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# Ghostwriting is bad medicine, say critics

MICHAEL STUPARYK/TORONTO STAR

"All those years, I thought I was doing something good for my health," says Jackie Smith, who did HRT for 13 years and now has breast cancer. A Canadian class-action lawsuit against U.S.-based Wyeth is awaiting an appeal.

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Jackie Smith thought she was doing the right thing.

With an asthmatic 4-year-old boy at home and a sick father a world away in Australia, she had no room in her life for osteoporosis or early menopause. It was 20 years ago, and when her gynecologist suggested hormone replacement therapy to stave off the effects of aging, she agreed.

"I was having these awful hot flashes," the 62-year-old recalls. "I found it really hard to deal with. There was a lot of stress in my life."

It's a moment she is revisiting now, with news that the company behind her treatment used ghostwriters to promote HRT in academic journals and play down any health threats, including breast cancer and stroke.

Last month, Smith, who was on HRT for 13 years, was told she has breast cancer.

"The hardest part was telling my son," she says, adding that her boy, now living in British Columbia, flew home immediately.

News of ghostwriting has been seeping out for years, with lawsuits in the U.S. forcing drug companies to admit to the practice.

But a lawsuit against HRT manufacturer Wyeth Pharmaceuticals has gone further, finally pulling back the veil on the shadowy world of academic publishing and laying out how ghostwriting works.

An appeal decision is pending on a Canadian class-action lawsuit against Wyeth, a U.S. company. Wyeth's position is that a Canadian class-action should only be able to target a Canadian company and the American

parent company should not be included in the case. Depending on the outcome of the appeal, the Canadian class action will proceed – if only against the Canadian branch, says Vancouver lawyer David Klein.

Whatever happens, says Klein, the ghostwriting revelations coming out in U.S. courts will form part of the Canadian case against Wyeth.

"Physicians in Canada go to conferences in the U.S., they read American journals," he says. "There's no question it has an impact here."

Medical ghostwriting, it seems, operates a lot like the essay-writing firms that tempt students to pay someone else to write their term papers – except there's much more money involved.

According to documents released in court this week, Wyeth hired Princeton, N.J.-based DesignWrite Inc., a medical communications company, in 1997 to write up to 30 articles on HRT for publication in respected academic journals between 1998 and 2005. For one study in 2003, DesignWrite billed Wyeth $25,000 (U.S.).

DesignWrite's job was to prepare medical articles and then recruit an expert in the field to review the work and put his or her name on the top, claiming to be the author. The articles would then be submitted for publication to a respected medical journal, which would be unaware of DesignWrite's role.

Wyeth has admitted to the practice, with company spokesman Doug Petkus saying the articles were scientifically sound and subject to rigorous review. Three years ago, Wyeth began including experts earlier in the writing process and acknowledging its payments and the use of hired writers to compose the articles.

Smith, an ethics instructor at Ryerson University's school of nursing, says ghostwriting makes for dangerous medicine and should be stopped altogether.

"The concern is the huge issue of trust," she says. "The patients rely on their doctors, who rely on medical journals to tell them what's safe. Anything that interferes with that is problematic."

Bioethicist Trudo Lemmens has harsher words, saying that academics engaging in ghostwriting "undermine the integrity of the whole system.

"It's a prostitution of their own academic standing," the University of Toronto professor of law and medicine says.

The full extent of ghostwriting is hard to verify, he says, since few academics will admit to it. A 1998 study in The Journal of the American Medical Association, which is co-sponsoring a conference on the issue next month, found that at least 11 per cent of the articles in top journals were ghostwritten.

Lemmens says ghostwriting is most likely for a company's top drug. A 2003 study in The British Journal of Psychiatry found 57 per cent of articles on the Pfizer drug Zoloft over a three-year period were written by the New York ghostwriting firm, Current Medical Directions (CMD). Those articles tended to be more positive about Zoloft, an antidepressant, than the independent ones, the study found.

For pharmaceutical companies, the importance of favourable articles cannot be understated.

At Wyeth, sales of HRT drugs Premarin and Prempro soared to nearly $2 billion within a few years of hiring DesignWrite. The articles helped create a medical consensus that HRT can protect against aging skin, heart disease and dementia, while playing down treatment risks.

Then in 2002, two major U.S. studies linked HRT to breast and ovarian cancer, heart disease, stroke and blood clots. Other studies found a link to dementia. Hormone prescriptions soon plummeted and are now barely one-fifth of their peak eight years ago.

Dr. Joseph S. Ross, a professor of geriatrics at Mount Sinai School of Medicine in New York, compares the inherent danger of ghostwriting to that of steroids in baseball.

"You don't know who was using and who wasn't; you don't know which articles are tainted and which aren't."

Those behind the latest revelations stand by the accuracy of their studies. DesignWrite president Michael Platt says his 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."

Sergio Sismondo, a philosophy professor at Queen's University, attended a conference of ghostwriters a few years ago and says he was struck by how up-front the writers were about their role in marketing drugs, at the same time remaining confident they were doing nothing ethically wrong, since their work was rooted in science.

"They believe they are providing a valuable service," he says. "They know they are marketing, but they believe they are doing so with science."

Smith, who includes lectures on how science can be used as a marketing tool in her nursing classes, is having none of it.

"Writers are paid to write for the company, and the pharmaceutical companies are in the business of selling, and marketing, their drugs," she says. "All those years, I thought I was doing something good for my health."

Smith says that if any of her students handed in an essay written by someone else, she would fail them.