Drug-Company Sponsored Ghostwriters Are Getting Busted By Some Medical Journals

Drug Industry Document Archive (DIDA) Adds Newly Released Wyeth Ghostwriting Documents In September 2009

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 18, 2009; see http://bit.ly/bvGZR)

A September 18, 2009 article, "Medical Editors Push for Crackdown on Ghostwriting", published by *The New York Times* (*NYT*) provides a very good overview of how some big pharmaceutical companies have effectively turned scientific articles into marketing vehicles for their new drugs by means of industry-financed "ghostwriting".

From the beginning and ending parts of this September 2009 *NYT* article:

> The scientific integrity of medical research has been clouded in recent years by articles that were drafted by drug company-sponsored ghostwriters and then passed off as the work of independent academic authors....
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> In January, editors at Blood, the journal of the American Society of Hematology, discovered that an unsolicited manuscript submitted by a prominent researcher involved significant contributions from a pharmaceutical company employee named in the acknowledgments — a major role in the manuscript that should have qualified the employee to be listed as an author of the paper. Further detective work quickly turned up two other ghostwritten manuscripts.
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> Editors decided to make their discoveries public in an editorial titled "'Ghostbusting' at Blood" in which they wrote that the journal would henceforth reject opinion pieces that had industry ties. [link to editorial added]

While the revelation about this practice of ghostwriting as concerns medical journal articles is news to most people, this practice is far from being a recent development. Again drawing from the September 2009 article, written by *NYT* reporters Natasha Singer and Duff Wilson:

> Allegations of ghostwriting first surfaced several years ago in the promotion of the diet drug combination fen-phen, which was taken off the market because of safety concerns in 1997, and the painkiller Vioxx, withdrawn in 2004. And last month, documents made public in litigation against the pharmaceutical giant Wyeth showed that the company had paid a medical writing firm to draft articles, published through 2005, favorable to its Premarin family of hormone drugs even as evidence mounted that certain hormone drugs could increase the risk of breast cancer.

Now the Wyeth ghostwriting documents that were "made public" last month -- *i.e.*, unsealed by a Federal judge last month at the request of the *Public Library of Science* (*PLoS*) and *The New York Times*-- have been added to this Archive which has been created by the University of California at San Francisco (UCSF).

Here is an excerpt from an annoucement -- which we (thankfully) received from Kim Klausner, who is the Tobacco Digital Library Manager at University of California, San Francisco -- regarding the addition of these Wyeth ghostwriting documents to the DIDA:

> As you are probably aware, the documents illustrate how Wyeth Pharmaceuticals contracted with DesignWrite, a medical communications company, to write articles for top-tier medical journals with the intention of bolstering the sales of the Premarin family of hormone replacement products. After the articles were written, DesignWrite solicited prominent health professionals to appear as "authors."
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> The documents are full-text searchable and limited metadata, such as names of people and organizations mentioned, has been created for most documents to aid searching. The documents can be found by entering "ddu:2009*" without the quotation marks in the query box on DIDA's home page (http://dida.library.ucsf.edu)
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> I have selected a few of the 1,120 documents that, taken together, show how the integrity of the scientific process was compromised.

A summary of DesignWrite's work: a "comprehensive publication program for Premarin… [which] includes peer-reviewed journal articles, editorials, letters to the editor, sales training backgrounders, and critiques of the current literature, all designed to support the [company's] marketing efforts."

An August 2000 contract between DesignWrite and Stephen Gutkin, President and founder of Rete Biomedical Communications, to write 8- to 10-page manuscript on "Can a Healthy Endothelium Influence the Cardiovascular Effects of HRT?"

A September 12 letter (page 4 of the document) to Gutkin paying him for completing the outline.

A DesignWrite document (page 2 of the document) from September 27 indicates that Professor Kwang Kon Koh has been approached to "author" the paper but "needs to be confirmed."

An October 13 letter (page 3 of document) from DesignWrite Medical Editor to Gutkin about revisions to the manuscript: "Anything that doesn't bolster the main message that early intervention with estrogen in order to maintain a healthy endothelium in postmenopausal women can go." The Editor accepts that the academic "author's" "own additions will probably have to stay [in the article] no matter what."

A letter (page 2 of document) from DesignWrite to Gutkin asking for further revisions to the manuscript in January, 2001.

In April, Koh suggests in an email that DesignWrite staffer Karen Mittleman be listed as co-author of the paper. (This document should be read from page 4 to page 1.)

The paper is published in the International Journal of Cardiology in 2003. Mittleman's "editorial assistance" is acknowledged. Stephen Gutkin's name is nowhere to be found.

As I reported last week, the Drug Industry Document Archive (DIDA) already contained over 1500 documents of various types before this addition of these Wyeth ghostwriting documents in September 2009.

We thank the good folks at DIDA for their efforts, and look forward to seeing more insightful documents about Big Pharma conduct added to this Archive in the future.
