Relationships between physicians and Pharma

Why physicians should not accept money from the pharmaceutical industry

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If we have learned anything from a decade's worth of litigation, it is that the pharmaceutical industry pays the vast majority of physicians for one reason: to market their drugs. And why would we have ever thought otherwise? Pharma companies are not charitable organizations. They are not in the business of education, or philanthropy, or poverty relief, or even—let's be honest—health care. Their business is to manufacture and sell drugs. Unlike most any other businesses, however, pharmaceutical companies must go through an intermediary in order to sell their product. This places physicians in a position of singular trust. They stand between corporations and the vulnerable, sometimes desperate patients that those corporations call “customers.”

How have physicians managed that delicate task? Make that judgment for yourself. In 2010, the pharmaceutical industry surpassed the defense industry as the leading defrauder of the federal government.¹ Pharmaceutical companies were forced to pay \$19.8 billion in penalties over a 20-year period, with a dramatic upswing coming in the mid-2000s. Although the largest category of penalty was for off-label promotion, that particular violation was just the visible face of a more far-reaching scandal. Thanks to the efforts of whistleblowers, expert witnesses, and investigative reporters, we know that pharmaceutical companies have rigged clinical trials, buried unfavorable results, published ghostwritten journal articles, paid kickbacks to high-prescribers, bullied academic critics, produced fake medical journals, and manipulated treatment guidelines.² Without the help of physicians, very little of this could have been accomplished.

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It is true that as the blockbuster drug era has faded, the pharmaceutical industry has cut back on small gifts to doctors. Branded pens and free donuts are not nearly as easy to score as they were a decade ago. But the most serious hazard to the health of patients has always come from the larger payments dispensed to physicians for speaking engagements and consultation. Many doctors insist they cannot be bribed, but as former drug rep Michael Oldani points out, a skillful rep will learn how to pay off doctors without giving them the sense that they are being bought. “Bribes that aren’t considered bribes,” Oldani says. “This, my friend, is the essence of pharmaceutical gifting.”³

The available evidence does not suggest that doctors who receive payments and gifts from industry will reciprocate directly. Rather, the influence of gifts and payments is unconscious; most doctors believe they are not affected. Again, this should be no surprise. In fact, it is the cornerstone of effective marketing. Just as nobody thinks they are influenced by advertising, nobody thinks their decisions are altered by gifts and payments, simply because they cannot observe the influence themselves. But pharmaceutical companies have been able to track the effects of their marketing efforts with great precision since the 1990s by using prescription-tracking data compiled and sold by companies such as IMS Health. These data allow companies to measure precisely how many prescriptions physicians write for their products, and how those prescriptions change in response to various marketing tactics. Gifts, speaking fees, samples, and consultancies increase prescriptions—and if they do not, the tap is simply turned off.

In the string of recent pharmaceutical scandals, neurologists have often been at center stage, and not just because of the Sidney Gilman affair.⁴ Perhaps the most notorious case is that of Neurontin (gabapentin). The Food and Drug Administration approved Neurontin only as adjunct therapy for seizures, but Parke-Davis (now part of Pfizer) deployed a breathtaking array of covert marketing tactics to persuade doctors to prescribe the drug for all manner of conditions for which there was no evidence of efficacy, from migraines to bipolar disorder. Parke-Davis didn’t simply buy neurologists tickets to Hawaii or the Olympics. Its “tactical plan” for Neurontin included “encouraging titration to higher doses through peer-to-peer influence,” capturing the pediatric market by creating a Child Neurology Advisory Board, and recruiting neurologists to present case studies to their peers. It deployed a sophisticated publication strategy along with CME activities as ways of driving off-label prescriptions. As a Parke-Davis executive told his staff, “That’s where we need to be holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything.”⁵

One of the most damaging tactics used to market Neurontin was the STEPS seeding trial.⁶ Parke-Davis recruited 772 physicians to serve as “investigators” for an uncontrolled, unblinded study ostensibly aimed at studying the efficacy of Neurontin. In fact, the trial was a marketing exercise designed to familiarize the investigators with Neurontin and write more prescriptions. Eleven patients in the study died and 73 others experienced serious adverse events, but the marketing worked. Even after Pfizer (which bought Parke-Davis) was forced to pay \$430 million in criminal fines and civil damages, the popularity of Neurontin skyrocketed, mainly for off-label uses.

Neurontin was by no means an isolated case. Nor are the tactics that Parke-Davis deployed a thing of the past. Similar strategies have been uncovered in case after case: the \$1.4 billion settlement and criminal fines paid by Eli Lilly for illegally marketing Zyprexa in 2009; the

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\$2.3 billion paid by Pfizer in 2009 for illegally marketing 13 different drugs, including Lyrica, Geodon, and Bextra; the \$3 billion paid by GlaxoSmithKline in 2010 for illegally marketing Paxil, Wellbutrin, and Avandia; and most recently, the \$2.2 billion paid by Johnson & Johnson for illegally marketing Risperdal in 2013.

Some physicians who do not accept speaking or consulting fees from industry will still agree to do industry-sponsored clinical trials. But the pharmaceutical industry has demonstrated that it can corrupt clinical research just as easily as it can corrupt clinical practice. One of the most striking revelations to emerge from documents unsealed in recent litigation is the extent to which the industry rigs clinical trials in order to produce results favorable to their products. This is not hard to do, as former *British Medical Journal* editor Richard Smith and others have pointed out. The sponsor can underdose the competitor drug to make its own drug look more effective, or overdose the competitor drug to make its own drug look less toxic, or perform any number of far more complex statistical and design tricks that are difficult for nonexperts to detect.

Nor is it hard to find physicians willing to sign onto rigged studies as “authors” once a ghostwriter has written it up. Physicians are more than willing to accept academic credit for work they have not actually done. Of course, they are usually less willing to accept responsibility for a rigged design or buried results. As the lead author of Merck’s seeding study of Vioxx told the *New York Times*, in defense of his “authorship” of the study: “Merck designed the trial, paid for the trial, ran the trial. Merck came to me after the study was completed and said, ‘We want your help to work on the paper.’” The author appeared to believe this cleared him of responsibility.⁷

A small but vocal movement to clean up this financial mess has emerged, with the moderates in the movement arguing for full disclosure. Some states have enacted sunshine laws mandating that Pharma companies publicly report gifts and payments to doctors, and with the enactment of the Physician Payment Sunshine Act, that mandate will become national. However, it is a naive to imagine that sunshine laws will solve the problem. Disclosure makes the money trail clearer, but finding the trail has never been the real issue. The real issue is the money itself.

There are at least 2 strong reasons for physicians simply to say no to industry money. The most obvious is the way that industry money distorts the judgment of physicians. There are ample data showing that physicians who take money from a pharmaceutical company are more likely to write prescriptions for that company’s products, more likely to recommend that the company’s products be added to hospital formularies, and more likely to publish research findings favorable to that company. One would like to think that actions such as these would be based on fidelity to the truth and a clinical judgment of what is best for a patient, rather than on the names at the bottom of a paycheck.

But a second reason relates to the trustworthiness of the pharmaceutical companies themselves. Nearly every major pharmaceutical company has paid or settled large penalties for fraud, many for marketing drugs that have later turned out to be ineffective or carry dangerous side effects that the company has hidden for years. These drugs have killed or injured many people. How can a physician feel comfortable working with companies that have repeatedly betrayed their trust, not to mention the trust of patients?

It is possible that institutional mechanisms could be developed to reduce or eliminate the bias produced by industry funding. But no such mechanisms are on the table now, nor is it likely that the pharmaceutical industry will agree to them in the future. For now, as long as physicians continue to accept money from industry, patients will suffer the consequences.

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