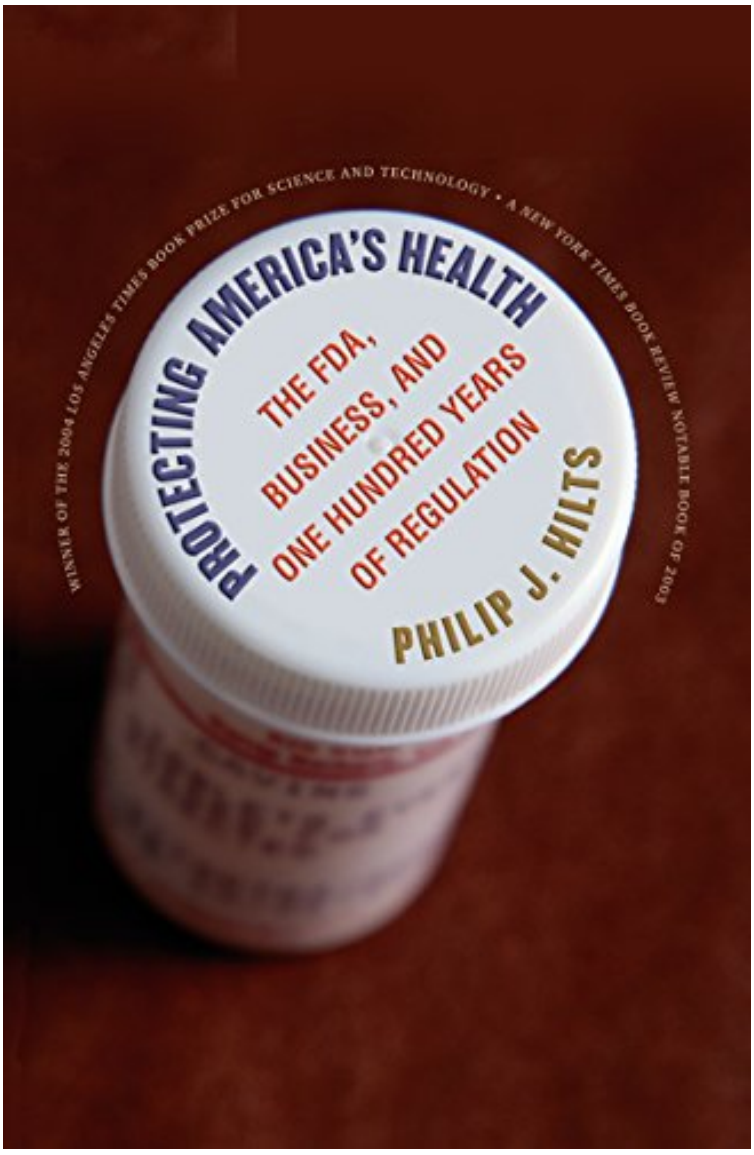
Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation

Philip J. Hilts
*audiobook | *ebooks | Download PDF | ePub | DOC*



#847532 in Books The University of North Carolina Press 2004-09-27 2004-09-27Original language:EnglishPDF # 1 9.75 x .96 x 6.38l, 1.34 #File Name: 0807855820424 pages | File size: 16.Mb

Philip J. Hilts : Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation before purchasing it in order to gage whether or not it would be worth my time, and all praised Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation:

4 of 4 people found the following review helpful. Plus Ca ChangeBy Henry GreenspanHilts' 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.1 of 1 people found the following review helpful. Fantastic book!By kmbusbyFantastic 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.0 of 0 people found the following review helpful. Great bookBy MeghanI 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.

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.

From Publishers WeeklyA 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.From Library JournalA 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.From The New England Journal of MedicineThe Food and Drug Administration (FDA) is one of the most misunderstood, underfunded, and important government agencies. In largely invisible ways, the FDA safeguards our food, drugs, cosmetics, and medical devices. In an engaging style, journalist Philip Hilts details a century of scientifically grounded work by the FDA and the commissioners who shaped the agency. He nimbly moves chronologically through FDA history, using key examples to illustrate shifts in power and policy. Several themes recur throughout the book. One is the tension between business interests and public health. From the first hints of regulation in the early 20th century, trade groups have lobbied for reduced enforcement. Seldom do consumers act similarly. A second theme is the persistence and inventiveness of quackery. Patent medicine's dubious claims look remarkably similar to some health-related claims made for supplements and herbal products. A third theme is the evolution of changes in regulatory power. Almost every law strengthening the FDA passed because of a constellation of events: a proposed law, of which the public was aware, languished in Congress, and then serious injury or death spurred Congress to act. A fourth theme is the "drug lag," real or imagined. Once a serious problem, the situation improved in the 1990s largely because the FDA itself worked with industry to facilitate quicker approval of drugs, not because of increased allocations. Stories of deaths from sulfanilamide elixir in 1937, of problems caused by chloramphenicol in the 1950s, and of the near-disaster of thalidomide in the 1960s are all recounted. One of the strongest sections of the book examines the attempts of the "New Right" to dismantle the FDA in 1994. The account of political maneuvering is fascinating, from the witnesses flown in by pharmaceutical groups, none of whom were denied treatment because of FDA policy, to conference committee meetings, in which a group predicated on bipartisan support could not, and

would not, advance policy to diminish the FDA's power. Other items regulated by the FDA, however, including medical devices, cosmetics, food, and biologics, are not mentioned in the book. We read about the results of a 1976 law requiring safety testing for new medical devices, yet we learn nothing about the problems caused by the Dalkon Shield that led to that decision. The agreement to regulate vitamins in the 1970s, which generated more mail to Capitol Hill than did the impeachment hearings of President Richard Nixon, passes without notice. Some of these omissions reflect the author's sources. Hilts acknowledges the historians in the FDA's history office yet does not properly credit the FDA's oral-history collection, which he used effectively and extensively. The holes in his story mirror holes in that historically valuable collection; concomitantly, the FDA's strength in collecting interviews from its former commissioners and former field investigators is reflected in the rich text. At heart, Hilts sees the FDA as negotiating between scientific standards that are intended to protect our health and, on the other side, pressures from industry. Because history does repeat itself, and because we depend on the FDA to ensure our safety, this book is important. Those who are curious about what the FDA can and cannot do will enjoy the revelations and thought-provoking argument. Gwen Kay, Ph.D.