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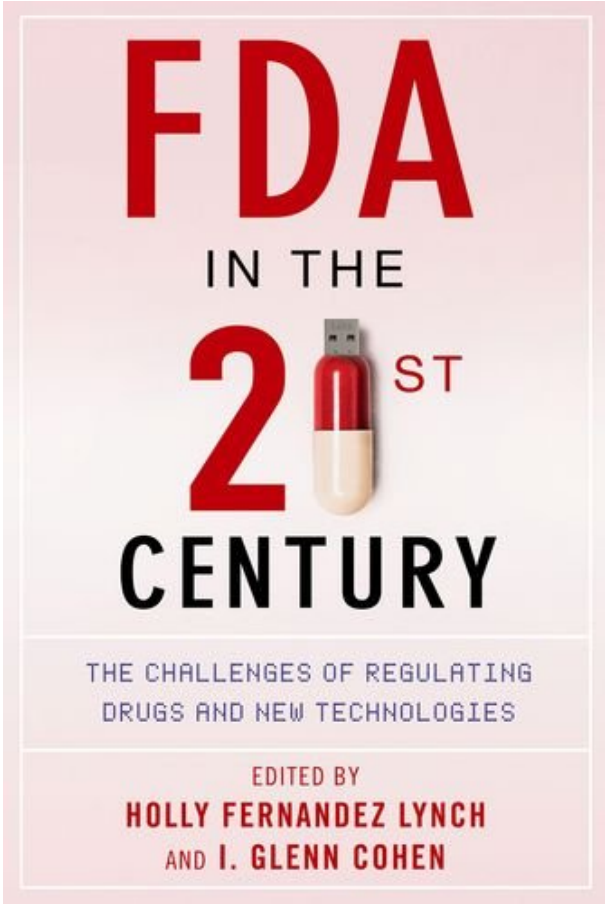

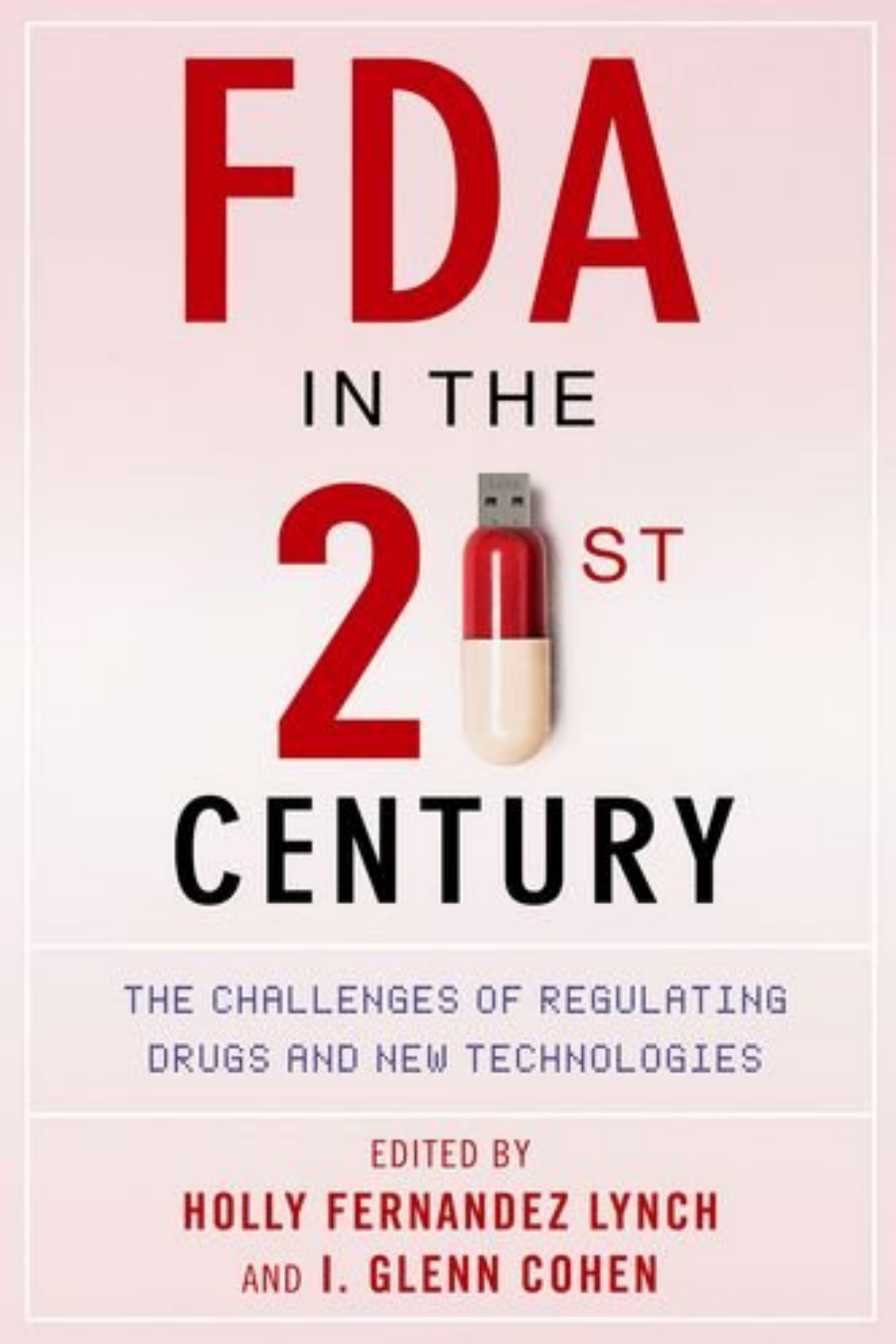

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Review

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.

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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!

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About the Author

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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.

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