

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

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