

# The Ghosts Of Big Pharma

October 11, 2010 by [Bob Livingston](#)

When you have an ailment and go to the doctor you expect that if he or she prescribes medicine for your treatment that the choice of medicine would be made based on proven results for your disease. But that is probably not the case.

Physicians may think so, and you may think so, but the fact is that the information physicians get — even from some publications that are purported to be peer-reviewed — is often just a product of Big Pharma’s marketing arm. This is because Big Pharma is using ghostwriters to draft articles for publications and getting top-flight physicians to sign on as the “author” even though all they do is read the articles and suggest changes.



This fact came to light in late 2008 when Congress began to take an interest, and then surfaced again in 2009. It was in 2009 that *The New York Times* and The Public Library of Science (PLOS) gained access to documents used in a court case filed by more than 14,000 plaintiffs who developed breast cancer while taking the menopausal hormone therapy drug Pemprom.

The drug was manufactured by the pharmaceutical company Wyeth (since bought by Pfizer). Wyeth hired a marketing company named DesignWrite to produce articles and solicit big-named physicians to endorse them as authors.

According to a report in *PLoS Medicine*, the journal of PLOS, hormone therapy first began in 1942. It was then that the drug Premarin (Pemprom’s forerunner) became the first Food and Drug Administration-approved treatment for hot flashes. Promotional efforts implied that estrogen could preserve youth and health. By the 1970s physicians, under the mistaken impression that menopause was an endocrine disease similar to hypothyroidism, were prescribing estrogen to millions of asymptomatic women. By 1975 the incidence of endometrial cancer in women who were using estrogen had increased 800 percent.

To counteract the endometrial cancer, progestin was added to the hormone replacement therapy. This was touted through the 1990s as a preventative for cardiovascular disease, osteoporosis, Alzheimer’s disease, colon cancer, tooth loss and macular degeneration. However, by 2002 studies showed that hormone therapy failed to prevent cardiovascular disease and increased the risk of breast cancer, stroke, dementia and incontinence.

Yet, despite definitive scientific data to the contrary, many gynecologists continue to believe the benefits of hormone therapy outweigh the risks. This non-evidence-based perception may be the result of decades of carefully orchestrated corporate influence on medical literature, writes *Plos Medicine*.

*Plos Medicine* tells us that between 1996 (when Prempro was first marketed) and 2004, Wyeth worked with several medical education and communication companies — but mostly with DesignWrite — to market the Premarin family of products. In its communications with Wyeth, DesignWrite noted that “Research shows high clinician reliance on journal articles for credible product information.” So, in addition to “full-length review articles,” DesignWrite recommended that the publication plan for Premarin products should include mini-reviews, case reports, editorials, letters and comments.

DesignWrite suggested that short pieces could be published quickly and were an efficient “means of placing important information about the therapeutic profile of an agent into the hands of influential physicians.” The company also explained that it would help Wyeth decide what data to present, recruit “authors,” choose journals, create abstracts and posters for medical meetings and “Position the product appropriately to influence subscribers.”

DesignWrite then drafted the articles — casting the drug in the best possible light — and submitted them to physicians for review. The reviewing physicians then became “authors.”

*PLoS Medicine* reports that there is no evidence the “authors” were paid for the use of their name. There is also little evidence that authors did much more than review the article and occasionally make an editing suggestion.

It is illegal for pharmaceutical companies to promote a marketed drug for a use other than those which are approved by the FDA. But articles in medical journals, newsletters and magazines are not considered promotional and the FDA considers them free speech and doesn’t regulate them. (However, try to get that past the FDA if you are touting the benefits of a natural supplement... or even natural foods.)

*PLoS Medicine* writes that, in the absence of data (or in the presence of data adverse to marketing goals), review articles in medical journals are crucial vehicles for encouraging off-label uses, promoting unproven benefits and for downplaying harms. In other words, Big Pharma can say anything it wants about the benefits of a drug or completely ignore known harmful side-effects as long these articles are run in medical journals, newsletters and magazines.

This excerpt from “Medical Papers by Ghostwriters Pushed Therapy,” in the Aug. 4, 2009 issue of *The Times*, demonstrates how the process worked:

Sometime in 2003, a DesignWrite employee wrote a 14-page outline of [an] article; the author was listed as “TBD” — to be decided. In July 2003, DesignWrite sent the outline to Dr. Gloria Bachmann, a professor of obstetrics and gynecology at the Robert Wood Johnson Medical Center.

Dr. Bachmann responded in an email message to DesignWrite: “Outline is excellent as written.” In September 2003, DesignWrite emailed Dr. Bachmann the first draft of the article. She also pronounced that “excellent” and added, “I only had one correction which I highlighted in red.”

The article, a nearly verbatim copy of the DesignWrite draft, appeared in 2005 in *The Journal of Reproductive Medicine*, with Dr. Bachmann listed as the primary author. It described hormone drugs as the “gold standard” for treating hot flashes and was less enthusiastic about other therapies.

The acknowledgments thanked several medical writers for their “editorial assistance,” not disclosing that those writers worked for DesignWrite, which charged Wyeth \$25,000 to generate the article.

Dr. Bachmann, who has 30 years of research and clinical experience in menopause, said she played a major role in the publication by lending her expertise. Her email messages do not reflect contributions she may have made during phone calls and in-person meetings, she said.

“There was a need for a review article and I said ‘Yes, I will review the draft and make sure it is accurate,’ ” Dr. Bachmann said in an interview Tuesday. “This is my work, this is what I believe, this is reflective of my view.”

In response to a query from a reporter, Michael Platt, the president of DesignWrite, wrote that the company “has not, and will not, participate in the publication of any material in which it does not have complete confidence in the scientific validity of the content, based upon the best available data.”

But, as *PLoS Medicine* reports, DesignWrite had a specific agenda as a paid marketing agent of Wyeth. That was:

- Mitigate perceived risks of hormone-associated breast cancer.
- Promote unproven, off-label uses, including prevention of dementia, Parkinson’s disease and visual impairment.
- Raise questions about the safety and efficacy of competing therapies (competitive messaging).
- Defend cardiovascular benefits, despite lack of benefit in randomized controlled trials.
- Position low-dose hormone therapy.

Unfortunately for more than 14,000 women, DesignWrite did their job well. So now you must ask yourself: Did my physician choose the drug I’m taking because of a well-written marketing piece? Probably so. Because it’s articles like these that drive physicians’ decisions about prescribing drugs for the patients.