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

**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. 7/5/01
Professor, Director,
Depression Research Unit,
Mood and Anxiety Disorders Section
Department of Psychiatry
University of Pennsylvania

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