

PHARMACEUTICAL ETHICS?

Ethics and the Pharmaceutical Industry, Edited by Michael A. Santoro and Thomas M. Gorrie. Cambridge University Press, New York, 2005

One criterion of a book's quality is that it raises more questions than it answers. This multi-authored book certainly does that. Early in the book we are told that its authors are outstanding leaders and thinkers from all segments of healthcare, and that they provide a fair and balanced view of the troubled relationship between the industry and society. Puzzling, I thought, because by page 3, after I had read these assertions, I had already leafed through the list of authors and hadn't noticed the names of the major critics of the industry's ethics, namely John Abramson, Marcia Angell, Jerry Avorn and Merrill Goozner. Surely, I thought, some of their well-documented examples will show up later, but both they and their ethical concerns are missing in action.

There is virtually no mention of industry's major ethical lapses, such as hiring ghostwriters to write favorable journal articles, jiggering study designs to produce favorable results, hiding unflattering results, failing to publish negative studies, promoting off-label drug use, giving bribes and kickbacks in return for promises to prescribe, and intimidating researchers whose results counter a company's interests. There is also little mention of shameless company attempts to extend their monopolies, to block the manufacture and sale of generic drugs, to put undue influence on the FDA, to buy-off large cadres of doctors, to promote drugs to treat social conditions, and to spend more money on marketing than research. And when all this is said and done, to produce a shrinking list of truly innovative, clinically useful drugs.

Inexplicably, with minor exceptions, the majority of the chapters have little relevance to the ethics of pharmaceutical companies. There are many "primer" chapters (some first class) on the implementation and ethics of clinical trials, research in children, drug prescribing practices, the role of the FDA, direct-to-consumer advertising, intellectual property rights, the influence of activists on the industry, and application of cost-effectiveness analysis. These discussions bear mostly on the ethics of researchers and doctors, not on the ethics of companies.

Eventually it becomes clear that the sole ethical issue addressed in the book is the disjunction between the profitability of the drug companies and the vast health needs of the public; between the companies' profit-seeking culture versus their societal responsibility. Industry has little interest in developing drugs for serious illnesses in large populations when there is no market mechanism to buy their drugs. Corporate ethics aim to maximize profits without regard for such populations, hence the practice of concentrating on blockbuster drugs and lifestyle drugs for shyness, sexual dysfunction, hair loss and ugly toenails.

Pharmaceutical executives argue that their private profits achieve a public good, that they are the good guys, just using their profits to innovate; and that because their products are so expensive, they are just the victims of bad PR. Without the hefty profits, they claim,

and without strict patent protection, the development of important new drugs would cease. In three chapters, top executives of major companies tell us in no uncertain terms what we must do: pay them adequately for their products, reduce approval times for drugs, and eliminate calls for longer or more complex clinical trials. We must not interfere with their intellectual property rights, consider price controls or profit limits; or allow importation of cheaper drugs. Their message is: if you mess with our profits, you'll be the ones to suffer. We'll hunker down and produce a lot of me-too drugs and nutritional supplements; we'll convert our research dollars into more marketing. One executive even believes that there is a worldwide conspiracy, a "campaign against innovation." The very idea sounded absurd, and even a little paranoid, but it triggered a thought of my own: just what motivated this book? If it was a desire to counter public resentment and disdain, ignoring the chief criticisms leveled recently at the industry dampens any such effect, and the rationale provided here for continuing their high profit levels is no more powerful now than at times in the past.

Many corporations face a disconnect between their company's goals and the public's interest. What prescription do these pharmaceutical CEOs offer when their industry's private money dominates over the public good? How do they suggest that we get drugs to the millions of people around the world who need them to survive but can't afford them? Their solutions involve cooperative ventures among private companies, government agencies, and foundations. Several examples are rolled out, some repeatedly throughout the book: Merck's Mectizan program for the eradication of river blindness and its program against HIV with the Gates Foundation in Botswana, the Johnson and Johnson royalty-free agreement for distribution in resource-poor countries of a microbicide for the prevention of HIV infection in women, and the Abbott Laboratories Fund partnership with the Axios Foundation and the Tanzanian government to improve the health infrastructure in that country.

These and a handful of other similar programs instantiate that diseases can be controlled or eradicated and that care can be delivered even in the poorest and most underserved areas, but the burden of world poverty and the ravages of disease are so great that the number and scope of these programs would have to be increased by some huge multiplier to cope with all the problems. One executive's solution, namely to get developing countries to institute market oriented health care systems with adequate reimbursement opportunities, seems completely out of touch with reality.

Unless the incentives for the pharmaceutical industry's executives become determined by factors other than profits alone, there is little hope that the companies will contribute more effectively to the medical commons or stop the behavior that has made them so unpopular. Books dressed up in ethical cloaks, token cooperative programs, and threats will certainly not salvage the pharmaceutical companies' dismal reputations.

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