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DIRTY MEDICINE

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Here's a blog I wrote several years ago. I publish it again here, because of all the controversy stirred up by our new magazine, What Doctors Don't Tell You:

Dirty Medicine

After 23 years of reporting on the excesses and dangers of modern medicine for my newsletter (and how our magazine) What Doctors Don't Tell You, I have become a bit ho-hum when confronted by yet another new revelation about the practices of drug companies.

But I have to tell you that I was shaken to the core by published evidence in 2010 that a good percentage of the medical research published in the world's top medical literature is ghostwritten.

In the pharmaceutical world, 'ghostwriting' has a particular meaning. A drugs company will hire a PR firm — known in pharma-speak as a 'medical education and communication company (MECC)' – to prepare clinical trials, engage a ghost to write an article with a positive spin on the results, and then enlist a prominent academic to put his name to a paper he's had nothing to do with in order to give it a patina of respectability.

This 'study' will then be submitted (and usually published) in a respectable medical journal.

Class action

This practice only came to light several months ago during the discovery process in a class action of a lawsuit against drugs manufacturer Wyeth by 14,000 women who developed breast cancer after taking Premarin, its bestselling hormone replacement therapy drug.

It was only with the efforts of PLoS Medicine, the Public Library of Science's peer–reviewed open access journal, and the New York Times that Wyeth's sealed documents about the marketing of Premarin were made available to the public.

The 1500 documents afford an unprecedented glimpse into the underworld that is pharmaceutical marketing. The paper trail shows clearly how an MECC called DesignWrite hired by Wyeth launched a major damage-limitation exercise after the first clear study emerged demonstrating a link between HRT and life-threatening illness.

Wyeth's HRT products had reached annual revenues of $2bn but that all changed in 2002, when the US National Institutes of Health-sponsored Women's Health Initiative (WHI) study discovered that HRT increases the risk of breast cancer, ovarian cancer, stroke and heart disease. The risk was so unequivocal that the researchers running the study called a halt to HRT use in their patient population.

Wyeth's sales abruptly nosedived by some 65 per cent after the first WHI reports, when doctors were understandably loath to prescribe the drugs to their patients.

Marketing plan

DesignWrite produced an ambitious marketing plan to flood the professional press with positive stories about Premarin. This "comprehensive publication program", it claimed, would include "peer-reviewed journal articles, editorials, letters to the editor, sales training backgrounders, and critiques of the current literature, all designed to support the marketing efforts by Wyeth-Ayerst for the Premarin Family of Products."

The disclosure papers show that the articles appeared in 18 prestigious medical journals, including the American Journal of Obstetrics and Gynecology and The International Journal of Cardiology.

The true purpose of all this was a massive effort to influence the prescribing habits of doctors; as DesignWrite noted in correspondence with Wyeth, 'Research shows high clinician reliance on journal articles of credible product information."

Downplayed risk

Virtually all the studies were 'meta-analyses' — a review pooling all previous trials on a drug or procedure. A meta-analysis is the gold standard in medicine for reviewing the safety and effectiveness of a drug.

According to Adrian Fugh-Berman, of the Georgetown University Medical Center in Washington, D. C., who has carried out a complete analysis of the Wyeth disclosure documents, the ghostwritten articles downplayed the carcinogenic potential of HRT, claimed that HRT had cardiovascular benefits, and promoted off-label and unproven uses of HRT, such as for prevention of dementia, even though off-label prescribing is illegal.

DesignWrite was paid $25,000 apiece to write four clinical trials on low-dose Prempro, another of Wyeth's HRT products. Many of DesignWrite's articles disputed the WHI's conclusions, or implied that breast cancers caused by HRT are less aggressive and easily treatable.

Aside from its ghostwriting campaign, several months after the WHI results, the Council on Hormone Education, working with University of Wisconsin-Madison's School of Medicine and Public Health, launched a medical education program for doctors to promote hormone therapy and downplay the risks.

To date, thousands of doctors around the US have taken this online course, entirely funded by a $12 million grant by Wyeth. The University of Wisconsin received $1.5 million of the money and university faculty were also individually paid.

The course material was largely developed by — you guessed it — DesignWrite. The Council on Hormone Education was formed by DesignWrite, Wyeth and the University of Wisconsin. Of the 40 member physicians on the council, 34 —including the course chairman, a UW doctor and professor of medicine — have financial ties to Wyeth.

File-drawer research

As the full scale of Wyeth's deception is laid bare, there is evidence that their practices are simply standard operating procedure.

In a review carried out between 1994-5, the Scientific-Ethical Committees for Copenhagen and Frederiksburg concluded that as much as three-quarters of every medical journal could be 'ghosted' – either the paper was prepared or promoted by an MECC or the author didn't write it.

Medical researchers and university professors are encouraged to lend their names to studies because of the 'publish or perish' practices in most academic institutions.

The problem is, there is no way of smoking out research that is either ghostwritten or the result of biased reporting. As Dr. Joseph S. Ross, professor of geriatrics at Mount Sinai School of Medicine in New York, put it: "It's almost like steroids and baseball. You don't know who was using and who wasn't; you don't know which articles are tainted and which aren't."

Crumbling edifice

These disclosures do nothing less than to undermine the entire edifice of modern medicine. As the British Medical Journal noted at the time, it is likely that a vast swath of medicine's "current evidence base. . . contains incomplete and questionable evidence".

Although new Food and Drug Administration regulations will make these practices more difficult, what is to be done about the mountain of published material on which doctors, patients and policy makers have relied for many years to make clinical decisions?

Some critics of WDDTY take issue with me for highlighting that British Medical Association's estimate that only 12 per cent of some 2500 standard medical treatments have any proof of benefit – by which I mean a single study showing that benefit outweighs the risk. They say that is 'a significant percentage.'

So let's think of it another way, as my husband said this morning. Let's imagine that you have a gun which is 88 per cent loaded and you are being asked to put it to your head. Does 12 per cent seem a high percentage now?

To me, this is evidence of the same problem that gripped the finance world. We have come to the very end of 'naked tooth and claw' commercial enterprise, the mindset that must make a bigger and better a profit every year, at any cost.

We need an open forum and open access to all forms of health care. Anything less is simply dirty medicine.