Philip J. Hilts, Protecting America’s Health: The FDA, Business, and One Hundred Years of Regulation (NY: Knopf, 2003).

This is the best overall history of the FDA. The author uses a lively journalistic approach, personalizing the stories (the opening scene with Roosevelt’s ideological conversion is a grabber) to make regulation, ultimately, a morality tale. Regulation is necessary, Hilts concludes, because personal morality degrades as systems become large and complicated. Two forces are at work, he suggests: Size itself is a culprit, as people in large organizations are distantly connected to the moral consequences of their action; and authority is to blame, as business managers have an unalloyed duty to make more money. Morality alone can’t fight these forces, and so regulation is needed. At that level, the book is a rejection of the Reagan era attachment to deregulation. The book shows how the evidence is compelling—compare conservative complaints about the FDA’s approach to risk (not “balanced”) with the FDA’s needed recall of several drugs in the decade prior to the book’s publication, because of deaths that could have been avoided had drug companies been more forthcoming with data about drug trials. Voluntary compliance and reliance on privately generated data is inherently doomed to the pressures on those in the industry. Public health will suffer without a stronger FDA.

Tom Nesi, Poison Pills: The Untold Story of the Vioxx Drug Scandal (NY: Thomas Dunne/St. Martin’s, 2008) describes the trajectory of Vioxx (Merck’s main name for the drug rofecoxib), originally seen as an aspirin that did not damage the stomach—and possibly staved off alzheimer’s and cancer. If it was “safe and effective” as declared by the FDA, would possibly be the biggest money maker in the industry. Alas, people died because they took the drug. One estimate of Merck’s loss at the announcement of withdrawing the drug was $26 billion. That fortune is one of the culprits in Nesi’s account—the company simply had an irresistible incentive to look the other way at negative results, frame their trial studies in too narrowly, and advertise the drug in ways that were, in retrospect, obviously at odds with the way the drug would be used. In addition to greed and myopia at Merck, physicians and patients have their own perverse views of medicine, which start with a mistaken view of medicine as a tree for miracle drugs. The information that they needed to use the drug correctly was publicly available, but its proper use would mean that people who actually needed it would be making big changes in their lives and
spending more time talking with their doctors. The FDA’s failures in this were many. Key officials had worked for or otherwise had close ties with Merck—and people at Merck had once worked for the FDA, even supervising the FDA officials who were overseeing the Vioxx studies. Nesi does not prove that the poor review of Merck data was a product of these connections, but he clearly suggests it. The book is not hopeful that there is a miracle pill that will overcome these pressures.

Marcia Angell, The Truth About the Drug Companies (NY: Random House, 2004). Angell has top credentials to analyze the industry. She was editor in chief at the New England Journal of Medicine and is a Harvard professor in their Department of Social Medicine. In the book and in articles since then, published chiefly in The New York Review of Books, she lays out in great detail how commercial incentives inherently compromise medicine. Drugs have become big business—their share of GNP was static in the twenty years prior to 1980, and has tripled since. 1980 stands as a statistical watershed because of the pro-business policies of the Reagan era. Drug companies should never offer gifts to physicians—in any other industry we would call them bribes. While drug companies may be asked to finance research, as is the common practice, they should have no influence over the commercial versus scientific aspects of the studies, or over the interpretation of results. Drug company pricing practices are “rapacious,” charging the most from those who are least able to afford drugs, and spending far more on advertising than they do research. Their research is geared mostly to finding small variants on successful drugs in order to cash in on lucrative markets. World wide drug research is increasingly based here in the U.S. because companies benefit from public funding for medical research—and laws enabling the companies to keep private patents on the publicly financed innovations, and keep their marketing monopolies for longer periods—coupled with our lack of price controls. Drug company profit margins as about six times as large as those in typical US industries. Angell suggests several policy changes that would improve the situation, offering suggestions on how to accomplish each. Drug companies should focus more of their work on new drugs, not “me-too” reworkings of old drugs. The FDA has to be stronger and more independent of the drug companies. Drug companies should not have control over clinical testing of drugs. Their monopoly rights should be
restricted. They should not be in the business of medical education. They should have transparent books, and should price drugs in ways that does not encourage kickbacks and gouging. Angell clearly rejects the ideology of the Reagan era.