acute myocardial infarction (MI). In the United States, there are approximately 150,000 deaths in the first year after an initial MI, and Carney and Freedland (2003) estimate that at least 90,000 of these deaths may be related to post-MI depression. The cumulative body of evidence in support of an association between depression and cardiovascular disease is large and impressive; Carney and Freedland (2003) evaluate this literature and outline future directions for research, including studies that will better elucidate the role of depression in the development and progression of atherosclerosis, ischemia, and arrhythmias.

One particularly diverse and robust field of research is dedicated to better understanding the mechanisms that underlie the relationship between depression and cardiovascular disease. In their paper, Joynt and colleagues (2003) overview seven probable mechanisms associated with depression that may be related to cardiovascular disease: noncompliance with cardiac rehabilitation and medical regimens; risk factor clustering (e.g., smoking, hypertension, diabetes, hypercholesterolemia, obesity); hypothalamic-pituitary-adrenal (HPA) axis hyperactivity and cortisol elevation; decreased heart rate variability; elevated plasma levels of pro-inflammatory cytokines leading to atherosclerosis; platelet activation and hypercoagulability; and psychological stress.

The demonstrated adverse effect of depression on the risk of new and progression of established CHD has spurred the next emergent area of clinical study in this field: the consequences of depression treatment on cardiovascular morbidity and survival. As noted in the paper by Roose (2003), findings from the few open-label or randomized, controlled clinical trials suggest that the selective serotonin reuptake inhibitors (SSRIs), bupropion, and certain psychotherapeutic interventions are safe and effective treatment of depression in patients with CHD. The tricyclic antidepressants (TCAs) increase heart rate, cause orthostatic hypotension and conduction delays, have been shown to increase the risk of cardiac mortality, and should be avoided in this patient population. There is one published placebo-

controlled trial, which suggests that SSRI treatment of depressed post-MI patients may improve outcome and increase survival, but this study was not adequately powered to find significant changes in these cardiac disease outcomes. Thus, it is still not known whether treatment of depression enhances the outcome of the cardiac disease. Further study is clearly needed.

Cancer

As with cardiovascular disease, there is a large and growing body of evidence in support of a relationship between depression and cancer. Research efforts have focused on depression as a risk factor for cancer, depression as a consequence of cancer, and the dynamics of comorbid depression and cancer. Large population studies suggest that depressed mood or stressful life events may increase the risk of cancer. Although it is acknowledged that these observations of increased risk may be due in part to earlier, undetected malignancies or factors other than depression (Lillberg et al 2003; Penninx et al 1998), these findings are compelling and further study is warranted.

Depression also is a common occurrence in patients with a wide range of different malignancies and often prevents patients from complying with treatment regimens and other health-promoting behaviors, thus worsening the prognosis. A diagnosis of cancer represents a significant life stressor, which in vulnerable persons can precipitate an episode of depression. In addition, patients with cancer may develop "sickness behavior" or depressive syndromes due to proinflammatory cytokine activation that is the result of tumor cell burden, tissue destruction, radiation treatments, and chemotherapy. The papers by Raison and Miller (2003) and Spiegel and Giese-Davis (2003) review the relationships between depression and cancer and offer insight into disease progression and treatment. Of immediate clinical utility are the findings of studies showing that pretreatment with serotonergic antidepressants can prevent neurotoxicity and clinical depression in patients treated with interferon-alpha.

HIV/AIDS

Mood disorders, including depression and mania, are prevalent in persons with human immunodeficiency virus (HIV) disease and may be associated with impaired quality of life, neurocognitive and functional impairment, and poor adherence to antiretroviral therapy. In addition, emerging data suggest that depression is associated with declining CD4 cell counts, accelerated disease progression, and increased mortality. In their paper, Cruess and colleagues (2003) discuss the negative impact of mood disorders on HIV/AIDS and review evidence for safety and efficacy of antidepressants, mood stabilizers, and novel pharmacotherapies in this population (Evans et al 2002a). Leserman (2003) also reviews this topic, but with a focus on the biological mechanisms underlying the relationship between mood disorders and HIV disease

and the immune effects that result from this comorbidity (Leserman et al 1997; Evans et al 2002b). Patients with HIV/AIDS and comorbid depression are a significantly underserved and understudied population. Further epidemiologic, biological, and therapeutic studies are urgently needed to better understand the nature of this comorbidity, increase case-finding, and develop effective treatment strategies.

Neurologic Disease

This special issue also includes papers devoted to the topics of depression and comorbid neurologic disorders, such as stroke, Parkinson's disease, Alzheimer's disease, and epilepsy. Of these neurologic disorders, the relationship between mood disorders and cerebrovascular accidents is particularly well-studied. As reviewed by Robinson (2003), depression is common in poststroke patients, with reported prevalence rates of approximately 20%; bipolar disorder is less common. There is no standardized diagnostic approach for poststroke depression, and the controversies surrounding various approaches are summarized by Robinson (2003). The findings of treatment studies showing efficacy of antidepressants, electroconvulsive therapy, psychostimulants, and cognitive behavioral therapy in patients with poststroke depression are of considerable clinical importance. Importantly, treatment of depression improves measures of function and cognition and may result in improved survival. Evidence that antidepressants may prevent poststroke depression offers hope. As with many other medical comorbidities, depression may increase the risk of stroke, and the findings of two large epidemiologic studies support the role of depression as a risk factor for stroke. These findings further underscore the importance of identifying the underlying biological mechanisms associated with depression comorbidity.

Depression occurs in roughly half of patients with Parkinson's disease and is associated with significant impairment, including reduction in fine motor skills and cognitive function. In their paper, McDonald and colleagues (2003) review the distinct presentation of depression in this population, discuss the challenges associated with diagnosis, and highlight the need for more sensitive screening and diagnostic tools.

Depression in this population may not be due simply to the disability and added life stressors associated with Parkinson's disease. Rather, emerging evidence suggests that depression in these patients may be a consequence of neurodegeneration. Treatment of depression in Parkinson's disease is complicated by variable responses, sensitivity to adverse effects, and drag interactions. Randomized, placebo-controlled trials, particularly of the SSRIs and dopamine agents, are needed. The findings of functional neuroimaging studies are presented, which may eventually lead to the improved understanding of the neurocircuitry of depression in Parkinson's disease.

Even though depression occurs in as many as 50% of patients with Alzheimer's disease, contributing to accelerated

functional and cognitive decline, impaired quality of life, care-giver depression, and earlier institutionalization, surprisingly little evidence-based data are available to inform diagnosis and treatment. The diagnosis of depression in this cohort is particularly challenging because symptoms, such as psychomotor retardation, insomnia, and emotional liability, which occur in nondepressed patients with Alzheimer's disease may be difficult to differentiate from a true depressive episode. Moreover, symptoms of dementia may mask an underlying depressive disorder. In an effort to guide research and better inform clinical care, the National Institute of Mental Health has undertaken the task of developing diagnostic criteria for depression in Alzheimer's disease. Lee and Lyketsos (2003) review these developments and describe an ongoing longitudinal study of depression and other neuropsychiatric comorbidities in new cases of Alzheimer's disease, which will provide valuable information on the epidemiology, natural course, and diagnosis of depression in this population.

Epilepsy is another neurologic disorder that often is complicated by comorbid depression. As many as 50% of epileptic patients seen in tertiary treatment centers may have depression, and suicidality among depressed epileptics have been reported to be as high as 10 times the rate than in the general population. Kanner (2003) reviews the challenges related to diagnosing depression in epilepsy: patients often present with atypical depressive symptoms (e.g., anxiety, irritability, hypomania, pain); the peri-ictal period often is associated with a recurrent and short-lived dysphoria that is clinically significant but does not conform to standard diagnostic criteria; and antiepileptic drugs and surgical intervention can be iatrogenic causes of depression. Clearly, epilepsy is a risk factor for depression; however, recent evidence suggests that depression may increase the risk for epilepsy by 4- to 6-fold. Further studies are needed to better characterize this complex relationship.

Call for Action

The contributions made by this conference and the papers published in this special issue of *Biological Psychiatiy* should not simply be measured by the quality and quantity of the data, which are impressive. Rather, the strength of this publication also lies in the fact that the views of experts from widely divergent fields of clinical and scientific endeavor resonate along 4 basic themes: 1) Depression is very common in chronic medical illness; 2) Comorbidity with depression inevitably hinders recovery and worsens prognosis; 3) Medical illness is a risk factor for depression because of psychosocial stressors, functional impairment, and other biological mechanisms (e.g., Parkinson's disease); and 4) Depression may figure prominently as an etiologic factor in the onset and course of medical illness, particularly cardiovascular disease, stroke, HIV/AIDS, cancer, and epilepsy. The latter observation is truly remarkable. Much more research is needed to better understand this bidirectional relationship and identify possible common pathogenic, mechanistic pathways that link depression and serious medical illness.

These are powerful messages that must not be ignored. The weight of evidence is so persuasive that there should never again be a valid reason for not aggressively seeking out and treating depression in medically ill patients. Increasing awareness, reducing stigma, and maintaining a high level of vigilance for depression in medically ill patients must become a priority for clinicians. In addition, the efforts of the research communities must continue to better elucidate the prevalence, risk profile, diagnostic criteria, treatment, and biological underpinnings of the comorbid relationship between depression and medical illness. Only by furthering research efforts and aggressively diagnosing and treating depression, will we be able to achieve substantive gains in health care and in our patients' quality of life.

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We acknowledge Sally K. Laden for editorial support.

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December 23, 2021

Kenneth Jaffe's comment

Jay Amsterdam, now Emeritus Professor of Psychiatry at the University of Pennsylvania and esteemed psychopharmacology researcher, has been a good friend since our days together as medical students 50 years ago. I have closely followed the story of the Paroxetine 352 case. I commend Dr. Tom Ban and INHN for providing an important service to both our profession and the public by exposing, in meticulously documented detail, this sordid story.

I wish this was a rare case of Big Pharma's money and power corrupting clinical research and in so doing corrupting an academic institution and likely harming patients. It is not. Instead, it is an unusually well documented example of a common practice that has been going on for many years and reached into many, perhaps most, prestigious academic institutions

The most wide-spread and deadly recent example of this practice is the prescription opiate epidemic. It was built on a big lie that OxyContin was less addictive than older opiates. This lie was sold to doctors. Far too many chose to buy it and were

hardly blameless in the process. Lots of political contributions from Pharma also likely played a big role in the DEA and other federal regulatory agencies turning a blind eye to the prescription opiate epidemic until it exploded in the media and could no longer be ignored. Sadly, corruption is as old as civilization.

"Nothing is so strongly fortified that it cannot be taken by money."

Marcus Tullius Cicero

January 27, 2022

Kenneth Gillman's comment

Many of us share feelings of anger and dejection when reviewing yet another example, like Jay Amsterdam's Study 352 exposé of the myriad instances of corruption of science by naïveté, stupidity and venality. It is but one facet of how, society-wide, such behaviors are destroying the planet, as unbridled greed, fomented by capitalism, overwhelms and devours our world.

Greed is to aspiration, as rape is to love

Ken Gillman 2021

I remember my sense of foreboding when, as a young man, I saw the potential downside of the Reagan-Thatcher laissez-faire, neo-neoliberal, self-regulating capitalism asserting dominance. There is insufficient recognition that we live in a plutocracy, not a democracy — the greed and inequality thus catalyzed are reflected in all branches of society, including medical science. The adverse effects of this plutocracy on medical science, facilitated by the massive wealth of pharmaceutical companies, is now threatening to complete its ruination. It encourages a short-term outlook and a descent to the lowest common denominator, of which the epithet "publish or perish" is a prominent exposition.

Much of the educational system is now dependent on, and ghost-manipulated by, the wealth of industry — and while aspiration and ambition may be fine qualities, when they transmute into greed and short-term gain, disaster is close at hand. It is the belief among many that short-term goal-directed research is the efficient way forwards. However, most discoveries and advances are serendipity and come from "left field," an observation that has become lost to the common consciousness.

Deceit, outrageous deceit, has been perpetrated on three levels: first, deceit about the mechanisms by which drugs work (pharmacology); second, deceit about whether they do indeed work well, or at all (efficacy); and third, deceit about on how many manufactured diagnoses they can be claimed to work (disease mongering). I have written extensively concerning the deceit and misrepresentation of the pharmacology of how drugs work. This is so extensive and affects such a large proportion of the drugs about which I write that it is impossible to discuss the pharmacology without explaining that much of the data in the literature is either misrepresented, or frankly deceitful.

Jay writes more about the misrepresentation of the efficacy, via manipulations of trials and the unethical behavior of individuals. These three facets combine to produce an unsettling exemplar of George Orwell's "universal deceit."

> *"In an age of universal deceit, telling the truth becomes a revolutionary act"* and,
>
> *"The further a society drifts from truth, the more it will hate those who speak it."*

Jay Amsterdam's analysis of the deplorable, unethical and unprofessional behavior surrounding the 352 charade is necessary and laudable in its probity, thoroughness and historical value.

The society of medicine has drifted sufficiently far from probity and truth that Jay will be disliked and even reviled. His analysis will be read in its entirety by too few. Nevertheless, it must be "on the record" for those who in the future wish to learn from history — forlorn hope as such learning might be — I will leave research on the exact wording of Hegel's quotation about "people not learning from history" to others.

When I say “Greed is to aspiration, as rape is to love” I acknowledge that incentive, aspiration and ambition may help to drive discovery, but, when without a moral compass and unbridled, as all too evidently, they have become, they soon take a destructive downhill path.

What more can be said? We live in times where nurturing optimism is difficult and where acting as an ethical academic is to be a stranger in your own land. Those who are affecting these undesirable outcomes are, in part, and moral judgements aside, simply reflections of the wider changes in culture and society — just soiled flotsam bobbing along on the floodtide of history.

Will the tide change in our time?

February 10, 2022

Daniel Kanofsky’s comment

INHN is to be commended for publishing all the exhibits regarding the Paroxetine 352 study controversy. As I have commented previously, "It is astonishing that Amsterdam and McHenry were able to unearth and deconstruct, from these emails and documents, what is nothing short of an alarming story. Their deconstruction gives a unique glimpse behind the Wizard's Curtain of documented skullduggery in academic publishing within our field" (Kanofsky 2020).

INHN and Amsterdam are now taking this one step further. Every week we are exposed to more primary evidence. Most of history is a secondhand account of what transpired. The historian views primary documents and we are privy to his interpretation of them. In the case of the Paroxetine 352 study controversy now we get to see "them.” This is a rare achievement. Transparency is king. Primary evidence is being presented on a weekly installment plan.

Which brings me to my second point. These short installments, serious indictments which they are, nevertheless, make for entertaining reading. I look forward to studying them every week. It is reminiscent of how a Charles Dickens novel was presented in the 19th century. For more on this I recommend reading "When Dickens Came Via the Installment Plan" (Reif 1996). To continue the analogy Dickens was

critiquing unjust economic and social conditions in Victorian era England. His writings contributed to important social reforms. It may be that future historians will use similar language to praise this INHN series.

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March 17, 2022

Leemon McHenry's comment

It has been my pleasure to work with Dr. Jay Amsterdam on exposing the scientific misconduct in the SmithKline Beecham (now GlaxoSmithKline) Paroxetine Study 352 clinical trial, comparing the antidepressant drugs imipramine and paroxetine for the treatment of bipolar type I major depression (or manic depression). During our 10-year collaboration we published two papers on this study, "The Paroxetine 352 Bipolar Trial: A Study in Medical Ghostwriting," in the *International Journal of Risk & Safety in Medicine*, 2012, and "The Paroxetine 352 Study Revisited: Deconstruction of Corporate and Academic Misconduct," in the *Journal of Scientific Practice and Integrity,* 2019, as well as other articles on the general problem of corrupted industry-sponsored trials.

As a research consultant for the law firm, Baum, Hedlund, Aristei & Goldman of Los Angeles I had collected documents on the 352 trial as part of on-going litigation against SmithKline Beecham for harms done to patients prescribed paroxetine. I was then working on the now-infamous Paroxetine Study 329 with Dr. Jon Jureidini but was well aware that the 352 trial was part of a much larger strategy in SmithKline Beecham's competition with other SSRI manufacturers to gain market share. The documents from

the now-defunct medical communication company, Scientific Therapeutics Information (STI), showed the same pattern of misrepresentation of trial results we found in Study 329 via ghostwriters employed by STI. When Dr. Amsterdam contacted Baum Hedlund, he had no idea that what was coming. His suspicions were completely vindicated by what was revealed in the documents.

The evidence was indisputable that the 352 trial was grotesquely manipulated by SKB and STI aided by academic key opinion leaders named as "authors" on the ghostwritten study. When reality would not cooperate with marketing hype, the results were fudged to publish a "positive" trial in the pages of the *American Journal of Psychiatry.* The key opinion leaders and the journal editor well understood the commercial value to SKB. What they didn't count on was the lone voice of Dr. Amsterdam who courageously stood up against the corruption and the law firm, Baum Hedlund, that stood behind him. Once the misconduct was exposed to the light of day, instead of following the path of science and correcting the record, the powers that be circled the wagons, stonewalled and doubled down to silence Dr. Amsterdam. This left an enduring stain on the University of Pennsylvania that partnered with GlaxoSmithKline, Scientific Therapeutics Information that did the ghostwriting, *The American Journal of Psychiatry* that published the fraudulent paper and the Office of Research Integrity for failure to act on Dr. Amsterdam's complaint.

As one peruses the pages posted on this INHN site, it is perhaps not surprising that scientific integrity means very little when enormous profits are at stake, but it is disheartening when the government fails to stand up for science.

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April 28, 2022

Edward Tobe's comment

New comments have been submitted about misconduct in scientific research. Before the Jay Amsterdam Leemon McHenry 2020 article exposed scientific misconduct in the Paroxetine 352 Bipolar Study and provoked an outpouring of disquiet, Barry Blackwell spoke to corporate corruption in 2016.

My prior comments addressing the Amsterdam and Leemon post include: "The Iceberg of Improbity" posted to INHN Controversies on April 23, 2020; and a comment on Barry Blackwell's comment on Jay Amsterdam and Leemon McHenry's reply to his comment on Barry Blackwell's comment on Jay Amsterdam and Leemon McHenry's reply to his comment posted to the same INHN section on July 1, 2021. I also commented on Blackwell's 2016 post on October 8, 2020, with the tagline: "Then sometime, with great luck, he will succeed."

I was particularly moved by Mark Kramer's 2021 comment on Samuel Gershon's 2021 comment on Amsterdam's collated document:

> "Why isn't there an outcry from every quarter? Why aren't those who perpetrated these crimes against academia, industry and big publishing, outcast – made to pay in some way?"

I would ask why would there be an outcry? We live our lives with various illusions that offer hope, comfort, and in a group setting, camaraderie. Why forfeit the illusion?

It is a comfortable idea that big corporations and government search for avenues to help promote health and safety. Democratic governments are elected by the people and represent the people. The last sentence of the United States Declaration of Independence offers a very high standard of human behavior: "…we mutually pledge to each other our Lives, our Fortunes, and our sacred Honor."

But there is a different standard. "Business as usual" means doing what you want as long as you can get away with it. "Business" represents a goal to achieve; "as usual" means to achieve the goal in an expedient manner without sanctions. This is especially a successful formula when the offended are not valued by themselves and by others.

From the legal correspondence of Dr. Amsterdam's attorney, Mr. Esfandiari, we observe a bold acceptance of "business as usual":

> "On April 3, 2001, Dr. Rickels sent Dr. Amsterdam a letter discussing what he had learned during his investigation. (Attachment K.) In that letter, Dr. Rickels noted, among other things, the following information:
>
> (1) Dr. Amsterdam was co-investigator of the trial;
>
> (2) Dr. Amsterdam had enrolled more patients in the trial than Dr. Gyulai;
>
> (3) The ghostwriting firm, STI, had chosen Dr. Gyulai as the paper's first author;
>
> (4) GSK had decided to replace Dr. Gyulai as first author with Dr. Charles Nemeroff; and
>
> (5) Academic investigators in the trial never reviewed or even saw the submitted manuscript."

The University of Pennsylvania's Department of Psychiatry knew about ethical violations in scholarly representation of science, yet the department wanted a vanilla "resolution" with no apparent consequence for those breaching ethical standards.

In attachment X, Bijan Esfandiari, Esq. provides information suggesting ghost writing benefitted an employee of NIH:

> "According to documents, Sally Laden of STI ghostwrote the 2003 editorial for Biological Psychiatry for Dr. Dwight L. Evans and Dr. Dennis Charney. Dr. Charney was then an employee at the NIH Intramural Program and he is now Dean of Research at the Mt. Sinai School of Medicine in New-York.
>
> "In an email to a GSK employee, Ms. Laden wrote, 'Is there a problem with my invoice for writing Dwight Evans' editorial for the [Depression and Bipolar Support Alliance], s comorbidity issue to Biological Psychiatry?' [See Attachment W] When the editorial was published, Drs. Evans and Charney 'acknowledge[d] Sally K. Laden for editorial support.' (Attachment X.)"

Authority coupled with large corporate interests is not likely to face significant consequence. Government may use its authority, often without risk, to advance the peculiar interests of some.

Between 1932 and 1972 the "Tuskegee Study of Untreated Syphilis in the Negro Male" studied 399 black men living in Tuskegee, Alabama, infected by *Treponema palladium*, the spirochete that causes syphilis. The researchers lied to the infected men stating that the men were being treated for health problems caused by "bad blood." The main purpose of the study was to collect postmortem data about syphilis, and the men were considered laboratory animals. There was no effort to treat the men or to warn their families of the potential dangers of the disease. There was no informed consent. When penicillin emerged as the treatment of choice for syphilis in 1940s, none of the subjects were offered penicillin.

The consequences to the families included 40 wives became infected with the syphilis spirochete and 19 children were born with congenital syphilis. The study involved John A. Andrew Memorial Hospital located in Tuskegee, Alabama, the Tuskegee Institute, the Alabama State Board of Health, the Macon County Health Unit, United States Public Health Service (USPHS), Centers for Disease Control and Prevention (CDCP) and the United States National Institute of Health. There were no legal consequences for those conducting the 40-year study (Tobe 2017).

Fraud is easier and more acceptable when performed on something less valued. What is not valued is usually not as well documented. In the Tuskegee experiment, the subjects of the study were not valued; those conducting the study were associated with national and state government, large corporations and universities. Protection is assumed.

The treaty between the Canadian government and the First Nations included a provision that after 1920 there was mandatory education of the First Nations children presumably on the Reserves. But residential schools for education were established distant from home, not on the reserve, with mandatory attendance. The schools aimed for a complete cultural transformation of the child. The conditions of some schools were compromised. About an estimated 150,000 First Nations, Métis and Inuit children who were taken from their home and attended Indian Residential Schools. Many parents did not know their child died. Deaths were not regularly documented. There are estimates of 4,100 child deaths at the Indian Residential Schools; however, recently discovered mass grave sites raise more questions.

Recently, after almost 100 years, Canada has attempted to address the explosion of information. Over many years there was no public outcry because the First Nations

people were not valued. Famous athletes were followed, but not the fate of dehumanized people (Eshet 2915; Hill-MacDonald 2017; Honderich 2021).

Pertinence of remarks to fraud in psychiatric research

The vulnerability for fraud includes people or subjects that are disparaged, dehumanized. The subject of the fraud is not valued and documentation is either obscure and easily manipulated.

Mental illness has historically been perceived as shameful, poor behavior, volitional or a minacious ghost to chain to the wall. It was fear of the lunatics that led to the founding of Pennsylvania Hospital. Although there was hope that good care would relieve some madness, lunatics were confined to barred cells in the basement of the building. In 1828, William Malin, a clerk and librarian at Pennsylvania Hospital noted the morbid curiosity of the public to see mad people (Gamwell and Tomes 1995).

The fear of madness, like all fears, is handled in a limited number of ways. When dealing with the very mentally ill, fear also includes helplessness and hopelessness. Devaluation of what is feared is a common method of responding to fear. Observing madness from a safe distance provided an opportunity to scoff at what was once intimidating.

The science of mental illness lacks replicable biological markers for many psychiatric disorders. Published pharmacological studies or reviews of the literature about mood disorder are based upon a phenomenological presentation of patient history and some observations. The rating scales in mood disorder assume merit not established by biological marker. Expressed concern exists about the alliance between the United States Food and Drug Administration, the American Psychiatric Association and the pharmaceutical industry. Although the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* is influential in clinical practice, there are those who raise another diagnosis "Conflict-of-Interest Disorder" (Cosgrove 2010; Cosgrove, Bursztajn and Krimsky 2009; Frances 2012). There are members on the panels creating the DSM with ties to pharmaceutical industry. These members do not recuse themselves when discussion or decision is made that might be relevant to their economic allegiances. The diagnostic system shows significant overlap in signs and symptoms and

responses to psychotropics. Perhaps a preferable concept would be a Modulation System Disorder (Tobe 2000).

The extraordinary incidence of placebo speaks negatively to the merit of drug studies in the scientific investigation of mood disorder. The very methodology of studies creates an opportunity to economically advantage a very unsophisticated system. Many studies struggle to show superiority of drug over placebo in achieving a 50% response on a rating scale. This is different from response to antibiotics or antihypertensives.

Joseph Schildkraut recognized "the significant effects which social and interpersonal factors have on the clinical response to antidepressant drugs" (Schildkraut 1965).

My assertion that psychiatry is not currently well regarded is demonstrated by the pervasive presence and acceptance of a procedure called a medication check. Thousands of psychiatrists perform and bill for this procedure. This procedure is now a standard of care whether declared not. The "med check" is performed by the psychiatrist perhaps every few weeks or months.

The med check restricts the thoroughness and importance of determining emotional stability of the patient, examination for blood pressure, extrapyramidal signs, weight changes, appropriate laboratory studies, interim personal family and work history, interim medical history, and current medication evaluation. The patient is prescribed a drug that affects their central nervous system. How serious could mental illness possibly be! Commonly, the patient is sent to a counsellor for therapy, to reveal their lives and ask for help. The counsellor is often perceived as the real doctor and why not!

Doctor in Latin means "a teacher" from *docere*, "to teach" (Webster's 1975). As a contrast to the med check, allow one possible translation of Hippocrates's Epidemics, Book I, Section XI, which reads "Declare the past, diagnose the present, foretell the future; practice these acts. As to diseases, make a habit of two things – to help, or at least to do no harm."

To summarize, the lack of outcry about fraud in psychopharmacological research reflects a vulnerable area of science where forces of powerful economic interests may advantage without consequence. There continues to be a devaluation of the mentally ill.

Psychiatrists and organized psychiatric associations have allowed pharmaceutical companies and insurance companies to guide them adding further to the denigration of the science of psychiatry.

Mark Kramer's success was to follow a path of dignity possessing both scientific and musical talent. To be able to not only hear but to listen to the music of life as we travel through this voyage is an accomplishment.

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May 5, 2022

Janusz Rybakowski's comment

I would like to add a short comment to the endeavor of my long-lasting friend, Jay Amsterdam, to unmask industry corruption in psychiatric trials. That the participants in this rigamarole are prominent psychiatrists is probably one of the worst aspects of this.

The present story concerns the publication of Nemeroff, Evans, Gyulai et al. (2001) in the *American Journal of Psychiatry*, comparing imipramine and paroxetine as an add-on to a mood stabilizer in the treatment of bipolar depression. The paper presented the results of a multicenter Paroxetine 352 study carried out in the 1990s of which Jay Amsterdam was a Co-investigator. The results of the study showed that both paroxetine

and imipramine were superior to placebo in patients with low (> 0.8 mmol/l) serum lithium levels and that, compared to imipramine, paroxetine resulted in a lower incidence of adverse effects.

Despite recruiting a substantial number of patients for this study, Jay Amsterdam was not listed among the authors and was only recognized in the Acknowledgments as a collaborating investigator. On the other hand, Dr. Laszlo Gyulai, from the University of Pennsylvania, providing a lower number of patients than Jay was among the authors, and, on some stage of the publication, was even considered to be the first author. The authors were also Dwight Evans, the future chairman of the Department of Psychiatry at Penn, and other prominent psychiatrists such as Charles Nemeroff, Gary Sachs and Charles Bowden. Jay Amsterdam became aware that the results of the study were about to be published in April 2001 and in the following two months had an excessive e-mail exchange with Dr. Karl Rickels, the supervisor of Dr. Gyulai. It resulted in Dr. Gyulai's letter of apology to Dr. Amsterdam which was far from giving him satisfaction. Later, it also turned out that the paper was written by the STI (Scientific Therapeutic Information), hired by SmithKline Beecham, the producer of paroxetine.

Ten years later, Jay Amsterdam produced a complaint of scientific misconduct against Dwight Evans, Laszlo Gyulai, Charles Nemeroff, Gary Sachs and Charles Bowden for allowing their names to a manuscript that was "ghostwritten" by the STI. Additionally, he indicated several flaws of the paper of 2001, which was since this time been widely cited, among others, in the article published in such a prestigious journal as the *New England Journal of Medicine* (Sachs, Nierenberg, Calabrese et al. 2007). And another 10 years later the extensive documentation of this story is being displayed on the INHN site.

As the President of the Editorial Board of the main Polish psychiatric journal, *Psychiatria Polska*, I arranged a publication in this journal of the paper titled "Industry-corrupted psychiatric trials" written by Jay Amsterdam and co-authored by Leemon McHenry from the Department of Philosophy, California State University, Northridge, and Jon Jureidini from the University of Adelaide, Australia (Amsterdam, McHenry and Jureidini 2017).

The paper exposes the research misconduct of pharmaceutical industry-sponsored clinical trials via three short case studies of corrupted psychiatric trials that were

conducted in the United States such as the SmithKline Beecham Paroxetine Study 329, Forest Laboratory Citalopram Study CIT-MD-18 and, last by not least, SmithKline Beecham Paroxetine Study 352. The common elements that enable the misrepresentation of clinical trial results include ghost-writing for medical journals, the role of key opinion leaders as co-conspirators with the pharmaceutical industry and the complicity of top medical journals in failing to uphold standards of science and peer review are discussed. The authors conclude that the corruption of industry-sponsored clinical trials is one of the major obstacles facing evidence-based medicine. *Psychiatria Polska* is a journal of international reputation (IF=1.657) and the paper has reached a wide audience.

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