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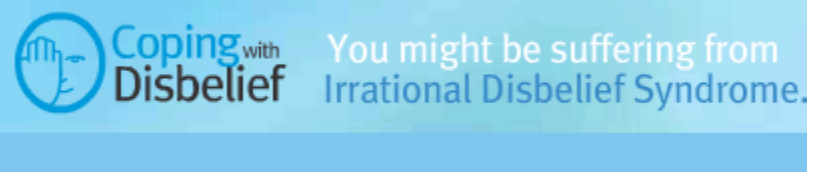
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Side Effects | Are Doctors' Loyalties Divided?

UW linked to ghostwriting

By John Fauber and Meg Kissinger of the Journal Sentinel

Posted: Aug. 15, 2009

Side Effects

An occasional series examining doctors, drug companies and conflicts of interest.

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As fears were growing about the link between hormone therapy and breast cancer, a drug company paid the University of Wisconsin to sponsor ghostwritten medical education articles that downplayed the risks, records obtained by the Journal Sentinel show.

The five articles were funded by Wyeth, the company that made the top-selling hormone therapy products. The articles, published in 2001, appeared under the names of doctors who specialized in diseases common to menopausal women, but actually were written by professional writers paid by the company.

The articles came shortly before a long-term \$1.5 million arrangement between Wyeth and UW to educate doctors and patients around the country about hormone therapy. The initiative promoted the benefits and softened the risks of drugs that produced sales of more than \$1 billion a year.

The five articles alone reached up to 128,000 doctors and other clinicians who could get medical education credit by reading the reports and taking a quiz.

"These articles contributed to widespread prescription of hormones to women who did not need them, but who were put at risk of blood clots, breast cancer, and other adverse effects," said Adriane Fugh-Berman, associate professor of physiology and biophysics at Georgetown University Medical Center, a pharmaceutical industry critic.

Doug Petkus, a Wyeth spokesman, said there was no evidence that Wyeth ever supported articles that it knew were false or misrepresented the science.

UW course for doctors pushed risky therapy

"The bottom line is that the authors of the articles in question exercised substantive editorial control over the content of the articles and had the final say, in all respects, over the content - all of which was scientifically accurate," Petkus said.

Although Wyeth's financial contribution to UW was supposed to be unrestricted, Petkus acknowledged that Wyeth executives played a role in producing the articles.

"Wyeth employees did provide suggestions," he said. "Were those suggestions put into the final version of the articles? I don't know."

Earlier this month, court records involving litigation against Wyeth were unsealed by a federal judge. The records show dozens of Wyeth-funded papers - including those involving UW - were actually written by Design-Write, a New Jersey medical communications company.

The records were provided to the Journal Sentinel by Cleveland attorney James Szaller, who spent four years investigating Wyeth on behalf of women who got breast cancer after using the hormone products.

The records show that DesignWrite orchestrated various aspects of the articles from developing the topics to writing the text to submitting them for publication.

"DesignWrite is responsible for writing and editing the papers as shown in the outline," Rosie Lynch, Design-Write's vice president for scientific affairs, said in one of the unsealed documents. "We will arrange and coordinate all activities with the CME (continuing medical education) provider, University of Wisconsin School of Medicine as well as the journal."

These revelations call into question the validity of UW's Council on Hormone Education, which also was assembled by DesignWrite and paid for by Wyeth.

The five articles were written by members of the hormone council. Wyeth paid \$12 million for the hormone therapy education project. UW got \$1.5 million of that.

Well-published writers

Both the 2001 articles and articles produced by the hormone council were reviewed for the university by Julie Fagan, a UW doctor and associate professor of medicine.

Fagan said she was disturbed when she first learned of the company's practices in June, when she gave a deposition in the court case.

"I find myself wondering about every medical article I read, certainly studies sponsored by industry," she said in an e-mail to the Journal Sentinel.

The doctors on the hormone council were all distinguished, well-published writers, she said.

"So, I, like doubtless many readers, assumed they had written the articles themselves," she said. "I probably should have been more skeptical going into the project."

George Mejicano, director of UW's continuing medical education program, said the medical school was not aware of Wyeth's role in preparing the ghostwritten articles.

"Had we known, we would not have allowed employees of a commercial interest to be involved in creating CME content," he said in an e-mail.

Clinical trial stopped

The 2001 articles were done at a time when many women and their doctors increasingly were concerned about hormone therapy causing breast cancer. Less than a year later, a large clinical trial would be stopped early when the drugs were found to increase the risk of breast cancer.

Doctors say the practice of ghostwriting continues to be commonplace.

James Stein, a UW cardiologist, said he was approached twice in the last week to put his name on educational material for different drug companies. He said he turned down both offers because, "frankly, it's plagiarism."

"If an undergraduate did this, he would be expelled," Stein said.

When a drug company puts a doctor's name on an article that actually was written by a professional writer, it is able to present a more biased and promotional version of an issue as though it were coming from an independent source, Stein and others say.

The company's ultimate goal is to sell more drugs, said Steven Miles, a physician and professor at the Center for Bioethics at the University of Minnesota Medical School.

"These ghostwritten articles are advertising masquerading as scientific reviews," he said. "It's dishonest."

One of the listed authors, Leon Speroff, then a professor of obstetrics and gynecology at Oregon Health Sciences University, actually thanked the DesignWrite writer for writing the article.

"You did a super job of writing this paper - succinct and makes the points very well," Speroff said in a May 2001 e-mail.

Speroff is listed as the author of an article titled, "Inconsistency in Epidemiologic Findings on Postmenopausal Hormone Therapy and Breast Cancer."

Speroff, reached at his home in Oregon, said the practice of ghostwriting remains commonplace, and he defended it.

"There is nothing dishonest about it," he said.

He laughed at the idea that someone might be offended by the lack of transparency.

"If you don't like the way it works, that's your business," Speroff said.

Practice defended

In January, the Journal Sentinel reported that both Wyeth and DesignWrite got letters from U.S. Sen. Charles Grassley (R-Iowa) requesting information about how the articles were assembled.

Each of the five 2001 articles sponsored by UW involved breast cancer and hormone therapy. The articles appeared in a supplement to the journal Women's Health in Primary Care. The articles were titled "Postmenopausal Hormone Therapy and Breast Health: A Review for Clinicians."

Michael Platt, president of DesignWrite, said in an e-mail the articles were scientifically accurate and the doctors had editorial control over the content. UW reviewed and approved the articles for balance and objectivity, he said in an e-mail.

At the time the articles were published, he said, it was not the norm to disclose the names of those who "provided editorial assistance to physicians."

He also said it was an acceptable industry practice to offer a courtesy review to the drug company.

In January, the Journal Sentinel first reported on Wyeth's funding of UW's hormone council. From 2002 to 2008, the school's hormone council offered the online course to thousands of doctors.

Even after the course was no longer available, the Web site and course material remained on the Internet, accessible to consumers and doctors. The university dropped the site Jan. 15, one day after the Journal Sentinel began questioning UW officials about the propriety of the program.

More stories online To read the full Side Effects series, which looks at the influence of drug companies on doctors and universities, go to www.jsonline.com/sideeffects.

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