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[\[em.jcp.0.42eea1.40a47146@editorialmanager.com\]](mailto:em.jcp.0.42eea1.40a47146@editorialmanager.com) On Behalf Of Journal of Clinical
Psychopharmacology [em@editorialmanager.com]
Sent: Wednesday, 6 May 2015 2:44 AM
To: Jon Jureidini
Subject: Decision on your Submission to the Journal

CC: barbara.kern@tufts.edu

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

The Journal of Clinical Psychopharmacology

Dear Dr. Jureidini and Dr. Amsterdam:

Your manuscript has been reviewed. The Editors would like you to Revise your paper into the format of
a "Guest Editorial" and address their comments as well as those of the 3 reviewers (See BELOW).

Editors' Comments to Address (required):

We would like to reconsider a revised version of your manuscript in the form of a "Guest Editorial".

However quite a bit of work will be needed -- to be described below.

Let us first mention some points regarding the overall outlook of the Journal of Clinical
Psychopharmacology. We do not share your concerns about what you term "ghostwriting" -- more
properly described as manuscript preparation assistance. This is just another form of assistance or
collaborative effort in the course of research -- similar to technical assistance with measurement of
plasma drug levels, or statistical consultant input in analysis of data. In the end, the listed authors take
responsibility for the content of the manuscript, and that is what matters.

We also are not worried about the participation of the pharmaceutical manufacturer in the execution of
the study, or the preparation of the manuscript. This is to be expected -- they are the sponsors, and
they have the most knowledge about the candidate drug and the data.

Finally, we are not interested in the litigation. Whatever is going on in the courts will proceed according
to that process.

[We also note that we ARE concerned that you are serving as a reimbursed expert witness on behalf of
the plaintiffs, proposing in the present manuscript what we expect are similar arguments as presented
in the context of the litigation.]

With all of that said, we certainly could reconsider a revised manuscript in which the focus was ONLY
on the scientific content of the
paper(s) in question. If you disagree with the scientific content or its interpretation, that can be
presented, but without the court documents and internal E-mails, and without accusations of
malfeasance, misrepresentation, manipulation, whitewashing, complicity, etc. The issue of manuscript
preparation assistance is also not in the picture.

We hope that you will elect to go this route. Should your revised manuscript be acceptable for publication, we will invite Dr. Wagner and/or Forest Laboratories to submit a response.

[Some other administrative issues. References # 1, 6, 19, 28, and 29 are identical. There are a number of other redundancies in the references as well. One additional publication that you need to review and cite is: Wagner KD. J Am Acad Child Adolesc Psychiatry 2006; 45: 280-288].

Journal Style Items to Address/Check:

1. When the revision is submitted online, please select "Editorial" as the type paper from the drop down box. Number all text pages.

2. Figures/Tables: Place each on a separate page at the end of the manuscript, not within the text, and each should be labeled. Check that figures pass the online art quality check for approved format.

3. Reference List: Specific and General Items to Address/Check:

- NOTE: There are MANY DUPLICATE REFERENCES -- some are repeated 3 or 4 times. Each should only be cited ONE time. Please fix all of these.

- Double-space the entire list.

- Please make sure that EACH reference is cited in the text in order by number.

- NOTE: You only need to give the first 3 authors' names and then use "et al".

- Provide inclusive page numbers (such as 340-345).

- NOTE: Remove months of publication and issue numbers.

- Citations for "DSM" publications or package inserts should be cited in the text only with no number.

When you submit your revised manuscript, include a Cover Letter or list explaining ALL the changes made, responding in DETAIL to each item raised by the Editors and the Reviewers. The revision cannot be re-evaluated if this information is missing.

Please do NOT highlight the changes or use track changes in the revised manuscript; we require a CLEAN manuscript copy. The files for the title page, manuscript, and tables must be submitted in WORD format.

No files should be loaded in the category "Supplemental Digital Content" unless the item is to be posted on the Journal web site only, sometimes requested by the Editors.

To submit a revision, go to <http://jcp.edmgr.com/> and log in as an Author. You will see a menu item called "Submission Needing Revision," and you will find your submission record there.

There is no deadline for submitting revisions.

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NOTE: If you already submitted the forms with your original submission, please make sure to CLICK on

"Carry Over" when loading your revision files online, so that they will be included.

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We look forward to receiving and evaluating the revised version.

Sincerely,

David J. Greenblatt, M.D.

Editor-in-Chief

and

Ms. Barbara Kern, Managing Editor

The Journal of Clinical Psychopharmacology

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Comments of the 3 Reviewers:

Reviewer #1:

This paper provides a concrete example of how scientific accuracy and clinical equipoise can be corrupted by vested interests and commercial incentives. The authors provide a descriptive account of how agents working for pharmaceutical companies can fail to uphold the standards of integrity and transparency that are core values for many scientists. The significance of the study is amplified given that the clinical population represents a highly vulnerable group - children and adolescents suffering with major depression. The presentation of the substantiating information is done in an even-handed manner and although the evidence is from a somewhat unconventional source (post-trial court documents) the material is presented clearly. This work provides a clear reminder of the importance of transparency and openness in scientific enquiry.

The following minor points warrant consideration in any revision of the manuscript:

p.5 - It is not clear where the authors propose that Fig 1 should be placed.

p.8 - capitalise Psychiatry in American Journal of Psychiatry

p.8 5 SAE's leading to discontinuation are noted but only 4 examples are provided.

p.9 should point 3 read: "not presenting unfavourable outcome data"?

Reviewer #2:

I have only some minor points regarding the paper:

1: in page 3 the authors state that protocol not provided a formal power analysis, but since there is a two-tail test an alpha-level reported, sure there was. Another thing is that this sample size was estimated on the assumption of between-groups differences without accounting for strata or subgroups that is one of the main points raised in the paper.

Please check references, a paper must be referenced only once and Wagner et al 2004 and 2005 are referenced several times with different numbers. If needed please quote in text page and paragraph related with the relevant issue.

[Editorial Note: There is no Reviewer #3.]

Reviewer #4:

I might suggest that the author use ³ a breach of academic ethics² is place of ³ academic malfeasance². By definition, malfeasance is defined as: commission of an act that is unequivocally illegal or completely wrongful.

I am assuming that Dr. Wagner did not review the raw data from the study and based her conclusions solely on a fraudulent data set given to her. Therefore, both the company and the ghostwriter may have misled her. In my opinion, Dr Wagner's paid authorship of the clinical study is solely the result of hubris that violates academic ethical standards, and her oath as a physician. While her conduct was odious, it did not meet the standard for malfeasance.

If the manuscript is accepted for publication, the editors might consider an epilog, which discusses the outcome of the Department of Justice investigation, the FDA position on Celexa and Lexapro, and the outcome of any UTMB investigation of putative scientific misconduct by Dr. Wagner in the publication of the clinical study.