The Write Stuff

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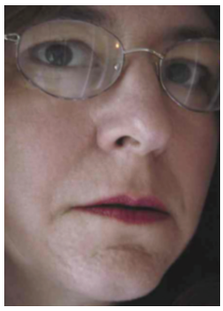

From over the pond: Plagiarism in the pharmaceutical industry

by Susanna J Dodgson

After I was offered my appointment as Professor and Director of the MS Program in Biomedical Writing at the University of Sciences in Philadelphia (USP) last Spring, I wrote an "Over the pond" article on how to become a medical writer. Because I mentioned the Biomedical Writing Program, I sent a draft of my article for comment to my predecessor, Jennifer J Connor. Jennifer was not pleased that I wrote the most important skill of any medical writer was cutting and pasting. She told me that since the widespread use of the Internet, plagiarism had become such a problem on university campuses that I needed to make quite sure I was not endorsing it in any way. I modified the article and promised to write a follow-up article on plagiarism. This was to let the world know that under no circumstances is plagiarism endorsed by USP, which was founded in 1821 as the first US College of Pharmacy.

We take plagiarism very seriously at USP; seriously enough to have a policy of expulsion from the Program if a student is caught appropriating another person's work. According to the University Student Handbook:

'Ghost authors' are plagiarised by 'guest authors'

"… ideas are highly valued, and so is the language that expresses those ideas. In both a legal and moral sense, words and ideas are the property of their authors. Plagiarism is the theft of that property. When you plagiarize, you are presenting someone else's words and/or ideas as if they are your own. This situation applies to all printed material as well as to words and ideas found through electronic sources. Plagiarism may be intentional or unintentional. In either case, the penalty for plagiarism can be… expulsion from the institution." (www.usip.edu/writing/plagrsm.shtml).

According to the USP definition, a student lifting a paper from the Internet and submitting it for a grade without quoting the source is a plagiarist. Our MS Program in Biomedical Writing first enrolled students in August 1997. Since then 182 students have enrolled in courses. We have expelled a single student from both the Program and the university for submitting course papers with lifted content. This student fought our accusations, claiming to have only taken blocks of text from government websites, and that everyone on the planet has the right to pass off this work as their own because government websites are not copyright. The University's argument is that we do not care who copyrights what, any document submitted for credit or publication needs to have been written by the person for whom credit is given.

I take the argument further. I have come to the conclusion that the use of medical writers, who have been called "ghost authors" to prepare papers is also plagiarism by those who have been called "guest authors". These are the persons whose names appear on papers they did not write, and who may also take money for lending their name to the paper. My reasoning for identifying these people as plagiarists follows.

From over the pond

The International Committee of Medical Journal Editors (ICMJE) have been concerned about who writes papers since 1979 when they started publishing the first of evolving sets of guidelines. These define what constitutes authorship. In 2004 and 2005 their main concern was the data included in papers describing clinical trial results. From July 1st 2005 these papers may only be written on data deposited in the publicly accessible Clinical Trials Registry. This development has arisen from the distrust of these data, specifically, because editors had no way of knowing whether favourable results in a paper had been observed for a part or the whole duration of a clinical trial, how long a clinical trial lasted or the negative effects of the drug. Part of the ICMJE Statement on Clinical Trial Registration published in March 2005 states:

Only when the manuscript had all the company signatures was it sent to the selected author

"Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making."

The ICMJE published their October 2004 guidelines, like the March 2005 Statement on Clinical Trial Registration, in several medical journals, including the *New England Journal of Medicine* and the *Journal of the American Medical Association*. In these guidelines, the rules for being the named author are:

"…… biomedical authorship continues to have important academic, social, and financial implications. …..Authorship credit should be based on

1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content; and

3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3……. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship."

All authors declared they had done all the work

As a working medical writer, I have seen flagrant non-compliance with these rules in American and European medical communications companies, whose work is entirely funded by pharmaceutical companies.

In one medical communications company, now defunct in the US, manuscripts describing issues in HIV/AIDS, gastroesophageal reflux disease, cardiovascular disease, and hepatitis B therapies were outlined by medical writers. After the outlines were approved by the pharmaceutical sponsors (four of the world's largest pharmaceutical companies) the medical writer wrote the manuscripts. Most manuscripts were reviews, although some were clinical papers describing patients seen in healthcare offices. The finished review manuscripts were reviewed by the committees permanently employed by the sponsor, and when the manuscripts were acceptable, then and only then were pharmaceutical company-selected authors (PCSAs) sought. The clinical manuscripts about patients resulted from the pharmaceutical representatives out in the field identifying

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A contract research company was acknowledged for 'some help with the data collection'

healthcare professionals with interesting patients or clusters of patients, whose illness and reaction to treatment were in line with that predicted for one of their marketed therapies. By telephone, the medical writer talked to the healthcare professional about the observations, and prepared a complete paper around this information. When the manuscript had all the signatures from the pharmaceutical company and medical communications company, the files of the manuscript and cover letter with the names of the PCSA was sent to the PCSA chosen to be named first. The PCSA then signed the letter saying it was all his or her own work, and e-mailed or posted the package from his or her own address. As far as the journal editors knew, the manuscript came from the local post-office or e-mail server of the PCSA, who had done all the work and fulfilled all requirements of authorship.

This medical communications company was not unique. This is how manuscripts are written for pharmaceutical companies. The problem with authorship is that the sponsoring drug companies and marketers make decisions about the qualifications of an expert who they want as the public face of their drugs. These experts seldom have any skills in statistics, researching their own area of expertise, or writing and preparing manuscripts for publication. I have been told by other medical writers that the worst thing that can happen to a manuscript is have the PCSA make changes to the manuscript. The sponsor is happiest when the PCSA cashes the cheque and signs his or her name on the letter submitting the article to the journal.

In reality the research company had done all the work

Manuscripts written breathlessly describing the results of human testing of promising drugs in clinical trials are a whole industry in themselves. I was once asked to prepare a paper from clinical trial data for an upstanding pharmaceutical company, which has a code of ethics. I have been told this requires that all papers with their employees given as authors have to be written and prepared entirely by these professionals. That may be partly or even entirely true for pre-clinical studies; certainly I wrote part or all of several pre-clinical papers on research I did for this company when I was an academic bench scientist. However, clinical trials are expensive procedures. They involve safe administration of drugs to healthy and sick volunteers, teams of statisticians, medical writers, clinical research associates and project managers. Paradoxically, appointing PCSAs for these manuscripts is much easier than appointing PCSAs for other manuscripts because the healthcare professionals needed as signatories on the clinical trial protocols have been seen as natural PCSAs.

The ICMJE has done its best to ensure all parties are being honest

I was startled to read a manuscript in a premier US medical journal in November last year, that had been written on the results of a large post-marketing clinical trial with data-lock in August. The journal editors required statements from each author in line with the IJCME guidelines. Each PCSA earnestly declared that he or she had done all the work, including all the statistical analysis and written every word in the paper. I looked carefully through the paper. Right at the end of the acknowledgments I saw a contract research organization thanked for "some help with data collection". In reality this contract research organization had done all the work, including conceive and

write the protocol and collect and analyze data for 5 years. What really interested me was that one of the PCSAs, who had cheerfully taken the role as one of the two public faces in the study, was one of the most vocal critics of the FDA and the drug company, whose non-steroidal anti-inflammatory drug was recently voluntarily removed from the market. Even more startling were the conclusions of the study: healthy people with no risks for the investigated disease need to take drugs. Reading the data carefully with my students in my NDA submissions documentation class, we found that the conclusions were not supported by the data.

The ICMJE no longer believes professionals tell the truth

The inability of drug companies and healthcare professionals to understand the complexity and skill needed to research and write a review, or a paper from a clinical study report has led to healthcare professionals plagiarizing the work of medical writers. Until this practice is recognized as plagiarism and not disguised with the plagiarizer called the "guest author" and the medical writer called the "ghost author", the profession of medical writing will never be given the respect it deserves.

The International Committee for Medical Journal Editors has done its best to ensure that all parties are being honest in the journals that agree to abide by their guidelines. Their guidelines calling for posting data on all clinical trials relating to therapies from which publications are generated indicates that the ICMJE no longer believes that professionals submitting papers for publication tell the truth. For the first time ever, the data in clinical papers must be verified. This guideline does not apply to data generated by life or physical scientists, only for healthcare professionals making claims about clinical trials. I have to ask why, and I find I can answer my own question immediately. Reports of bench science findings have always been verified, or discredited, by other scientists in other laboratories. This self-regulation is not possible in clinical trials because of their expense. Once a therapy is approved for marketing and has been taken by patients with the approved indication, its ineffectiveness can be blamed on the patient not taking the pills in the right quantity at the right time.

From 1 July papers describing clinical trials can only be written on data deposited in a public registry

I had been thinking about composing this article for several months, and had started writing when I read a post on the US Medwriters list serve in April. The writer, Adriane J Fugh-Berman, MD, is an Adjunct Associate Professor of Physiology at the University of Georgetown, and a bona fide expert in the field of complementary medicine. She wrote that she had recently written two articles, one in the Guardian (http://education.guardian.co.uk, April 21, 2005) and one in the *Journal of General Internal Medicine* (2005; 20) , on her reaction to an invitation to be a PCSA on a completed article on complementary medicine. Adriane is the first potential PCSA to write about PCSA solicitation, which she has done with some disdain. My admiration for her writing the articles is huge; she is one of the few healthcare professionals to report the practice of pharmaceutical company-sponsored plagiarism. I thank her for reading this manuscript and for her warm encouragement.

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