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essay

Pharma Goes to the Laundry: *Public Relations and the Business of Medical Education*

BY CARL ELLIOTT

What's the difference between medical education and pharmaceutical public relations? Not much, according to the people who do it. "(T)he broad distinction between healthcare PR and medical education is becoming obsolete," writes Neil Kendle, chief executive officer of Lowe Fusion Healthcare, in a recent issue of *Pharmaceutical Marketing* magazine. So slender is the difference between education and

PR than that Kendle cannot even say for certain which business he is in. "Sometimes I describe Lowe Fusion as a 'PR consultancy', sometimes as a 'healthcare communications agency'. Sometimes I just cop out and list the things we do."¹

Here's how the business works. The pharmaceutical industry puts up the money, usually in the form of an "unrestricted educational grant." The grant goes to a for-profit medical education and/or communications company (MECC), which, in consultation with its pharma sponsor, puts together an "educational program."² The company and the MECC recruit academic physicians to

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deliver the program in return for a small cut of the grant. If the MECC is accredited by the Accreditation Council for Continuing Medical Education, it can offer the educational program on its own. If not, it must go through the CME office of a medical school, which—again for a cut of the grant—accredits the program and certifies it free of commercial bias. Then doctors, nurses and other health care workers attend the “educational program” that pharma has funded in order to satisfy the CME requirements of their professional organizations.

It is, as the corporate manuals like to say, a win-win situation. The doctors and nurses get CME credits; universities get a new revenue stream; academic physicians get some extra pocket money; MECCs get a lucrative market niche (over a billion dollars a year, according to *The Lancet*), and the pharmaceutical industry gets to shape the minds of medical America.³ By laundering its message through the MECCS, pharma gives up some control, but the pay-off is even better: advertisements with the appearance of objectivity. PR practitioners call this a “third-party” strategy. As Kendle puts it, “Third party sources of information, as long as they are perceived to have expertise in the area they are talking about, are much more credible sources of information than the pharmaceutical company itself.” Pharma now funds over 60 percent of continuing medical education in the United States.⁴

Not bothered that your doctor’s education comes from pharma? Have a look, then, at the “communications” arm of this lucrative business. Here the results are scientific articles, often in peer-reviewed medical journals. The money is laundered in much the same way. Pharma pays the MECC; the MECC puts together the articles; academic physicians are paid to sign onto the articles, and the MECC places the articles in medical journals. Some academics simply sign ghostwritten articles, while others work from a draft supplied by the company. Sticklers for honesty merely take the money and write the articles themselves. Fees vary. Some academics have signed on for as little as \$1,000 or \$1,500 per article, including the two faculty members at the Medical University of South Carolina who recently “authored” a ghostwritten article on Ritalin for Novartis.⁵ Others command much higher fees. When the debate over second-hand smoke was heating up in the early 1990s, the tobacco industry paid a biostatistician \$10,000 to write a single letter to the *Journal of the American Medical Association*.⁶ Warner Lambert, the maker of Neurontin, a seizure drug, gave a professor at the University of Minnesota over \$300,000 to write a textbook on epilepsy.⁷

None of this is exactly new. What is new is the magnitude of the phenomenon, which has only become evident through recent litigation. For years, nobody really knew how much of the medical literature was ghostwritten, or even how much had originated from pharma. (Ghosts take care to remain invisible.) The most widely cited article on ghostwriting, published in *JAMA* in 1998, found evidence of ghostwriting in 11 percent of articles published in six major American medical journals.⁸ To the uninitiated that figure may sound alarmingly high. But according to a recent study by David Healy

and Dinah Cattell in the *British Journal of Psychiatry*, it may actually be unrealistically low.⁹

As Healy and Cattell explain, a lawsuit brought against Pfizer in 1999 turned up documents produced by a medical communications company called Current Medical Directions. Current Medical Directions was working on a publications strategy for Pfizer’s antidepressant, Zoloft (sertraline). These documents listed all the Zoloft studies that Current Medical Directions was preparing for publication in 1999. The documents listed the journals where their papers had been submitted, the conferences where the papers had been presented, the authors of the articles, and so on. It was this last category—authorship—that was the most revealing. On a number of articles, the authors were listed as “TBD,” or “to be determined.” Apparently, Current Medical Directions had written the articles but was still searching for an academic to sign on.

Healy and Cattell decided to track down the articles on Zoloft that Current Medical Directions was working on in 1999 and see what had happened to them. They picked three years—1998, 1999, and 2000—and scanned the medical literature for all articles published on Zoloft during that time. What they found was stunning. First, the ghostwritten and agency-prepared articles outnumbered the articles written in the traditional way. Forty-one “traditionally authored” articles on Zoloft had been published, while fifty-five articles had come from Current Medical Directions. Second, the articles that came from Current Medical Directions had been published in far more prestigious journals than the traditionally authored articles (ranging from *JAMA* through *Archives of General Psychiatry* and the *American Journal of Psychiatry*.) In fact, the citation rate for the Current Medical Directions articles was over five times higher than the citation rate for the traditionally authored articles. Finally, the Current Medical Directions articles painted a much happier profile of Zoloft than did the traditionally authored articles. For example, the articles prepared by Current Medical Directions on pediatric psychopharmacology failed to mention five of the six children taking Zoloft who took action towards committing suicide.

Still not worried? Have a look at another piece of litigation. Readers of the business pages are becoming familiar with headlines like this one: “The cost of Wyeth’s diet-drug disaster: \$16.6 billion. And the claims keep coming.”¹⁰ That \$16.6 billion is the latest price tag for litigation over Fen-Phen, the diet drug combination produced by Wyeth. Fen-Phen is a combination of fenfluramine and phentermine that was promoted as a weight loss drug in the mid-90s. Wyeth produced two versions of fenfluramine: Pondimin and a newer chemical cousin, Redux, or dexfenfluramine. The FDA approved Redux in 1996 despite worries that it might cause primary pulmonary hypertension. As many as seven million people used the drugs. In 1997, Fen-Phen was withdrawn from the market after being linked to valvular heart disease. By some estimates as many as 30 percent of the seven million users would contract valvular disease.¹¹ Soon the link to primary pulmonary hypertension became even clearer. By 2001, at

least 365,000 users had joined a mass federal settlement and Wyeth had acknowledged that at least 45,000 patients had become ill as a result of using the drug. No uncontroversial figures exist as to how many Fen-Phen users have died, but it is safe to say that they number in the many hundreds.¹²

As Alicia Mundy has documented in her alarming book, *Dispensing with the Truth*, the behavior of Wyeth officials during the safety crisis was not exactly a model of corporate responsibility. In 1997, clinicians in Fargo, North Dakota, and the Mayo Clinic notified Wyeth that they had seen thirteen patients on Fen-Phen who had developed valvular disease. How did Wyeth respond? Their safety officer destroyed the data. She went to the files and “overwrote” them to avoid any mention of valvular disease.¹³ Wyeth then sat on the information about valvular disease for several more months before notifying the FDA. Wyeth’s approach to the worries about primary pulmonary hypertension was hardly better. Typical of its attitude was a memo from a company bureaucrat, later unearthed in litigation, that read, “Can I look forward to my waning years signing checks for fat people who are a little afraid of some silly lung problem?”¹⁴

The irony is that Fen-Phen was never an especially effective drug. Wyeth’s own data showed only a 3 percent difference between Fen-Phen and placebo.¹⁵ The average weight loss on the drug was less than 5 percent.¹⁶ For this very reason, the success of Fen-Phen was enormously dependent on PR. At the center of Wyeth’s PR campaign was the message that being overweight is not merely a matter of personal aesthetics. It is a health issue—and thus a matter that doctors need to take very seriously. To a background chorus of slogans such as “Obesity—The Public Health Crisis” and “Obesity—A Chronic Disease,” Wyeth pounded out a dubious statistical message: obesity causes 300,000 deaths a year.¹⁷ Wyeth needed to cast obesity as a dangerous medical problem in order to justify the potential risks of Fen-Phen.

Wyeth’s “medical education” campaign for Fen-Phen was a model of the genre. It included pay-outs to academic physicians, lavish conferences, and generous grants to professional medical societies. The \$54 million set aside by Wyeth to launch the drug included grants to the American Academy of Family Physicians, the American Diabetes Association, the North American Society for the Study of Obesity, and the American Society of Bariatric Physicians. Wyeth budgeted \$700,000 for C. Everett Koop’s advocacy group, Shape Up America, \$275,000 for a “State of Weight” teleseminar, \$179,000 for “Dear Doctor” letters, and \$50,000 for a Women’s Health seminar.¹⁸ Wyeth also maintained a stable of high-profile academic consultants—known in the business as Key Opinion Leaders (KOLs) and “advisory board” members. These KOLs included JoAnn Manson of Harvard and Gerald Faich of the University of Pennsylvania, who wrote a complimentary editorial on Fen-Phen for the *New England Journal of Medicine* (without disclosing their corporate ties) and George Blackburn, the chair of the Committee on Nutrition for the Massachusetts Medical Society, who was instrumental in getting Massachusetts to lift a ban on Fen-Phen.¹⁹ When Redux

was being considered for approval by the FDA, Wyeth also sent another KOL to testify on its behalf: Tufts University’s Louis Lasagna, the noted expert on clinical trial methodology whose essays on research ethics appear in many standard bioethics textbooks, and whose revised version of the Hippocratic Oath is repeated every year by students at many American medical schools.²⁰

One of the most ingenious pieces of the Fen-Phen public relations strategy was its ghostwriting scheme. In 1996 Wyeth hired Excerpta Medica Inc, a New Jersey-based medical communications firm, to write ten articles for medical journals promoting obesity treatment. Wyeth paid Excerpta Medica \$20,000 per article. In turn, Excerpta Medica paid prominent university researchers \$1,000 to \$1,500 to edit drafts of their articles and put their names on the published product. Wyeth kept each article under tight control, scrubbing drafts of any material that could damage sales. One draft article included sentences that read: “Individual case reports also suggest a link between dexfenfluramine and primary pulmonary hypertension.” Wyeth had Excerpta delete it.²¹

What made Excerpta Medica such an inspired choice is that it is a branch of the academic publisher, Reed Elsevier Plc., which publishes many of the world’s most prestigious science journals. Excerpta Medica manages two journals itself: *Clinical Therapeutics* and *Current Therapeutic Research*. According to court documents, Excerpta Medica planned to submit most of the articles it produced to Elsevier journals. In the actual event, Excerpta managed to publish only two articles before Fen-Phen was withdrawn from the market in 1997. One appeared in *Clinical Therapeutics*, the other in the *American Journal of Medicine* (another Elsevier journal). In neither case did the authors of the articles disclose that they were paid by Excerpta Medica. So clean was the laundering operation, in fact, that many of the authors did not even realize that Wyeth was involved. Richard Atkinson of the University of Wisconsin wrote a letter to Excerpta Medica congratulating them on the thoroughness and clarity of their article. “Perhaps I can get you to write all my papers for me!” he wrote. He did have one reservation about the piece he was signing: “My only general comment is that this piece may make dexfenfluramine sound better than it really is.”²²

It wasn’t until evidence had mounted that Fen-Phen was actually causing people to die that Wyeth put its PR machine into high gear. After Fen-Phen had been withdrawn from the market, Wyeth spent \$100 million on public relations to convince the public that the response had been overblown.²³ It convened an “Expert Panel” of cardiologists and gave Arthur Weyman of Harvard an honorarium of \$5,000 per day to chair it.²⁴ It put together a “Very Important Visiting Professor” (VIVP) program and flew the VIVPs to CME events at exotic resorts.²⁵ Most critically, Wyeth funded studies to discover evidence that would minimize the safety worries about Fen-Phen, and if the studies were favorable, it publicized those studies heavily. For example, Wyeth spent over \$18 million on a study by Neil Weissman at Georgetown University examining valvular damage. When a preliminary analysis of

the unpublished data looked somewhat favorable, it was presented at a conference, promoted by press release, and featured on the front page of *USA Today* with the headline, “Study: No Heart Damage from Diet Drug.” (That analysis was later discredited.²⁶)

Of all the depressing features of the Fen-Phen saga, perhaps the most depressing is just how little positive change it has produced. Wyeth has been punished, but academic physicians are still taking paychecks from pharma to sign onto ghostwritten articles; medical schools are still bringing in pharma-funded speakers to deliver lectures and Grand Rounds; and peer-reviewed medical journals are still publishing pharma-funded editorials, review articles, and journal supplements. What little action the professional bodies have taken has been purely cosmetic. Although the AMA developed clear, well-publicized guidelines governing gifts to physicians many years ago, the guidelines have been widely ignored, perhaps because the pharmaceutical industry funds the AMA itself. When the AMA’s Council on Ethical and Judicial

themselves against ghostwriting charges by pointing out just how widespread the practice was. “This is a common practice in the industry,” said Wyeth spokesman Doug Petkus. “It’s not particular to us.”

Why is it so hard to bring about change? Partly because change is in nobody’s financial interest. In the case of medical education, the funding operation is seamless. Not only does pharma fund the MECCS who organize the CME, the academics who deliver the CME, and the offices that certify the CME, it also funds the professional societies that require the CME. Specialty groups like the American Psychiatric Association and the American Academy of Family Physicians are heavily dependent on industry funds.³³ Pharma even helps write the accreditation guidelines. Nearly half of the membership of the task force which produced the original ACCME standards governing industry support of CME came from industry itself.³⁴

Another reason is that responsibility for the harm is so diffuse. Most of the people involved in these operations do not

We have known for many years that pharma funding influences behavior. Individually, the influence may be slight or even nonexistent; statistically, the result is a clinical and research agenda overwhelmingly shaped by pharma money. Still, we cling to the vast collective delusion that because we cannot see a provable causal link between funding and our own individual behavior, no real influence has been exerted.

Affairs decided to launch a campaign to educate doctors on the ethics of industry gifts in 2000, it made the stunningly inept decision to have pharma fund the campaign.²⁷ In June 2004 the ACCME published its new guidelines for commercial support of medical education, but the guidelines are vague and toothless.²⁸ They do little to punish offenders, much less to cut off the flow of money from pharma.

The Fen-Phen case is by no means unique. A similar pattern of deception is emerging in the story of SSRIs and suicide.²⁹ Warner Lambert’s off-label promotion of Neurontin has been, if anything, even more deceptive than Wyeth’s Fen-Phen campaign—and despite fraud sanctions, Neurontin is still a wildly profitable drug.³⁰ Many (if not most) MECCs are owned by advertising and marketing firms, some of which have begun conducting clinical research themselves.³¹ What is especially striking about the testimony of the people involved in these promotions is just how matter-of-fact they are about their marketing practices. When asked about the way the industry cultivates “key opinion leaders” and “advisory board members” to lecture on behalf of pharma, Hugh Gosling, the editor of *Pharmaceutical Marketing*, replied that it was the industry norm. “I think it’s exactly the same as it always has been,” he said. “I don’t feel that there has been a turning point in any way.”³² In the Fen-Phen case, Wyeth officials defended

see any harm in taking a piece of the industry money for themselves. The academic researcher says: what’s the harm if I take money for signing onto a MECC-produced editorial as long as I agree with everything that is in it? The doctor says: what’s the harm in attending an industry-funded symposium in Boca Raton as long as I look at the presentations with a skeptical eye? The department head says: what’s wrong with taking money from Janssen or Merck to fund our Grand Rounds program if it means we can bring in more high-profile speakers? The journal editor says: what’s wrong with publishing an industry-funded editorial or review article as long as it gets appropriate peer review? The ethicist says: what’s wrong with funding our centers with industry money as long as the gifts are unrestricted and the funders are not issuing any orders? But it is only when all these cogs click together that the machinery is put into motion.

We have known for many years that pharma funding influences behavior. We know that when research is funded by pharma, it tends to favor pharma.³⁵ We know that when doctors take gifts and fees from pharma, they are much more likely to prescribe the drugs produced by the company that has given them the gift.³⁶ We know that researchers don’t disclose their financial ties even when they are asked—and usually, they are not asked.³⁷ Individually, the influence may be slight

or even nonexistent; statistically, the result is a clinical and research agenda overwhelmingly shaped by pharma money. Still, we cling to the vast collective delusion that because we cannot see a provable causal link between funding and our own individual behavior, no real influence has been exerted. Nobody is willing to give up money or perks in order to combat a statistical problem.

One of the first ethicists to call attention to the problem of paid editorials was Troyan Brennan at Harvard, who addressed the issue over ten years ago. Writing in the *New England Journal of Medicine*, Brennan explained how he was offered \$2,500 by Edlmann Communications on behalf of a pharmaceutical company in exchange for writing an editorial for a peer-reviewed journal. Brennan turned down the money, but he was not willing to condemn paid editorials or pharma-funded CME. Instead, he called for transparency. “Rather than foreclose the participation of these physicians in such activities as editorial writing, we should consider improving disclosure,” wrote Brennan. “Conflicts will remain with us. They must be better managed.”³⁸

It is time to admit that as a remedy for conflict of interest, disclosure has been an utter failure. Disclosure is an empty ritual designed to ease the consciences of academics unable to wean themselves from the industry payroll. Its only purpose is to serve as a warning signal, like a fire alarm in a burning building. Disclosure does nothing to fix the underlying problem of pharma funding, which is not secrecy but power. It does patients no good to be told that doctors, researchers, and regulators are all in pharma’s pocket if there is nothing they can do about it.

If the right constituencies could be mobilized, the mess would not be that hard to clean up. Universities and journals could treat ghostwritten articles as cases of scientific fraud. Department heads could treat faculty who sign onto paid editorials the same way they treat students who sign their names to papers they buy on the Internet. Medical organizations could hold conferences without drug industry perks, just like other professional societies. Universities could pay their ethicists without the help of industry funds, in the same way that they pay their philosophers and sociologists. Journal editors could refuse to publish editorials, review articles, and ethics essays written by authors who are funded by the industry whose products they are addressing. Academic physicians could treat lectures and grand rounds as part of their duty as teachers, rather than as a way to generate extra income. But nobody will take action because nobody sees the problem as their own responsibility. It is hard to see any change taking place in the current climate unless litigators start going after the people who accept this money as well as those who offer it.

When Brennan was writing, bioethicists could have stepped into this debate. But we forfeited any credibility we may have had when we started taking pharma money ourselves. Pfizer may be commissioning ghostwritten

Zolof articles, fighting a lawsuit by parents of children who died in its Nigerian Trovan trials, and paying off a \$430 million fraud penalty, but you can still hear ethics lectures in the Pfizer Hall for Medical Humanities at New York University medical school, attend classes taught by the Pfizer Lecturer in Medical Humanities at Royal Free and University College Medical School, and read Pfizer-funded disquisitions on conflict of interest in the *American Journal of Bioethics*—which is housed at the Pfizer-funded Center for Bioethics at the University of Pennsylvania, whose director has served as a Pfizer consultant.³⁹ What should we make of the fact that the *Hastings Center Report*, which receives funding from Merck, one of many pharmaceutical companies undertaking clinical research in the developing world, has recently published an essay on the ethics of research in the developing world whose lead author is a paid speaker for Merck?⁴⁰

The degree of dissembling and rationalization here might be funny if the stakes were not so high. “I take the money but it doesn’t influence me.” “I take the money from many different sources in order to keep my objectivity.” “I take the money but I make sure that no more than forty percent of our center’s funding comes from corporate sources.” “I take the money but I always disclose.” “I take the money but I say what I want.” Or my favorite: “I take the money but I use it to advocate for social justice.” The rationalizations always begin with the phrase: “I take the money.” No one will just say no. In fact, only a few people in academic medicine will openly criticize those who won’t say no. With the exception of a few watchdog groups and an outspoken group of critics, most of them journal editors or ex-editors, academic medicine treats the issue as an embarrassing peccadillo, like an extramarital affair: an unavoidable temptation best handled with a wink and a grin. At all costs we must avoid what ethicist and drug industry consultant Thomas Donaldson calls a “holier-than-thou stance.”⁴¹

But this is no peccadillo. It represents an enormous betrayal of public trust. We count on doctors to make decisions based on what’s best for us, we count on researchers to publish impartial data, and we count on educators to tell us the truth—regardless of what the pharmaceutical industry says. Nobody who makes even a token effort to find out where their checks are coming from could conclude that consultancies, advisory board memberships, educational grants, and speaker’s bureaus are anything but thinly disguised marketing tools.⁴² Pharma needs to make a profit; that is part of its mission. But to surrender our impartiality to that mission is a betrayal of everything that universities are supposed to stand for. The cost of that betrayal is being paid in human lives.

Acknowledgment

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42. Petersen, "Madison Ave. Has Growing Role In the Business of Drug Research." See also the revealing account of a former drug representative: M.J. Oldani, "Tales from the 'Script': An Insider/Outside View of Pharmaceutical Sales Practices," *Krober Anthropological Society* 87 (2002): 146-76.