

Who's watching whose ethics? Slanted reporting of the medical writer's role in the *Neuropsychopharmacology*-Cyberonics case¹

by Karen Shashok and Adam Jacobs

Medical writing got some attention from the lay press, science mags and blogs during the summer of 2006, but it was mostly negative in slant, and mostly based on a misunderstanding of how medical writing can work under ideal circumstances.

What was the problem?

An article published in the News section of *Science* on 4 August 2006 [1] caught the attention of one of us, who felt that the item passed judgement unfairly on the role of Sally Laden, a professional medical writer. Ms Laden had been involved in the preparation of a review article that was published in a pharmacological subspecialty journal without proper disclosure of the authors' conflicts of interest. The review article suggested that vagus nerve stimulation with a device manufactured and sold by Cyberonics [2] is a potentially useful treatment for depression [3]. The news item in *Science* seemed to suggest that the medical writer, whose role was explained in the Acknowledgements, had behaved unethically.

Which journal was involved?

Neuropsychopharmacology, the official publication of the American College of Neuropsychopharmacology, is published by Nature Publishing Group (NPG). Doctor Charles B. Nemeroff was editor-in-chief at the time of the "Sally Laden affair" and also one of the named authors of the article in question. A few years previously the eminent and powerful Dr Nemeroff, an expert in treatments for depression, had been involved in a similar incident over undisclosed conflicts of interest relating to an article in *Nature Neuroscience*, another NPG journal [4]. He was accused then of choosing not to declare to the journal his many financial ties with pharmaceutical companies that market some of the products mentioned in that review.

For the review article that appeared in *Neuropsychopharmacology*, Nemeroff recused himself (as is appropriate) from editorial review. When asked later why his (and the other co-authors') conflicts of interest were not published, he answered that their omission had been due to an oversight. And what an oversight it was—eight of the nine co-authors of the item were, at the time, both members of the journal's editorial board and members of Cyberonics' advisory board [5]. (The ninth co-author was, as noted in the byline, a Cyberonics staff member.)

Medical writers support good publications practices

The European Medical Writers Association works hard to convince editors and the public that medical writers should not be assumed to practise blind obedience to the pharmaceutical and medical device industry. Moreover, guidelines are available for the industry regarding appropriate, public recognition for medical writers [6,7]. Nowhere in the Instructions to Authors or Authorship Disclosure Form for *Neuropsychopharmacology* [8] is there any mention of appropriate acknowledgement in the manuscript of writing or editorial assistance. We assume, then, that the medical writer was mentioned in a laudable attempt to uphold professional standards of transparency, accountability and responsibility for medical writers. Ironically, this attempt earned Ms Laden some undeserved and widely publicized criticism, rather than praise for upholding professional ethics.

Did the pundits overreact?

The pharmaceutical and medical device industry is rightly now a target of frequent journalistic scrutiny. Medical writers are sometimes presented as wishing to abet their employers' commercial objectives by misleading editors, prescribers, and the public about the benefits of Big Pharma's products. *Science's* reporter may have been swept along by the current fashion of assuming that everything connected with the industry is unethical, and she quoted Drummond Rennie—well known for his critical stance against pharmaceutical company involvement in research publication—as saying "It is very bad scientific and ethical practice to have a nonauthor write the first draft."

In fact, Ms Laden's role, and the fact that the authors maintained final control over the content, were reported in the Acknowledgements section in these words [3]:

We thank Sally Laden for editorial support in developing early drafts of this manuscript. We maintained complete control over the direction and content of the paper. Preparation of this report was supported by an unrestricted grant from Cyberonics, Inc.

Ms Laden was quoted in *The Wall Street Journal* as saying "This was not a ghostwritten project. I was just the facilitator." *The Wall Street Journal* noted that she developed the

¹ This article has also been published on www.emwa.org where it includes a copy of the follow-up email sent to *Science* on 1 November 2006 and the article's reference list.

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first draft “with materials from the company’s advisory board meetings” and that the manuscript “went through many revisions based on edits and suggestions by the listed authors” [9,10].

So what was there to criticize? From published accounts and from the wording of the Acknowledgements, the evidence suggests that she did her job in compliance with current professional guidelines for good practice, and that her role was acknowledged appropriately in print. Some critics complained, however, that there was no explicit mention of the fact that her fee had been paid by Cyberonics, and insisted stubbornly that the paper had been “ghostwritten” [11-14]. It must have been a harrowing experience for Ms Laden to have her reputation trashed unfairly in major print and electronic media.

Attempts to offer the medical writer’s point of view

Some of us wrote to *Science* [15] to point out that their article seemed to be shifting the blame away from the authors of the article and onto the medical writer. After all, the lead author of the contested article was also editor-in-chief of the journal, and most of the other co-authors were also members of the journal’s editorial board. Moreover, all co-authors were either employed by Cyberonics or were members of the company’s advisory board. Editors-in-chief have a responsibility to ensure that journal procedures relating to ethics issues are implemented consistently. Clarification of the co-authors’ conflicts of interest appeared in a later Correction to the original publication [16], after journalists and others protested publicly about the blatant violation of publication ethics [9,10,14].

We never received a reply from *Science*, so after two and a half months we e-mailed the author of the News article and the Executive Editor of the journal to inquire whether they might wish to consider offering readers a more balanced account of the medical writer’s involvement, and of efforts from within the profession to ensure high ethical standards of conduct. No reply was received. We then attempted to notify the journal that we intended to withdraw our letter from consideration and attempt to publish it elsewhere—but the automated answering service at the editorial offices of *Science* made it impossible to communicate with a human being, and their on-line interface for authors proved unsuitable for Letters to the Editor.

Having waited more than five months as of this writing for a reaction from the journal, and having taken all reasonable measures to avoid unintentional duplicate submission or redundant publication, we feel we can safely assume *Science* has decided not to publish our letter, so we are reproducing it here (see box). The e-mail in which we enquired about the fate of our submittal, and references for this *TWS* item, can be viewed in the online version of this article.

Copy of Letter submitted to *Science* on
15 August 2006

Transparency for industry-funded research

SCIENCE IS RIGHT TO BRING TO LIGHT this case of failure to publish a conflict of interest statement involving the editor-in-chief and members of the editorial board of a specialty journal (1). Given the direct involvement of the authors in the journal (and presumably their long experience in these matters) it is disappointing that such an oversight was not spotted at proof stage. However, as professional medical writers and author’s editors we take exception to the implication that the medical writer who helped prepare the manuscript was guilty of “ghostwriting” and that her involvement in developing the article was, of itself, inappropriate. The Acknowledgements section of the article suggests that the medical writer was appropriately credited, by name, for her work (2) whereas a true “ghost” must by definition remain hidden. The writer (Ms Laden) has also explained how the manuscript was developed “based on edits and suggestions by the listed authors” (3). The process appears to have complied with the guidelines for professional practice of the European Medical Writers Association (4)—a document developed to ensure transparency and accountability on the part of both hired writers and named authors, and which is cited in the instructions of several journals including the *BMJ*.

The issue in this case is not whether Cyberonics hired a professional writer to develop the article. The issue is whether appropriate procedures were followed at the editorial office of *Neuropsychopharmacology*. We feel it is wrong to focus attention on the medical writer when the fault in this case clearly lies with the journal and the named authors.

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Competing interests

AJ, EW & KS provide medical writing, editing and translation services for pharmaceutical companies and individual researchers. AJ and EW developed the EMWA guidelines. AJ is the immediate past president of EMWA.



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Consequences for the editor, the journal, the medical writer...and good publications practices?

Doctor Nemeroff decided in late August 2006 not to stay on as editor-in-chief of *Neuropsychopharmacology* after that year [17], as the journal's reputation was being tarnished by the incident. Since the 2006 incident, the Editorial Policy section of *Neuropsychopharmacology's* Instructions to Authors has added links to tables that list various types of relationships between editorial board members and commercial concerns which could give rise to conflicts of interest [18]. It's a step in the right direction, although readers of articles that appear in the journal may not realize they should consult the tables unless articles authored by members of the editorial board contain explicit notification that information about potential conflicts is available online. A clear description of authors' conflicts of interest in the article itself is a better way to alert readers to this source of potential bias.

Meanwhile, we wonder whether Ms Laden's unhappy experience will help or hinder attempts by medical writers to ensure appropriate acknowledgement of their role in preparing material for publication. Transparency and accountability are desirable, and the same ethical standards should apply to all. We hope that Ms Laden's experience will not discourage colleagues and their employers from trying to follow the EMWA [6], AMWA [19], and the Good Publication Practice guidelines [7], in efforts to ensure transparency. We also hope that editors and publishers will examine their own processes and consciences before pointing the finger at the medical writing profession when questionable behaviours come to light.

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This article raises issues that need to be discussed by all medical writers!

Medical writers are invited to write to *TWS* with their views on the extent to which medical writers are responsible for ensuring that authors comply with authorship guidelines issued by editor organisations (www.icmje.org, www.wame.org) and instructions to authors issued by individual biomedical journals. Views about ethics relating to medical writing in general are also welcome.

PLoS Medicine asks: Are we publishing 'The Right Stuff'?

Needless-to-say the title of this editorial [1], coming from one of the top Open Access journals, attracted my attention. I am pleased that it did because it is an article worth reading. It refers to a major study on predicted trends in global morbidity and mortality published in the same issue of the journal [2] and asks whether the journal is publishing research studies that address the conditions relating to these causes. The study updates the Global Burden of Disease Study published in 1996 [3]. The leading causes of burden of disease in 2030 are projected to be HIV/AIDS, unipolar depressive disorders, ischaemic heart disease and road traffic accidents. Looking at the study as a whole the editors are satisfied that their journal has covered HIV/AIDS but believe they need to publish more research on cardiovascular disease, diabetes, mental health, road traffic accidents and chronic obstructive pulmonary disease. But only research that has been done can be published and the greatest global needs are sadly not those that receive the greatest attention. The editors remark that only 10% of expenditure on health research is devoted to the problems that primarily affect the poorest 90% of the world's population [4]. They conclude that although factors such as international conflict cannot be brought into the calculations, many institutions and individuals would need to 'do the right stuff' and develop constructive policies if optimistic projections are to be realised.

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Ghosts exocised from Stanford Medical School

Stanford Medical School has introduced guidelines to regulate faculty members' interactions with industry, which include a ban on ghostwriting. Under the heading 'Disclosure of Relationships with Industry' individuals are prohibited from publishing articles under their own names that are written in whole or material part by industry employees.

<http://med.stanford.edu/coi/siip/policy.html#iv>