

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

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

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RE: Bipolar Paper Authorship

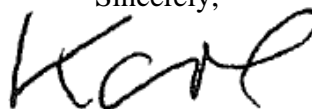
Dear Jay,

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,

A handwritten signature in black ink, appearing to read 'Karl', written in a cursive style.

Karl Rickels, M.D.

KR:tch

September 23, 2021