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14 May 2015

David J. Greenblatt, M.D.
Editor-in-Chief
The Journal of Clinical Psychopharmacology
Tufts University School of Medicine
Boston, MA 02111

Dear Dr. Greenblatt,

Thank you for your email regarding our manuscript Ref.: Ms. No. JCP-D-15-00062 "The Citalopram CIT-MD-18 Pediatric Depression Trial: A Deconstruction of Medical Ghostwriting, Data Misrepresentation and Academic Malfeasance" submitted to The Journal of Clinical Psychopharmacology.

We are grateful that you have openly articulated an editorial position that we believe is prevalent, but mostly unstated. We disagree strongly with your position, believing that the legal and ethical facts that we presented are essential to understanding the full context of how industry-sponsored clinical trials can misrepresent the data to the medical community. In our view, if medical journals are to achieve scientific status, they cannot censor legitimate criticism for fear of offending the pharmaceutical industry. Any attempt to edit out this content condones scientific misconduct and betrays patients who are damaged by the misreporting of clinical research published in the journals. Therefore we are not inclined to make the changes that you are requesting.

However we do seek your response to a number of points.

First, we note that all three reports from peer review were positive and supportive of publication of our paper with only a few minor suggestions for revision. Your decision not to accept our manuscript as a full-length, peer-reviewed research article is certainly at odds with these reviewer's opinions. Can you explain why you overruled your reviewers?

Second, we respectfully disagree with your characterization of ghostwriting as merely being "manuscript preparation assistance." We agree that if it were, there might be a plausible argument for its use. However the problem of ghostwriting as facilitating the misreporting of data is well documented in the medical and bioethics literature since the late 1990s. We have ourselves contributed numerous articles on the subject. In the present case of Forest and their hired PR firm, Prescott, the spin on the data is well documented and undeniable in the email correspondence that has been de-designated as confidential by the court. If you have another look at our paper, you will find that in Forest's marketing plan, they explicitly use the term "ghostwritten" to characterize their effort to use thought leaders as academic facades for industry marketing. (p. 6) Do you support a distinction between writing assistance to a legitimate chief investigator and a ghostwriter employed to present the sponsor's drug's profile in the most positive light, even if that means lying?

Third, we also believe you are mistaken in your view that the authors take responsibility for the content of the manuscript. As you are no doubt aware, the data and the manuscript are the intellectual property of the sponsor company and the latter is only released to the "lead author" by the company's legal department at the point of submission. In the cases that we have investigated, very few of the academics named on the papers contributed any significant writing or editing of the manuscripts nor did any of them have access to the data. The ghostwriter works from a clinical summary of the data provided by the sponsor company. Can you specify what constitutes adequate oversight by the named authors?

Fourth, we stand by our evaluation that this is not only scientific misconduct by the sponsor company, but academic malfeasance. We took on the burden to study the protocol, the study report and the published paper. In our view, the academics named on the paper were negligent in their failure to do the same. The most perfunctory effort on their part would have revealed serious problems with the ghostwriter's manuscript. Can you say what additional evidence would be required to demonstrate malfeasance?

Fifth, you claim that you have no interest in the litigation, but it is only from the discovery process of litigation that the confidential documents and the full clinical data are made available to medical experts for analysis and evaluation. Without litigation, the academic community and the public at large would remain in the dark about the misreporting of the science that guides the prescribing habits of doctors. In the particular case of Citalopram CIT-MD-18, this negative trial was misrepresented as positive to gain a license for escitalopram in adolescent depression. This requires a remedy beyond litigation. Can you explain why you think it is not in the public interest to analyse data only available through litigation?

Finally, as you well know, modern science depends in great measure on public disclosure of the studies and the data that support the conclusions. Equally, science advances through the public debate of those studies, including rigorous criticism. The exposure of bad science is at least as important as publication of well-supported science. What is often concealed is the criteria and reasoning behind peer review journals such as yours in making editorial and publication decisions. Those who read medical journals need to know why a manuscript that received favorable peer reviews has been rejected for publication. In light of this, we enlist your participation in the latter aspect of this important public conversation.

Yours respectfully,

On behalf of
Leemon B. McHenry
Jon N. Jureidini
Jay D. Amsterdam