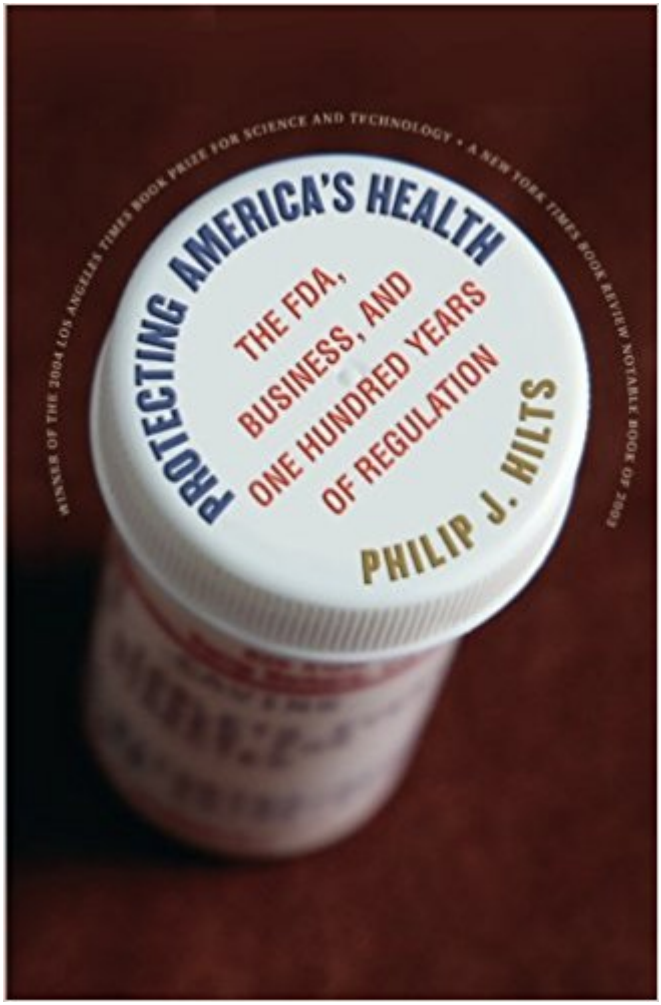
Protecting America's Health: The FDA, Business, And One Hundred Years Of Regulation



Synopsis

In this history of the Food and Drug Administration, Philip J. Hilts analyzes the century-long, continuing struggle to establish scientific standards as the basis for policymaking on food and drugs. The agency, which emerged out of the era of the robber barons and Theodore Roosevelt's desire to "civilize capitalism," was created to stop the trade in adulterated meats and quack drugs. In addition to highlighting the essential role the FDA plays in making sure that food and drugs are safe and effective, Protecting America's Health shows that FDA regulation, far from stifling innovation--as critics feared--has actually accelerated it.

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Customer Reviews

A century ago, store shelves were filled with products that were rotten, useless or even deadly. Today, we can be relatatively confident that "no cholesterol" on a product label really means what it says, and that the terms "fresh," "beef" and "reduces fever" accurately describe a product's contents or use. These protections, now taken for granted, have been the work of what is arguably the nation's most important regulatory agency, the Food and Drug Administration. Hilts (Scientific Temperaments), a health and science reporter who's written for the Washington Post and the New York Times, wonderfully documents the history of the FDA from its start in the administration of Teddy Roosevelt through various crises and triumphs to the deregulatory climate of recent years. From the start, FDA officials battled entrenched business interests. Industry argued that regulation hurt profits, stymied research and kept potentially beneficial products from reaching markets quickly.

How the FDA doggedly prevailed against this tide of opposition is a story of persistence, political maneuvering and make-it-up-as-you-go pragmatism. As Hilts shows, strong policies often emerged in the wake of tragedies or scandals: the case of thalidomide, a drug introduced in the late 1950s as a sedative and to relieve morning sickness but that caused pregnant women to give birth to severely deformed infants (the number is conservatively estimated at 8,000), shocked the world and led to congressional hearings and a strict new drug approval law. Even so, industry continues to lobby aggressively against regulation. Hilts has little sympathy for industry's point of view and has the facts to support this position. As the federal government once again starts talking about cuts, this book offers a sober reminder of the importance of maintaining vigorous protections against the dangers of profit-motivated decisions. Photos not seen by PW. Copyright 2003 Reed Business Information, Inc. --This text refers to an out of print or unavailable edition of this title.

A health/science reporter for the New York Times, Hilts tracks the growth of the federal agency charged with protecting our health.Copyright 2002 Reed Business Information, Inc. --This text refers to an out of print or unavailable edition of this title.

Hilts' readable book is the best introduction I know to the history and politics of FDA regulation. That history, as Hilts retells it, is a spiral. Clearly, there have been significant regulatory innovations since the days of T.R., and Hilts takes us through the key turning points. At the same time, the same core arguments about the virtues of regulation and the virtues of free markets recur.Specialists will find some of the retelling oversimplified, and Hilts' own position (some will say "bias") is always clear. Nonetheless, there is no better first immersion into these issues, a terrific foundation for more nuanced analysis.

Fantastic book! The content is very informative from a historical aspect and very entertaining from a reader's aspect. As an aspiring pharmacist, I particularly liked the content. There are numerous parallels between the history of the FDA and the Obamacare legislation currently going on. Great read for anyone. As a disclaimer, this is a very liberal book. Conservatives will either hate it and stop reading or find themselves a little more liberal by the end of it.

I think this is a really interesting book. It provides a lot of information about the history of the FDA and I found it to be an enjoyable read. The author uses a lot of examples, research, and personal interviews to present the content.

Excellent condition

This book contains iformation about how the FDA came to be from the days of one man working to prove preservatives unsafe to what it is today. Although the author seems a little biased at times, he definitely has his own political ideas, the book is easy to read and very interesting.

This was an assigned book for school. I was bored by the book.

much better than I thought.This used book almost new. Just little highlighter chirography on it. Hope these marks are the important points in the examination. aha~ just a dream

Philip J. Hilts is a journalist who has also written books such asÃ Â Smoke Screen: The Truth Behind the Tobacco-Industry Cover-Up,Rx for Survival: Why We Must Rise to the Global Health Challenge,Memory'S Ghost: The Nature Of Memory And The Strange Tale Of Mr. M, etc. He wrote in the Introduction to this 2003 book, "The FDA was born in a period of reform, but it was opposed bitterly because it was clear that the organization represented a precedent... The new agency was the people's investigator, with the specific mission of intervening on behalf of citizens and against businesses when necessary... This book describes the most significant events in the history of the Food and Drug Administration." (Pg. xii) [NOTE: page numbers refer to the 397-page hardcover edition.]He notes, "In the end, the [Pure Food and Drug Act of 1906] DID succeed in establishing two points: first, that the federal government was the agency that should take on widespread commercial abuses; second, that both patent medicines and regular formulas used by physicians should be counted as drugs..." (Pg. 54) But in the 1920s, "Anyone could concoct a medicine in his kitchen and sell it, with no testing required as long as it didn't contain narcotics or one of a few listed poisons. (Potentially fatal ingredients used in medicine were not counted as poisons at the time, only those so toxic that they killed IMMEDIATELY). If the new kitchen concoction turned out to be so damaging or fatal to some consumers, the maker was not required to pull it off the market, either... At most, the FDA could begin a court action that, if contested, could last for some years and result in a miniscule fine. At the end of it all, the maker would give his concoction a new name and start all over again." (Pg. 75)He observes that "The regulations and the government shepherding of the drug business did what the free market failed for at least sixty years to do---it weeded out the brutal, the stupid, and the needless that prevented the pharmaceutical industry from becoming a great engine

of discovery and sales. The tough markets had prevented companies from carrying out expensive and detailed research. The laying down of the scientific standard had come first, and the creation of the modern pharmaceutical industry followed. A scientific standard, administered by some body outside industry itself, was the essential ingredient." (Pg. 106-107)He points out, "The topic of drug profits was not within the balliwick of the Food and Drug Administration. The FDA does not have any authority to regulate drug prices, or any of the economics of the industry... Its authority centers on the products themselves: whether they are safe, whether they work, whether they are advertised honestly." (Pg. 130) Later, he states, "The agency was beginning to be a business-style hierarchy of managers with goals and strategies. Though it would never go away, the internal feud over how tough the FDA should be in drug review had quieted. Companies now had large teams of scientists and goals of their own in medical discovery." (Pg. 201)He admits, however, that "During the late 1980s the more upright generic companies began to notice that generic drugs did not seem to be approved on a first-come, first-served basis. Some shot through while others languished. Some seemed to be assigned to lenient reviewers, others were judged more stringently... [Companies] got hints from FDA officers that something was expected in return for speedy approvals... The scandal was first made public when, in May 1989, hearings were held by the Subcommittee on Oversight and Investigations... Eventually... Fifty-five employees of fifteen generic drug companies were convicted of felonies, along with five FDA officials." (Pg. 253-254)He concludes, "The FDA began as an agency to protect consumers from cheats: it has evolved into the body that sets the scientific marks against which progress is measured. It is fair to say that the FDA is not brilliant in all respects. The agency has suffered from bad leadership at times, and a lack of support in Congress... The agency has failed to press for a single independent and reliable source of data on drugs and their dangerous side effects. The FDA has nevertheless effectively handled many parts of its increasingly complicated role. It has created a base of medical testing, and has stood for public health standards against storms of self-interest... and is as broad and open an agency as seems possible in this conservative time in American history." (Pg. 337)This book may have more "history" and less discussion of "current controversial issues" than some readers might prefer, but for anyone wanting a largely "sympathetic" history of the FDA, this book will be of great value.

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