

Medical Papers by Ghostwriters Pushed Therapy

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Newly unveiled court documents show that ghostwriters paid by a pharmaceutical company played a major role in producing 26 scientific papers backing the use of hormone replacement therapy in women, suggesting that the level of hidden industry influence on medical literature is broader than previously known.

The articles, published in medical journals between 1998 and 2005, emphasized the benefits and de-emphasized the risks of taking hormones to protect against maladies like aging skin, heart disease and dementia. That supposed medical consensus benefited Wyeth, the pharmaceutical company that paid a medical communications firm to draft the papers, as sales of its hormone drugs, called Premarin and Prempro, soared to nearly \$2 billion in 2001.

But the seeming consensus fell apart in 2002 when a huge federal study on hormone therapy was stopped after researchers found that menopausal women who took certain hormones had an increased risk of invasive breast cancer, heart disease and stroke. A later study found that hormones increased the risk of dementia in older patients.

The ghostwritten papers were typically review articles, in which an author weighs a large body of medical research and offers a bottom-line judgment about how to treat a particular ailment. The articles appeared in 18 medical journals, including *The American Journal of Obstetrics and Gynecology* and *The International Journal of Cardiology*.

The articles did not disclose Wyeth's role in initiating and paying for the work. Elsevier, the publisher of some of the journals, said it was disturbed by the allegations of ghostwriting and would investigate.

The documents on ghostwriting were uncovered by lawyers suing Wyeth and were made public after a request in court from PLoS Medicine, a medical journal from the Public Library of Science, and *The New York Times*.

A spokesman for Wyeth said that the articles were scientifically accurate and that pharmaceutical companies routinely hired medical writing companies to assist authors in drafting

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manuscripts.

The court documents provide a detailed paper trail showing how Wyeth contracted with a medical communications company to outline articles, draft them and then solicit top physicians to sign their names, even though many of the doctors contributed little or no writing. The documents suggest the practice went well beyond the case of Wyeth and hormone therapy, involving numerous drugs from other pharmaceutical companies.

“It’s almost like steroids and baseball,” said Dr. Joseph S. Ross, an assistant professor of geriatrics at Mount Sinai School of Medicine in New York, who has conducted research on ghostwriting. “You don’t know who was using and who wasn’t; you don’t know which articles are tainted and which aren’t.”

Because physicians rely on medical literature, the concern about ghostwriting is that doctors might change their prescribing habits after reading certain articles, unaware they were commissioned by a drug company.

“The filter is missing when the reader does not know that the germ of an article came from the manufacturer,” said James Szaller, a lawyer in Cleveland who has spent four years going through the ghostwriting documents on behalf of hormone therapy plaintiffs.

Wyeth faces about 8,400 lawsuits from women who claim that the company’s hormone drugs caused them to develop illnesses. Twenty-three of the 31 cases that had been set for trial were resolved in Wyeth’s favor; the company has also settled with five plaintiffs. Others cases are on appeal.

Doug Petkus, a spokesman for Wyeth, said the articles on hormone therapy were scientifically sound and subjected to rigorous review by outside experts on behalf of the medical journals that published them.

Although Wyeth continues to work with medical writing firms, the company adopted a policy in 2006 mandating that authors become involved early in the publication process and that any financial assistance by Wyeth or contributions by medical writers be acknowledged in the published text, said Stephen Urbanczyk, a lawyer representing Wyeth.

Doctors have long debated the merits and risks of hormone therapy to treat the symptoms of menopause. Although studies have shown that hormones have benefits like reducing the incidence of hip fractures, they have also shown that the drugs can increase the risk of various cancers.

At one time, the Premarin family of drugs, which dominated the market for hormone therapy, was among Wyeth’s best-selling brands. And the company worked with several ghostwriting companies to maintain that dominance.

In 1997, for example, DesignWrite, a medical communications company in Princeton, N.J., proposed to Wyeth a two-year plan that would include the preparation of about 30 articles for publication in medical journals.

The development of an article on the treatment of menopausal hot flashes and night sweats illustrates DesignWrite’s methodology.

Sometime in 2003, a DesignWrite employee wrote a 14-page outline of the 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 School in New Brunswick, N.J.

Dr. Bachmann responded in an e-mail message to DesignWrite: “Outline is excellent as written.” In September 2003, DesignWrite e-mailed 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 e-mail 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.”

As medical journals learn more about ghostwriting through documents released in lawsuits and in Congress, some editors have started asking authors harder questions. A few leading journals, like *The Journal of the American Medical Association*, have instituted authorship forms that require contributors to detail their role in an article and to disclose conflicts of interest.

But many journals have yet to take such steps.