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February 20, 2018

Robert Freedman, MD
Editor
American Journal of Psychiatry
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Dear Dr. Freedman:

As concerned scientists, bioethicists and physicians, we previously wrote to you on May 9, 2016 in your capacity as Editor-in-Chief of the American Journal of Psychiatry, to request the formal retraction of Forest Laboratories report of study CIT-MD-18. This article was published under the alleged authorship of Wagner *et al.*: "A randomized, placebo-controlled trial of citalopram for the treatment of major depression in children and adolescents," in the American Journal of Psychiatry in June 2004. Your response to that undertaking was a curt reply that you would not retract the article; however, you provided no reason(s) for your decision.

In that May 9th letter to you, we provided evidence of fraudulent manipulation of the reporting of efficacy results from the CIT-MD-18 trial to the FDA, the American Journal of Psychiatry, and to the public by Forest Laboratories; and, indicated to you that additional evidence of this fraud would be forthcoming in de-classified court documents from ongoing litigation. In this regard, numerous court documents and trial testimony have now been de-classified and are publicly posted on the Drug Industry Document Archive (DIDA) web-site at the University of California, San Diego. Moreover, these documents have now been widely circulated to many concerned psychiatrists, academic researchers, biomedical scientists, and concerned citizens.

We now wish to bring to your attention several recent developments that have direct relevance to the misreporting of the outcome results of the CIT-MD-18 study and the serious misrepresentation of these results that were made to you when you previously inquired about whether or not the article's lead author, Dr. Karen Wagner, was aware that the manuscript was ghostwritten by Weber Shandwick and Prescott Medical Communications on behalf of Forest Laboratories.

First, while the misreporting of nine unblinded study subjects (the result of a dispensing error during the CIT-MD-18 study) was known to us in 2016, the newly-released court documents now reveal that Forest Laboratories intentionally misled the FDA about the unblinding problem that clearly invalidated the claim

that the Wagner *et al.* trial was a 'positive' study (as published in the American Journal of Psychiatry) (*see* attached email responses re. Letter to FDA for CIT-18, i.e., the now infamous "creative euphemism" document). Since four of the unblinded study subjects were derived from Dr. Wagner's own investigative site and she was lead investigator of the study, it is implausible that she was unaware of the unblinding problem during the CIT MD 18 study; yet Dr. Wagner completely failed to report this information in the published article in the American Journal of Psychiatry.

Second, additional de-classified emails and court testimony from Dr. William Heydorn, named Forest co-author on the Wagner *et al.* article, clearly shows that Dr. Wagner personally interacted with the manuscript ghostwriters, Natasha Mitchner and Mary Prescott, and knew that the manuscript produced in her name was, in fact, plagiarized (*see* attached 2016 Depo. W. Heydorn at 312:24-313:16).

We would also bring to your attention that, in the Editor's Note published in the American Journal of Psychiatry 166:8, August 2009, pp. 942-43, you specifically requested that Drs. Wagner, Robb and Findling provide information on their contribution to the drafting of the original CIT-MD-18 manuscript, and you were informed that the alleged authors had contributed to the manuscript production and had no knowledge that Dr. Heydorn of Forest Laboratories had outsourced the writing of the Wagner et al. manuscript to a medical ghostwriting outfit. Dr. Heydorn testified that what was reported to you was not a true statement (*see* attached 2016 Depo. W. Heydorn at 313:4-5).

As we predicted in our May 9th letter, the ongoing release of de-classified documents from litigation continues to expose the extent of industry manipulation of clinical trials data.

In light of the release of these new documents, we now ask whether the American Journal of Psychiatry regards these new revelations as significant enough to re-open your limited investigation of malfeasance into the case of CIT-MD-18 reporting in the American Journal of Psychiatry, and finally to retract the Wagner et al. article as a serious stain on the reputation of the American Journal of Psychiatry, the American Psychiatric Association, and the profession of academic and clinical psychiatry writ large.

We are making this letter available to interested parties and for possible posting in the public domain.

Sincerely,

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Attachments:
Baum Letter Memo to USAO
Email responses Re: Letter to FDA
Deposition of W. Heydorn at 312:24-313:16