

Indicting Big Pharma

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Indicting Big Pharma

Arthur L. Caplan

The Truth about the Drug Companies: How They Deceive Us and What To Do about It. Marcia Angell. xx + 305 pp. Random House, 2004. \$24.95.

On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health. Jerome P. Kassirer. xx + 251 pp. Oxford University Press, 2005. \$28.

Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs. Jerry Avorn. viii + 448 pp. Alfred A. Knopf, 2004. \$27.50.

Is the pharmaceutical industry a dangerous and crooked business that federal and state authorities need to bring to heel? Should those who develop, market or prescribe drugs hang their heads in shame when faced with the stark reality of what they do to earn a living? Is Big Pharma in fact the moral equivalent of the tobacco industry? One could well come away from Marcia Angell's *The Truth about the Drug Companies* or Jerome Kassirer's *On the Take* thinking so. In both books, the sort of moral opprobrium once directed against Big Tobacco is aimed squarely at the pharmaceutical industry, along with its legions of lobbyists, the politicians awash in its campaign contributions and the doctors it has bought, free meal by free meal, junket by junket, free sample by free sample and trinket by trinket.

Kassirer and Angell, who are physicians at Tufts and Harvard, respectively, and who are both former editors of the *New England Journal of Medicine*, are not the only authors currently taking a critical look at industry excesses. Harvard physician and pharmacoepidemiologist Jerry Avorn also has a new book examining some of the problems with the way prescription drugs are brought to market, the thoughtful and incisive *Powerful Medicines*.

It's not hard to see why demonization of the pharmaceutical industry has become such a popular sport. As Avorn points out, drug companies are now so obsessed with profits that they are no longer willing to pay for the innovative research that they claim justifies the high cost of their products. He and Angell each demonstrate that the numbers do not support the contention that without high prices there would be no money for the next generation of miracle drugs. Avorn notes that data from financial reports submitted to the Securities and Exchange Commission by nine of the largest U.S.-based pharmaceutical companies show the hollowness of this rationale for exorbitant prices. He cites a 2002 report by Families, USA, which indicated that these companies spent the greatest proportion of their revenues (27 percent) on marketing, advertising and administration. Next came profits at 18 percent—a rate of return that almost no other industry expects or can match. Money spent on research and development ran a distant third, at 11 percent of revenues. No matter how hard drug companies spin these numbers, they reveal priorities that serve neither patients nor the general public.

Other data in these three books strengthen the moral case against the industry. In the United States, patented, brand-name drugs sell on average for 80 percent more than in Canada and 100 percent more than in France and Italy. Efforts to redress price inequities by allowing the importation of drugs to the United States from Canada have met with fierce resistance from Big Pharma, which has waged a bizarre and deceitful campaign to impugn the safety of Canadian drugs. The campaign would be laughable had it not been so effective in keeping Canadian drugs in Canada.

The sins do not end with high prices, huge budgets for marketing and advertising, and efforts to restrain free markets. Drug companies, Angell and Kassirer remind us, have connived to do everything they can think of to capture the attention, allegiance and gratitude of physicians. And they have been able to think of quite a lot.

Dip anywhere at random into *The Truth about the Drug Companies* or *On the Take* and you will find disturbing passages such as this one (from Angell's book):

Suppose you are a big pharmaceutical company. You make a drug that is approved for a very limited use. . . . How could you turn it into a blockbuster? . . .

. . . You could simply market the drug for unapproved ("off-label") uses—despite the fact that doing so is illegal. You do that by carrying out "research" that falls way below the standard required for FDA approval, then "educating" doctors about any favorable results. That way, you could circumvent the law. You could say you were not marketing for unapproved uses; you were merely disseminating the results of research to doctors—who can legally prescribe a drug for any use. But it would be bogus education about bogus research. It would really be marketing.

Angell goes on to show that this is exactly what many pharmaceutical companies have done. In the name of "research," they have subtly encouraged doctors to use drugs for unapproved purposes, or for groups of patients (children, for example) in whom the agent's effectiveness has never been studied. The industry has also encouraged "innovative" prescription practices on the part of doctors who are not equipped to safely monitor and to learn from what they are doing. Outrage about this sort of conduct infuses every page of her powerful book.

Kassirer, like Angell, is no slouch at condemning ethical shenanigans:

Big business and physicians alike are involved in a massive charade. Representatives of the drug companies claim repeatedly that marketing serves an essential function in the health-care delivery system by helping to educate doctors so they can prescribe drugs more appropriately. At the same time, they press their drug salesmen to push the newest (and usually the most expensive) products, and their surrogate intermediaries, the medical education companies, are advertising their services as "persuasive" education.

Kassirer does not write with the same overt anger as Angell, but his quiet fury is palpable as he watches his beloved medical profession being corrupted by businesses willing to do whatever it takes to get their drugs prescribed.

It turns out to be relatively easy to make the case against bloated profits, the herd mentality of companies looking for blockbusters, dishonesty in marketing and crass schemes to pay off doctors, politicians and the media. No one can read these books and not believe that something needs to be done to reform the way drugs are discovered, patented, sold and used in the United States and around the world. But these books are far less satisfying when it comes to providing solutions.

Despite all the corruption documented by Angell, Kassirer and Avorn, the pharmaceutical industry is not the tobacco industry. Its products may sometimes be sold at bloated prices and marketed using techniques more commonly associated with used car dealers and Internet mortgage brokers. And some of those products may even turn out to be dangerous or ineffective. But Big Pharma, unlike Big Tobacco, is not selling inherently evil products. Many Americans have benefited from pharmaceuticals, and more do so every year, which is as much a cause of higher total expenditures for the nation as are increases in the prices of individual drugs. So medicine has no real choice but to deal with Big Pharma; nobody wants it just to go away. But clearly the drug industry must be better regulated.

Angell and Kassirer take a fairly straightforward route in their prescriptions for reform: Get the pharmaceutical industry away from the medical profession. Prohibit the drug companies from underwriting continuing medical education, get their sales representatives

("detail" people) out of hospitals and doctors' offices, and shut off the junket pipeline. And stop the industry from flooding the airwaves with ridiculously deceptive direct-to-consumer advertising.

Easy enough to say, but these are deeply ingrained practices that will prove next to impossible to eradicate. If you take the detail men and women out of doctors' offices, they will quickly reappear in the homes, country clubs, civic organizations and vacation spots of physicians. Companies are willing to invest heavily in these activities, which means that control (rather than eradication) is probably the most realistic goal.

Nor is there a lot of sentiment in Washington to take on Big Pharma. In the recent election the American people made it clear that they do not want or trust the federal government to regulate much of anything.

What Angell and Kassirer, for all the power of their books, fail to convey is that the activities they rightly condemn are all symptoms of deeper, more serious problems in the pharmaceutical industry. As Avorn correctly notes, it is a lack of science as much as venality that is responsible for the conflicts of interest and inefficiencies that are rife in medicine's relationships with the drug business.

Americans think that the U. S. Food and Drug Administration provides tight oversight ensuring the safety and efficacy of drugs. But the FDA lacks the authority and resources to do this job well. The FDA and its European counterparts can demand that pharmaceutical companies provide them with data to show that drugs are efficacious. But they have no mandate to show that drugs are effective—that they will work not only in closely monitored clinical trials but also in the real world under a variety of conditions. Nor is there any systematic, independent source of evidence about the comparative value of drugs and medical technologies. Head-to-head trials comparing a drug with a rival company's similar product or generic version are almost nonexistent. There are no databases that report the results of all trials in a standardized way, describing adverse events and efficacy in various subpopulations. "The initial FDA approval of a drug should be seen as the beginning of an intensive period of assessment, not the end," Avorn says. But that's not the case. And into this data vacuum rush the detail men and women bearing gifts.

Doctors, patients, policy makers and regulators are all blind as bats when it comes to having the data needed to rein in the huge excesses of the pharmaceutical industry. If no one can really say which drugs are the most effective for whom and which will get the job done most cheaply, then marketing based on trinkets, junkets and hype will continue to flourish. If no one challenges the industry to live up to its stated ethical goal of using science to benefit patients, then simply telling the industry's detail men and women to keep out of the lecture halls at medical schools will do little to weaken their influence.

Not only is there insufficient science guiding the pharmaceutical business, the financial incentives it has are pointing in the wrong direction. Big Pharma still looks to make its breakthroughs and find its blockbusters by creating pills that lots of us can take every day for most of our lives. This means that the supply of birth control pills, remedies for toenail fungus, cholesterol blockers and antidepressants is ample, whereas vaccines are scarce. Big Pharma and its university partners pay little attention to public health and the ailments of the poor because there is little money to be made from them.

To have drugs, we must have a pharmaceutical industry. The key to reforming it in the short run is, as these books show, going after its worst excesses and tamping them down. In the long run, more serious measures are needed. With its self-proclaimed ethical mission in mind, the industry must be restructured. It needs to be firmly grounded in science and properly motivated to provide us with the drugs that will do us all the most good. Accomplishing that is a matter of dialogue and redirection, not demonization.

Reviewer Information

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