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RE: MS# JOC20139, AUTHORSHIPS & IMPACTS: DATA ON THE CHANGING FACE OF SCIENTIFIC AUTHORSHIP

Dear ~~Dr Healy~~ David:

We have completed review of your manuscript and regret that we are unable to accept it for publication in JAMA. We are able to publish only a small fraction of submitted manuscripts and hence much good work must be rejected.

The comments of our reviewers are enclosed for your guidance should you wish to revise the manuscript and submit it elsewhere.

The reviewers were all as disappointed as I that they had to be so hard on your manuscript. You have an interesting idea but managed to convince no one, though I feel all may have had a bias in your favor.

It is the policy of The Journal not to return manuscripts that have been rejected. We will destroy and recycle the original manuscript and any copies. Only the original artwork, if submitted, is returned.

Thank you for the opportunity to review your work.

~~Sincerely~~,

Drummond Rennie
Deputy Editor (West)
(312) 464-2423

Sorry!

DR:sc
Enclosures

RE: Manuscript # JOC20139
Authorships & Impacts: Data on the Changing Face of Scientific Authorship
by David Healy and Dinah Cattell

Journal impact factors are crucial to the methodology used in this paper. Unfortunately, the flawed analysis is being applied to a very legitimate question.

The authors appear to be unaware of a significant body of literature reported both in information based and medical literature that addresses the question of using journal impact factors as surrogates for actual citation counts. The key paper in this is P. O. Seglen's paper ""Why the Impact factor of journals should not be used for evaluating research (copy enclosed)."[1]

The skewed distribution he reports are confirmed by a sample of citations counts I obtained by doing a citation search on the first 6 or so references in the CMED literature profile.

The variation in the results is remarkable. For example, the first paper on the list by Alderman (1997) has been cited 31 times whereas the journal impact factor is 5.7. The second paper by Ambrosini (1999) was cited 25 times but the impact factor is 3.6 and so on. An illustration in the opposite direction is the article by Berndt (2000) which has been cited only once. The impact factor for the journal is 5.8. The second article by Berndt (1998) was cited 10 times and the journal impact factor is 2.37.

It is incomprehensible why the authors would use the journal impact factors when they could just as easily have searched the *Web of Science* and found the exact cited frequency for each article.

In short, the journal impact factor should be replaced by the actual citation frequency to see where that leaves the hypothesis.

It is not impossible that there is also another factor that might be taken into consideration which is the paper length. On page 10, the authors mention the mean length of papers. There is evidence that citation frequency may be correlated with length of paper. That may help account for the higher average citation impact of review articles.

In regard to Medline, the authors use the terms Citations and Cites when referring to the Medline listings. This confused me when I looked at the column "authors no of cites" on the CMED Literature Profile. Cites do not refer to the number of citations made by the author but rather the number of papers published. This is very confusing and admittedly aggravated by Medline's use of the term citations instead of listings or references.

From my early experience with pharmaceutical companies, it is not unusual for their medical writing departments to help in the editing of papers written by their staff physicians and researchers. Apparently this now also extends to outside investigators. And as far as I know this is does not seriously affect the content of a paper. Authors inside of companies and outside need the help of editors but this does not prevent them from playing a key role in interpreting the data correctly. Of course, if they want to lie with statistics, that is another matter.

Based on the limited sample of one drug, sertraline, I think that it is quite unreasonable to draw any conclusions about the role of ghostwriting. If a more extensive sample had been drawn across different subjects maybe we could draw some conclusions but I don't think this is the case here.

Apparently the authors are unaware that the *Science Citation Index* lists citations to published articles whether or not the journal is covered in the *SCI* and its derivative *Journal Citation Reports*. The work of J. Stegmann[2] (copy enclosed) in Berlin on estimating impact factors is important in this connection and it is not known whether the authors followed this procedure or not..

On the top of page 7 they use the Medline term "listings" rather than "cites" or "citations." The term listings is appropriate to avoid confusion with citations from one paper to another.

The authors mention a Medline search on the term sertraline which came up with only 58 articles. I did the same search in the *SCI* (on the *Web of Science*) and found about 80 articles which was somewhat surprising but I have not determined whether any should be excluded on the basis of the search profile they used.

I agree with the comments on page 16 about the good aspects of the ghostwriting process. However, to draw conclusions based on the analysis of a single drug or topic seems to me to be rather a stretch. I am not a statistical expert but I think a better sampling procedure is needed.

The sentence on page 16 "The question of literature impact is tied closely to the nature of ghostwriting" is not clear to me. I cannot believe that prescribers are significantly affected by the quality of the writing. An influential author may or may not write the best prose but gets the facts right.

The comments on page 17 are convincing but these are merely opinions which might well be expressed in a commentary or editorial. The study itself does not justify such a discussion at this time. Furthermore, since the study is limited to the field of psychotherapy it may be that the article would be of interest to a journal in that field. But it needs considerable expansion to justify publishing it in *JAMA*.

This manuscript is poorly organized and written. I found it very difficult to determine what was being compared. The presentation suffers from poor definition of terms, incomplete description of methods, use of measures that may not be valid, undocumented assertions, inappropriately generalized conclusions.

There are many problems with the terms used. For example, "novel forms of authorship" is used for papers (some published and some not published) with which an industry sponsor has had a role that is not defined well, other than the paper is listed in the CMED list. There is no rationale presented for this being "novel" (ie, unique, unusual, or even new). Similarly, "traditional authorship" is inadequately used to described those articles in which the industry sponsor did not have this same role. These articles are identified via Medline and Embase searches and are apparently not on the CMED list and apparently most had no declared sponsorship. By a means not explained, the authors of these articles are assumed to have had independent access to the raw data, although this assumption is not justified or explained. In neither type of authorship, novel or traditional, is there any indication of the roles of authors or which had ghostwriters/authors.

This manuscript reports a comparison or papers included on the CMED list versus those not on the list (excluding 5 categories). Perhaps the two groups should be renamed along those lines.

The term "authorship" is not defined and is confusing. For example, it is not clear what "107 authorships from 105 authors means."

There is no indication that either the measurements (Medline listing rate and the literature profile) used have been used previously or validated. Why wasn't citation analysis of the individual articles done?

Specific Comments

Title: The title is not informative. The word "Changing" does not belong in this title as there is no assessment of data from different periods of time.

Abstract
Context statement is too broad. The Objective is not clear because the terms, novel authorship and traditional authorship, are not defined, and even if defined may not be the best choice of terms for this paper.
Design: The specific search terms used to search Medline and Embase should be listed.
Results: The determination of "probably authored in the traditional manner" is never fully described and is clearly not certain. The percentage confidence interval should be given.
What is the reason for separating 1998 from 1999/2000 articles?

Conclusions: This paper does not demonstrate a change in authorship over time, not even between 1998 and 2000, and thus, cannot conclude that there has been an "increase" in anything.

Page 4
Details of the unpublished Medline search of review articles on depression are needed.
In the second to last sentence, "Traditionally the individuals have authored all the drafts...", perhaps it would be better to say "Ideally, the individuals have authored all the drafts..." Studies have shown that authors do not all draft an article and some, for example, may not draft the manuscript but may review it critically. I am not aware of studies that have shown which authors actually have or had access to the raw data and which authors do or did not have such access.

Page 5
Why were the Medline and Embase searches restricted to the year 1998? With this restriction, how were articles published in 1999 and 2000 located? The specific search terms used in these searches should be listed.

A brief description of CMED and what it does would be helpful.

How were the CMED listed articles published after 1/29/1999 located? Why weren't the Medline and Embase searches for the non-CMED listed articles conducted into mid 2001?

The contrast between "ghost authorship and ghostwriting" and "traditional and non-traditional authorships" is not congruent.

It is not stated how determination of author access to raw data or sharing data was determined.

Page 6
Last line of first paragraph: how was it determined that "some of these authors appear likely to have had access to the raw data?" Or in second paragraph, "authors who appear likely to have had access to the raw data?"

It is not clear how impact factors for the 5 journals were estimated?

Page 7
The type of analysis done in this study is not described.
The first sentence in Results section is a limitation, not a result.

I found it very difficult to follow this section. The results should be presented is a straight forward manner (ie, total number of articles; n and % in Medline, Embase, CMED list; types of articles (ie, research/trials, case reports economic analyses, etc); year published; type of publication (peer-reviewed journal, supplement); sponsor role identified in article; company authors in byline; etc.

Page 8
It appears as though 5 of 6 reports of trials cited in Medline were not indicated as being sponsored, but one was, correct?

The rationale for excluding the 5 groups of papers is not clearly presented. Inclusion criteria are not described at all. I am not sure if the exclusion of large multicenter studies is appropriate.

Page 9
Again, how was it determined that the authors of these 3 supported papers were "in possession of the raw data?" How were the 39 papers determined to be "independent?" How many "probably" or "possibly" were not independent?

Were letters and editorials excluded from these 39 papers? If not, what were the average lengths of articles not including letters and editorials?
What are 107 authorships?

How were the publications statuses of the 57 papers determined? Why were these papers followed through mid 2001, when the non CMED papers were only searched through 2000?

Page 10
The speculation about serial rejection is not justified.

Do the 57 CMED articles include any letters or editorials?

Page 11
Why are the 5 journals that published one article listed and the other 13 not listed under Table 1?

Page 12
What is meant by "several senior academics appear on between 5 and 10 articles?" How was it determined that these authors were "academic" and "senior?" How was it determined that 13 CMED articles "do not appear to have a company author or to have been through an agency?"
In Table 2, is there overlap among the types of CMED articles listed?

Page 13
Have these literature profile measures been used before or validated?

Page 14
Why is an Overall Literature profile Medline/Embase articles restricted to 1998 when the profile for CMED articles is per annum? "p.a." is not defined. Percentage of confidence interval is not given.

Is there a difference in the proportion of reports of trials in the 2 groups?

Discussion: This paper does not compare authorship of articles in 1998-2001 to any previous time and thus cannot determine if anything has changed.

Page 15
No evidence is cited for the statements made about the roles of communications agencies. the only reference cited, reference 10, is not primary source of evidence. The comments about the "entire domain of therapeutics, including pyschotherapy and alternative therapies" goes way beyond the merits of this analysis.

Page 16
The methods used to determine that 50% of articles were authored in a non-traditional manner are not described.

The measurements used to compare impacts of these articles may not be valid.
This paper provides no evidence that specific journals were targeted. There is no analysis of the types of journals that published these papers or the types of journals that did not publish these papers.

What is meant by "the question of literature impact is tied closely to the nature of ghostwriting?"
There is no evidence presented to support the statement that "authorship lines from perceived opinion-leaders with minimal company representation and non-declaration of other authorship inputs increase the likelihood that these articles will be influential with prescribers and purchasers."

Page 17
This manuscript does not present any indication that measures of the publication process (efficiency and effectiveness) were done. No evidence is presented to support the comments that "most studies are now sponsored" or that the "primary questions being asked in the therapeutics domain will relate to the marketing interests or pharmaceutical companies."

Page 18
Actual access to raw data is not examined in this study.

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MS Number: JOC#20139
MS Title: Authorship & impacts: data on the changing face of scientific authorship
Author: Healy

Comments of Reviewer to Author

While I appreciate the authors' attempt to examine papers that are generated by a medical communications house on behalf of a pharmaceutical company, I have major reservations about this paper. My concerns are—listed in no particular order:

The authors' methodology for estimating the impact of articles that were written in "traditional" versus "non-traditional" manners is fraught with potential flaws.

- They state that "this article distinguishes between traditional and non-traditional authors, with the primary criterion being whether the authors are likely to have seen the raw data they report on and whether they are free to share this data with others." (p. 5) However, nowhere do the authors adequately describe their method of determining whether authors were likely to have seen the raw data or whether they were free to share this data. (The one sentence in the methods that seems to relate is insufficient and unconvincing: "In some of these [articles that acknowledge Pfizer funding] the authors appear likely to have had access to the raw data in that the studies have been run in either one or a small number of linked centers." (p. 6)) Yet, this determination is central to their analyses.
- They state that they "had to estimate impact factors for one journal in the CMED [non-traditional] series and four in the non-CMED [traditional] series" (p.6). But they do not describe how they made such an estimate, despite the fact that the impact factor score is central to their methodology.
- The authors do not explain or justify their choice of studying articles on sertraline.
- Nor do they describe why we should trust the CMED company list of "non-traditional" publications as being systemic, comprehensive, and accurate, although they are using it as the basis for their comparison group.

The authors also fail to characterize or define numerous important groups or terms—for example,

- "Current Medical Directions Incorporated (CMED)" (p.5): This is the group that generated the comparison list of articles with "non-traditional authorship," yet the reader is given no further information on it or its search methods. (Note, it is unclear why acronym does not match the company title.)
- "communications agencies," "academic and company authors," "articles... already published or being worked on without apparently originating in a communication agency," or "[articles] that do not appear to have been written within a communication

agency, and do not have a Pfizer name on them" (p.6): These terms are key to the authors' distinction between "traditional" and "non-traditional" authorship and yet are not defined.

The authors also make assertions that they do not support with references or data. To list a few examples:

- Despite claiming that "an increasing proportion of the therapeutics literatures is being written in a non-traditional manner" (p. 3), the authors give no evidence for a change over time. Rather, their paper compares the "impact" during one period of time (1998-2000) of articles with "traditional" versus "non-traditional" authorship.
- "Traditionally the individuals whose names appear on the authorship line of a scientific article have authored all drafts of that article...." (p. 4): There is no reference for this sentence, and it does not agree with the most widely used definition of authorship, that of the International Committee of Medical Journal Editors, which states that to be an author, amongst other things, a researcher should have participated in the writing *or* critical revision of a paper (emphasis added)—not necessarily the writing of all the drafts.
- "The new style of authorship can deliver good quality articles...." (p. 3): Because the authors do not define "good quality articles" anywhere in the paper, this assertion lacks support.

I have delayed critiquing the findings of this paper until I feel more confidence in the validity and reliability of the methods.