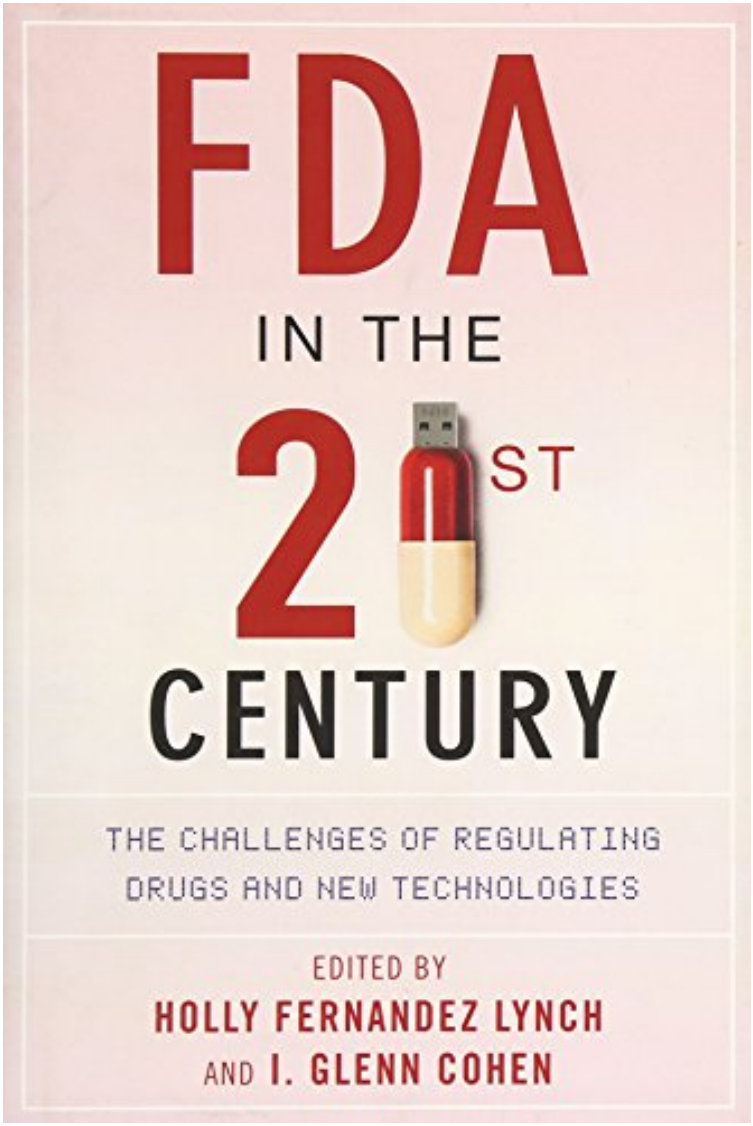
FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies

From Columbia University Press
*ePub | *DOC | audiobook | ebooks | Download PDF*



#1341202 in Books 2015-09-08Original language:EnglishPDF # 1 9.31 x 1.49 x 5.99l, 1.00 #File Name: 0231171188568 pages | File size: 44.Mb

From Columbia University Press : FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies before purchasing it in order to gage whether or not it would be worth my time, and all praised FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies:

In its decades-long effort to assure the safety, efficacy, and security of medicines and other products, the Food and Drug Administration has struggled with issues of funding, proper associations with industry, and the balance between consumer choice and consumer protection. Today, these challenges are compounded by the pressures of globalization, the introduction of novel technologies, and fast-evolving threats to public health. With essays by leading scholars and government and private-industry experts, FDA in the Twenty-First Century addresses perennial and new problems and the improvements the agency can make to better serve the public good.The collection features essays on effective regulation in an era of globalization, consumer empowerment, and comparative effectiveness, as well as questions of data transparency, conflicts of interest, industry responsibility, and innovation policy, all with an emphasis on pharmaceuticals. The book also intervenes in the debate over off-label drug marketing and the proper role of the FDA before and after a drug goes on the market. Dealing honestly and thoroughly with the FDA's successes and failures, these essays rethink the structure, function, and future of the agency and the effect policy innovations may have on regulatory institutions abroad.

This book contains a concise historical account of FDA regulation and an insightful analysis of the major challenges the FDA faces over the next quarter century. The contributors, drawn from a variety of fields, are all authorities on the issues at hand. Although they do not share the same opinions, their disagreements make this essay collection remarkably balanced. Essential reading. (Anup Malani, University of Chicago)A truly magisterial collection, FDA in the Twenty-First Century is a must-read for academics, practitioners, and social scientists interested in the future of drug and device regulation. The book's contributors offer thoughtful and well-researched policy approaches on conundrums facing the FDA and similar agencies around the world. Bravo! (Frank Pasquale, University of Maryland, Carey School of Law)This insightful and informative book draws on a variety of perspectives to chart a course for the FDAand societyas we confront the challenges of medical-product regulation in the twenty-first century. It should be read by regulators and the regulated alike, as well as by patients, policy makers, payers, physicians, pharmacistsanyone interested in human health. (Daniel Troy, general counsel, GlaxoSmithKline PLC, and chief counsel of the FDA from 2001 to 2004)FDA in the Twenty-First Century lives up to its title. Drawing on the historical evolution of the FDA, this book lays out, in a clear and thoughtful manner, key questions for the future. At a time when scientific opportunities are presenting at lightning speed and the expectations of the public for transparency, personalized medicine, and safety have never been greater, this is an important book. (Amy Rick, Food and Drug Law Institute)FDA in the Twenty-First Century does an excellent job of highlighting and explaining... it is a useful source for anyone interested in the nexus of modern medical bureaucracy. (Devorah Goldman The Weekly Standard)[These] essays provide an excellent survey of the growing challenges the FDA faces.... Highly recommended. (Choice)Essential reading for anyone who wants to understand the powerful forces driving the FDA's evolution. (Norman M. Goldfarb Journal of Clinical Research Best Practices)This informative book is a valuable read for lawyers, policymakers, and anyone interested in public health. (Harvard Law)About the AuthorHolly Fernandez Lynch is the executive director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. She is a lawyer and bioethicist, with expertise in the ethics and regulation of human-subjects research and drug development. She is also the author of Conflicts of Conscience in Health Care: An Institutional Compromise.I. Glenn Cohen is a professor at Harvard Law School and faculty director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics. He is the author of more than eighty articles and book chapters and the author, editor, or coeditor of seven books. In addition to the ethics and regulation of drug development, he works on reproductive technologies, medical tourism, rationing, the bioethics of professional sports, and other topics.