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# Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation

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## Recommended Citation

Merrill Goozner, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation*, 10 DePaul J. Health Care L. 523 (2007)

Available at: <https://via.library.depaul.edu/jhcl/vol10/iss4/3>

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## **BOOK REVIEW:**

### **OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION**

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*Reviewed By:* Merrill Goozner\*\*

Law professor Richard Epstein begins his brief against government regulation of the pharmaceutical industry with an important observation: the pace of medical innovation has slowed dramatically in recent years despite massive investment by government and industry in basic and applied biomedical research. Life expectancy rose 21 years between 1900 and 1950; over the next fifty years, it increased just nine years more. “Medical science is not immune from the iron economic law of diminishing marginal returns,” he writes. “Sooner or later we reach the point where an additional dollar of investment generates a lower return than the previous dollar. More colloquially, it is always easier to grab the low-hanging fruit than to reach the higher branches.”<sup>1</sup>

He uses this iron law, unnoticed by a public and press obsessed with the latest advances in medical technology, as his jumping off point for the core argument of “Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation.” If it is getting progressively tougher to come up with cures for the age-old scourges of mankind’s old age and infirmities, then the last thing public officials, consumer activists and the public should want is to throw additional roadblocks in the way of those who seeking to move the ball on medical progress. “Even if we cannot repeat the triumphs of an earlier

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<sup>1</sup> RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 5-6 (2006).

age, we can still make substantial progress,” he writes. “Take some slowdown in overall progress as a given, and it is all the more important to avoid any additional mistakes of policy that needlessly retard the level of innovation.”<sup>2</sup>

Yet that, in his view, is precisely what is threatening to take place in the very near future because of the growing momentum for pharmaceutical regulatory reform in Washington. The intellectual property system that underpins private sector investment in the sector is under siege. Price controls threaten to cut off the cash flow from older innovations that finance the search for the new. Excessive safety concerns on the part of the press and public have misaligned the risk-benefit tradeoffs that must inevitably be taken into account by regulators. Drug marketing is under assault by misguided critics rather than being seen for what it is: a necessary adjunct to product diffusion and, concomitantly, a boon to public health. And, finally, an out-of-control tort system is imposing an unnecessary tax on the fully anticipated adverse events that occasionally accompany the routine use of useful products.

If this sounds like a brief prepared by an advocate for the pharmaceutical industry, it should, because that is what it is. Epstein discloses in his introduction that he has been a consultant for Pfizer Inc. and many of the arguments have been prepared in the course of his work for the Pharmaceutical Research and Manufacturers Association, the industry’s trade and lobbying group. So before I address some of the issues raised by his book, allow me to make my own disclosure. I am a paid employee for a non-profit group that advocates for some of the changes that Epstein opposes. I have taken public positions in my writings and talks that are diametrically opposed to his point of view. If you’re looking for a dispassionate overview of his book, I suggest you look elsewhere.

To begin, a couple of general observations are in order. First, Epstein’s portrayal of the threats faced by the pharmaceutical industry largely ignores the longer-term context that gave rise to recent efforts to re-regulate the field. Over the past two decades, a succession of changes in the laws and regulations that govern the Food and Drug Administration have substantially liberalized the environment in which new drug development takes place. Congress and the FDA have reduced the time it takes to bring a new drug to market;<sup>3</sup> strengthened

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<sup>2</sup> *Id.* at 6.

<sup>3</sup> Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992); Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-

and extended intellectual property protections;<sup>4</sup> sharply reduced its oversight of drug industry direct-to-consumer marketing and promotion;<sup>5</sup> expedited the approval of new drugs for life-threatening conditions;<sup>6</sup> and opened the door to the use of surrogate markers for judging the medical efficacy of drugs and devices.<sup>7</sup> The net effect has been to make the regulatory environment substantially more hospitable for winning approval of new technologies.

Moreover, rather than becoming more safety conscious, the FDA's system for protecting the public from unsafe drugs was recently characterized by the prestigious Institute of Medicine as badly in need of repair.

“As more drugs are being approved faster with less time to intensively investigate premarketing safety data, FDA does not have adequate resources or procedures for translating preapproval safety signals into effective postmarketing studies, for monitoring and ascertaining the safety of new marketed drugs, for responding promptly to the safety problems that are discovered after marketing approval, and for quickly and effectively communicating appropriate risk information to the public.”<sup>8</sup>

The IOM also lambasted the agency's leadership for promoting an internal culture that was more interested in approving new drugs than in carrying out its core mission – protecting the public from unsafe and ineffective products. The IOM report was hardly a portrait of an

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250, 116 Stat. 1588 (2002) (codified as amended in scattered sections of 21 U.S.C. (2000)).

<sup>4</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ((codified in various sections of titles 21, 35 & 42 U.S.C. (2000)); Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as. amended at 21 U.S.C. § § 360aa-360ee (2000)); Best Pharmaceuticals for Children Act of 2002, Pub. L. No. 107-109, 115 Stat. 1408 (2002).

<sup>5</sup> U.S. GOVERNMENT ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: IMPROVEMENTS NEEDED IN FDA'S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING (2006), available at <http://www.gao.gov/new.items/d0754.pdf>.

<sup>6</sup> See FDA's Subpart E Regulations, 21 C.F.R. § 312.80.(1988); FDA Subpart H Regulations, 21 C.F.R. § 314.500 (1992); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, §§ 112, 403(b)(3), 111 Stat. 2296, 2309, 2367 (1997) (codified at 21 U.S.C. §§ 356, 371 (2000)).

<sup>7</sup> FDA Subpart H Regulations, 21 C.F.R. § 314.500 (1992)

<sup>8</sup> INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 17 (Alina Baciu et al. eds., 2007).

overbearing regulator. Economists have a phrase for describing the current state of affairs at FDA: industry capture. Yet Epstein's book, which rigorously applies economic logic in every sphere it addresses, ignores this useful concept and the substantial evidence that it should be applied to the FDA.<sup>9</sup>

Second, there is a general presumption suffusing the book that physician prescribed medicines and procedures are the primary reasons for America's improving life expectancy. People are leading longer and healthier lives. Therefore, he argues, protecting industry's capacity for innovation should trump other public health goals like protecting the public from unsafe drugs or obtaining lower drug prices.

That certainly wasn't true in the first half of the 20<sup>th</sup> century when improved sanitation, clean water, warmer and better housing and better diets resulted in that era's remarkable gains in life expectancy. And it is only partially true for more recent decades, when increased public awareness about the risks posed by inadequate or unhealthy diet, smoking, and sedentary lifestyles contributed to more people leading healthier lives. That, coupled with rising living standards, which is closely related to better health outcomes, deserves the greatest share of credit for more recent gains in life expectancy.

For example, despite the tens of billions of dollars poured into the medical war on cancer over the past half century, the greatest gain in that still unfinished struggle came from the public health campaign against smoking, not the pharmacopoeia of new drugs we have to fight the disease. Indeed, the importance of factors other than technological innovation in determining population health led one of the nation's leading demographers to project recently that rising obesity rates may soon cause the century-long rise in longevity to come to an end despite the health care system's technological brilliance.<sup>10</sup>

Epstein did not set out to write a book about the trajectory of the nation's health. But it is relevant, because only by ignoring these factors do his arguments about, say, patent law or direct-to-consumer advertising, gain significance. Each of his arguments against tougher standards or increased regulation ultimately rests on the presumption

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<sup>9</sup> See HarrisInteractive.com, *The FDA's Reputation with the General Public Is Under Assault*, May 26, 2006, <http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1060> (This Harris Interactive Poll in May 2006 found seven in ten adults did not believe the FDA was doing a good job in protecting the public from unsafe drugs).

<sup>10</sup> S. Jay Olshansky et al., *A Potential Decline in Life Expectancy in the United States in the 21<sup>st</sup> Century*, 352 NEW ENG J. MED 1138, 1138-45 (Mar. 2005).

that creating new technologies that expand physician and consumer choice in the marketplace – a marketplace that by his own admission is delivering less and less innovation for society’s marginal investment – is the most efficient way to improve overall public health. There’s not a lot of evidence to back up that presumption.

But even on the limited terrain of medical innovation, the evidence is weak that increased regulation will further retard its already slowing advance. Indeed, if two decades of efforts to reduce regulation and speed the review of new drugs and biologics could not prevent the dramatic decline in significant new therapies emerging from industry labs, isn’t it logical to presume that a reversal of the deregulatory trend in the name of increasing the safety of the nation’s drug supply will similarly have little impact on the overall trend?

I believe a strong argument can be made that re-regulating the industry will have a positive impact on innovation, a view I will explain briefly at the conclusion of this essay. But first to the task at hand, which is a review of the issues that concern Epstein.

He begins with a critique of efforts to enact new limits on public-private interactions because of concerns about conflicts of interest. Epstein recognizes the value of the public sphere in generating the basic scientific knowledge needed for biomedical innovation. Without understanding the natural history of a disease, from its biomolecular basis to its clinical manifestations, discovering a cure or a palliative measure would be impossible. Virtually all of the research needed to generate this understanding comes from non-industry scientists supported by government grants, foundations and prizes, which can be either financial or psychic.

But he fears that strict rules about conflicts of interest, which arise when public sector or university scientists take money in the form of grants, consulting contracts, speaking fees and other emoluments, will choke off the smooth transition of this knowledge to the private sector, which has the ultimate responsibility for bringing new technology to market. He focuses on the recent scandal at the National Institutes of Health, which adopted stricter rules governing the agency’s scientists’ interactions with industry after a number of top scientists failed to report their lucrative deals with private firms.<sup>11</sup> “The

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<sup>11</sup> Reporter David Willman of the *Los Angeles Times* has doggedly pursued this story over the past four years. See, e.g., David Willman, *Stealth Merger: Drug Companies and Government Medical Research*, L.A. TIMES, Dec. 7, 2003, at A1; David Willman, *NIH to Curb Its Scientists’ Deals with Drug Firms*, L.A. TIMES, June 23, 2004, at A1.

NIH rules had created such a chill within the agency that individual researchers were unwilling to answer emails about their research, to provide advance papers for publication, or to work *without compensation* (emphasis in the original) on any joint project – even on projects for which the entrepreneur had received NIH development licenses.”<sup>12</sup> The only problem he sees was inadequate disclosure of those financial dealings, which proper supervision by NIH could have easily resolved. Moreover, his fear now is that the ban on such dealings at NIH will be extended to grantee institutions, which account for 80 percent of NIH research funds. “Scientific research would be crippled in practice if the NIH chose to reverse field and expand the total ban it now imposes on employees to its grantees and their employees.”<sup>13</sup>

Epstein leaves out half the story. He’s absolutely right that there was confusion and misapplication of NIH’s new rules in the immediate glare of the media’s focus on the scandal (one scientist eventually pleaded guilty, returned \$300,000 in industry cash and was sentenced to two months of community service for failing to disclose his dealings). The confusion was fed by a grass roots effort by hundreds of agency scientists to reverse the new guidelines. However, the rules never prohibited government scientists from contacting or collaborating with industry. They prohibited scientists from receiving cash for exclusive dealings with private firms in the form of consulting contracts, speaking honoraria, and pay for serving on advisory boards. Those paid relationships have become standard operating procedure for many university scientists who receive extramural NIH grants, and it’s hard to fault NIH scientists for being somewhat envious of their academic colleagues. In some cases, those academicians don’t even have to divulge those dealings to their universities, which have a scattershot approach to enforcing their own conflict-of-interest guidelines.<sup>14</sup>

But there’s a solid rationale for prohibiting those dealings on the part of NIH scientists. Over the years, the rigorous intellectual and financial independence of the public sector has been one of the wellsprings of medical innovation. Some of the most successful NIH programs have been directed research campaigns where the government seeks not only basic knowledge about a disease, but its

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<sup>12</sup> EPSTEIN, *supra* note 1, at 32.

<sup>13</sup> *Id.* at 34.

<sup>14</sup> Elizabeth A. Boyd, Shira Lipton & Lisa A. Bero, *Implementation of Financial Disclosure Policies to Manage Conflicts of Interest*, 23 HEALTH AFFAIRS 206, 206-14 (Mar.-Apr. 2004).

cure. The development of the first AIDS drugs during the late 1980s and early 1990s, the development of virtually all of the first cancer chemotherapy drugs, and treatments for rare diseases like Gaucher's disease are good examples.<sup>15</sup> Each was the product of dedicated government scientists free to pursue whatever they considered the best path in their single-minded pursuit of a cure.

The NIH officials involved with or in charge of those programs often saw their roles as intellectual venture capitalists, sharing their knowledge with anyone with a good idea. The exclusivity inherent in private dealings would have only gotten in the way. Government scientists with lucrative consulting contracts from private firms may be less willing to cut their losses when a particular approach to a problem proves unworkable. Or they may be less forthcoming or simply less available to promising researchers in academia who have no money to offer.

This silo mentality in basic and early applied research has been the subject of much debate in the field of patenting, which Epstein addresses in his next section. He dismisses concerns, raised by Rebecca Eisenberg of the University of Michigan law school and others,<sup>16</sup> that excessive patenting of early stage research can create an intellectual property anticommons that chokes off scientific collaboration. He offers as contrary evidence an empirical survey of scientists who claim that it hasn't bothered them.<sup>17</sup>

Admittedly, the evidence that it has, such as the recent dust-ups in the emerging embryonic stem cell field over the seminal James Thompson patent marketed by the Wisconsin Alumni Research Foundation, is anecdotal.<sup>18</sup> But, then again, so is every successful new drug and biologic. How does one count the decisions of researchers to avoid fields entirely because someone else has already locked up key inventions?

On the downstream side of research, Epstein believes competition has offset the monopoly pricing power conferred by the patents required by the private sector before it will invest in the applied research and clinical trials needed to bring a new drug to market.

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<sup>15</sup> MERRILL GOOZNER, *THE \$800 MILLION PILL* (2004).

<sup>16</sup> See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, *SCIENCE*, May 1, 1998, at 698-701.

<sup>17</sup> EPSTEIN, *supra* note 1, at 52.

<sup>18</sup> Merrill Gozner, *Innovation in Biomedicine: Can Stem Cell Research Lead the Way to Affordability?* 3 *PLOS MEDICINE* e126 (Feb. 2006).



Supply side competition comes in the form of me-too drug development. Demand-side competition comes from the presence of “serious players” like physicians, insurers and pharmacy benefit managers who can counteract monopoly power through their prescribing and formulary decisions. He offers as his example AstraZeneca’s Nexium, an antiacid that replaced Prilosec after it lost patent exclusivity.<sup>19</sup>

It’s a curious choice. The two drugs are chemically similar. Nexium, for those not familiar with organic chemistry, is one of the enantiomers contained in Prilosec, which is a mixture of two mirror-image molecules. In other words, when you take Prilosec, you are already taking Nexium. I don’t quarrel with the company’s right to patent Nexium and sell it as a separate drug. In some cases, separating out an enantiomer of a useful drug can improve its performance by eliminating the half of a mixture that generates an unwanted side effect. But in this case, both halves are 90 percent effective and have similar side effect profiles. How AstraZeneca was able to rack up \$3 billion a year in sales of Nexium after Prilosec became available over-the-counter at a fraction of the cost is a textbook example of market failure, where marketing triumphed over science, the market’s pricing signals and the alleged countervailing power of the other players in the market.

But rather than rein in marketing, Epstein would expand it. He defends the industry’s large marketing costs by pointing out that they do not exceed other marketing-driven firms like Procter & Gamble and Coca-Cola. By increasing the number of patients taking the drugs, he argues, it improves public health. And by expanding the market, it draws more R&D investment to medicine. He is dismissive of rules that limit drug marketing to the narrow assessments contained on FDA labels. “The social loss of an excessively dour projection of risks and benefits is that people shy away from risky drugs that provide them with expected net benefits.”<sup>20</sup>

Moreover, efforts to limit access to physicians by eliminating gifts or excluding physicians with drug company ties from making hospital formulary decisions risks introducing an opposite form of bias: “a strong hostility to new products and the companies that supply them.”<sup>21</sup> Direct-to-consumer advertising, as long as it is accurate, increases social welfare by building popular awareness of untreated

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<sup>19</sup> EPSTEIN, *supra* note 1, at 63.

<sup>20</sup> *Id.* at 155.

<sup>21</sup> *Id.* at 160.

conditions, so concerns about its costs are outweighed by its benefits. And while he admits it may in some cases lead to patient pressure for inappropriate medicines, physicians are well-positioned to block such “ill-considered requests.”

Not really. Industry influence over physician behavior goes much deeper than the individual physician and consumer outreach efforts by drug firm marketing departments. Those are mere reinforcement mechanisms. The prime driver of choices made by practicing physicians in the field is clinical practice guidelines, which are mostly written by academic physicians with financial ties to industry. Drug firms also play a major role in underwriting the activities of professional societies, specialty annual meetings, and doctors’ continuing medical education, where most physician learning takes place.<sup>22</sup> The medical literature itself has been skewed by industry’s growing dominance in clinical trial research. Industry support of this crucial activity has gone from a one-third to two-thirds of all funding in the past quarter century. And, as has been well described elsewhere in the medical literature, studies financed by industry are more likely to come up with findings that favor their sponsors’ products than comparable non-industry funded studies.<sup>23</sup>

Epstein’s view that the medical profession and its supportive institutions are well-positioned to make independent judgments about the value of new or old medicines is simply unsupported by the evidence. Indeed, it is fair to say that accurate and objective information about medicine is a scarce commodity, which has made it difficult for participants in the health care marketplace to make well-informed decisions. But don’t take my word for it. Gail Wilensky, a senior fellow at Project Hope and former administrator of the Health Care Finance Administration (now the Center for Medicare and Medicaid Services) in the George H.W. Bush administration, recently joined in the call for a new multi-billion dollar agency to generate information comparing the relative effectiveness of various medical interventions, a public good that the private market has failed to provide.

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<sup>22</sup> JEROME P. KASSIRER, *ON THE TAKE: HOW MEDICINE’S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH* (2004).

<sup>23</sup> Justin E. Belman, Yan Li, & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review* 289 *JAMA* 454, 454-65 (Jan. 2003).

Moreover, she is very concerned about conflicts of interest among those asked to generate this evidence. “There is widespread agreement on the attributes that need to be associated with a comparative effectiveness center: objectivity in the selection of what is studied, credibility in the findings, and independence—from political pressures generated either by government or by private-sector stakeholders.”<sup>24</sup>

There is one argument in Epstein’s book to which I am somewhat sympathetic. His review of the legal landscape surrounding pharmaceutical product liability suits concludes that “no legal system can afford to try complex matters before a jury even one time, let alone ten thousand times.”<sup>25</sup> But is the answer to restrict access to the courtroom, which his proposals would entail? Or does it make more sense to create a regulatory and marketing environment that minimizes the chances that a product with known harms will reach millions of people in the first place?

In his relatively brief section on the FDA (just 30 pages in a 240-page book about excessive government regulation), Epstein pushes in the opposition direction. After lamenting the steady expansion of FDA power represented by the 1938 and 1962 amendments to the Food, Drug and Cosmetic Act, which ushered in the safety and efficacy requirements, respectively, he goes on to say that the safety requirement in the current law “is too stringent for its own good.”<sup>26</sup> He would reduce the agency’s ability to impose black box warnings (heightened alerts for physicians) in favor of the cacophony of the information marketplace where the opinions of the FDA, the drug companies, safety advocates like Public Citizen and physician groups can contend. As far as efficacy is concerned, “the standard should mean that so long as some significant fraction of the population can benefit on net from the use of the drug, it should continue to be sold.”<sup>27</sup>

Epstein repeatedly returns to the variability of individual response to drugs as his rationale for restricting the FDA’s powers. If I understand him properly, he would prefer to see a regulatory regime where free men can take their own medicine any way they wish, adequately warned about the known risks, of course. What this paradigm ignores is any notion of population health, and the well-

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<sup>24</sup> Gail R. Wilensky, *Developing a Center for Comparative Effectiveness Information*, 25 HEALTH AFFAIRS w572, w572-w585 (2006).

<sup>25</sup> EPSTEIN, *supra* note 1, at 231.

<sup>26</sup> *Id.* at 125.

<sup>27</sup> *Id.*

established principle that the government has an important role to play in protecting it through public health measures.

Much of the public debate in recent years – from the IOM report to Congressional efforts to tighten drug regulations for the first time in a generation – was triggered by the uproar over Vioxx, Merck’s ill-fated Cox-2 inhibitor. Epstein, after a selective reading and review of the medical literature, concludes “that Vioxx should still be the drug of choice for individuals with high intestinal risks and low cardiac risks.”<sup>28</sup>

But who are they? Forget for a moment that the reduced gastrointestinal (GI) side effect benefit from Cox-2s has never been proven to the FDA’s satisfaction: Vioxx, Celebrex and Bextra all carried the same GI warnings as all other non-steroidal anti-inflammatory drugs. Forget for a moment that the GI risks are almost all non-life threatening, while the cardiovascular risks took patients lives. Forget for a moment that no company has ever run a clinical trial testing the claim that some people benefit from this drug but not the others in this or other classes, which is the only medical justification for using Vioxx in the first place. And forget for a moment that Vioxx was mass marketed to millions of people indiscriminately, despite suspected cardiovascular risks that were the subject of a feverish outcry in the medical literature.<sup>29</sup>

How could a physician determine which patients met Epstein’s limited profile? There is currently no scientific method of determining who might benefit and who might be at risk when taking this drug. That doesn’t mean that some day there might not be. The sequencing of the human genome, the planned mapping of cancer tumor genomes, and the cataloguing of human genetic variations are early milestones in the coming era of personalized medicine. Should this scientific endeavor succeed, scientists and physicians will be able to look at an individual’s genetic profile (or the genetic make-up of their cancer) and know what drug to prescribe. However, that could have a largely negative consequence on the pharmaceutical industry’s current business model, which is based on selling one-size-fits-all drugs to mass populations.

Epstein would use the promise of this emerging science to beat back any increase in federal oversight that results from contemporary safety concerns. That misinterprets the promise of these new

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<sup>28</sup> *Id.* at 216-18.

<sup>29</sup> Debabrata Mukherjee, Steven E. Nissen, & Eric J. Topol, *Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors*, 286 JAMA 954, 954-59 (Aug. 2001).

technologies. One of the major tasks confronting the FDA today is developing in-house scientific expertise and writing new rules for using this technology to determine who should be taking which drugs in the existing armamentarium. This evolving science will also point industry down a scientific pathway for developing the innovative medicines that will be safer and more effective than ones now on the market.

The FDA evolved because the American people decided that science, not the market, should determine the value of new medicines. In that sense, Epstein's deregulatory agenda represents a complete misreading of history. Every major FDA reform (1938 and 1962) was enacted after drug safety scandals, and each helped the drug industry evolve to the next stage of its scientific development.<sup>30</sup> We're at a similar moment in time. Embracing the prescriptions in this book will only postpone the industry's rejuvenation.

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<sup>30</sup> PHILIP J. HILTS, *PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* (2003).