OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION

by Richard A. Epstein

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Reviewed By: Elliot N. Fruchtman[1]

Relevant Legal & Academic Areas: Intellectual Property, Patent Law, Tort Law, Product Liability, Government Regulations.

Summary: This book describes the current state of the pharmaceutical industry and discusses how current government regulations affect scientific innovation. Moreover, the author describes the advantages and disadvantages of various attempts to change the current system. In addition, the author analyzes the Vioxx litigation to illustrate his theory that government regulations restrain innovation and development of new drugs.

About the Author: Richard A. Epstein has taught at the University of Chicago Law School since 1972. In addition to his position at the University of Chicago, Epstein is currently a Senior Fellow at the Hoover Institution. Previously he has taught at the University of Southern California Law School. Epstein received an AB from Columbia College; a BA from Oxford University; and a LLB from Yale University.

[1] J.D. Candidate, Syracuse University College of Law, 2008; Executive Editor, *Syracuse Science and Technology Law Reporter*.

Chapter 1 – Rising Expectation and Diminishing Returns:

- **Chapter Summary**: In this chapter, Epstein provides historical background relating to how government involvement has affected the pharmaceutical industry. In addition, he discusses how those historical developments have shaped the current industry.
- **Chapter Discussion**: This chapter presents a historical overview of the events that shaped the pharmaceutical industry. In July 1945, Vannevar Bush submitted to President Truman what was later known as the Bush Report. In that report, Bush recommended establishing the United States Office of Research and Development, which later became the National Institutes of Health (NIH). During the next fifty years, there were vast improvements in healthcare, drugs, and surgical improvements, which resulted in longer life expectancy. However the author notes that this innovation could only go so far. According to Epstein, "today's advances in basic science and instruments dwarf in technological sophistication those improvements made in that halcyon 1900 to 1950." [2] Moreover, he goes on to state that "medical research no longer occupies that enviable 'takeoff' position of one hundred years ago." [3]

  According to the author, many recent proposals seeking to induce medical innovation are inappropriate because they seek to limit protection for patent holders or they attempt to set price controls on new drugs. Moreover, the author finds that both the Food and Drug Administration (FDA) and the tort system are responsible for further limiting innovation in medicine.

[2] RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 6 (Yale University Press, 2006).

[3] *Id.*

Chapter 2 – Property Generally: Externalities, Coordination, and the Public Domain:

- **Chapter Summary**: In this chapter the author gives a short overview of property law.
- **Chapter Discussion**: Epstein begins this chapter about property law through a discussion of Roman law and water law. The author subsequently goes on to discuss the effect of having an exclusive private property or an exclusive common property regime. To Epstein, society should be organized as a balance between the private and the public in order to best maximize our limited resources.

Chapter 3 – Intellectual Property: The Public Domain and Private Rights:

- **Chapter Summary**: In this chapter the author relates his theories on property to intellectual property law. Moreover, Epstein gives a brief overview of intellectual property law.
- **Chapter Discussion**: According to Epstein, the struggle between the public and private sphere, which is present in property law, is also present in intellectual property law. Universal ideas and laws of nature such as Newton's discovery of calculus should remain in the public commons because according to the author, protection of such ideas would virtually end all innovation. Incentive to create and personal gains are some of the many reasons why individuals continue to create new inventions. While the author recognizes that the current intellectual property system creates monopolies for patent holders, he states that this is only one of many issues that have affected the pharmaceutical industry.

Chapter 4 – Taming Conflict of Interest:

- **Chapter Summary**: In this chapter, the author discusses systems that have been put in place to minimize conflicts of interest for NIH employees. In addition, Epstein identifies some of the consequences of such protections.
- **Chapter Discussion**: In 2005, the NIH banned all stock ownership by NIH scientists of pharmaceutical companies. Moreover, it limited any consulting relationships between the NIH and pharmaceutical companies. According to the author, many fear that this policy will even further limit innovation because such a ban restricts interaction between the public and private sector. Likewise, the ban has the effect of limiting the number of qualified individuals working in the public sector. In that regard, Epstein notes that "an effective private sector cannot be built without keeping a vibrant public sector." [4] According to the author, strict separation should only be used as a last resort.

Chapter 5 – Federally Sponsored Research Under Bayh-Dole:

- **Chapter Summary**: In this chapter the author discusses the effect of the Bayh-Dole Act on patents.[5]
- **Chapter Discussion**: Under the Bayh-Dole Act, non-profit organizations, universities and other federally funded organizations who received grants for research and development can elect to patent any inventions that are the result of Federal funding. [6] If the organization elects to patent such inventions, the Act gives the US government nontransferable irrevocable paid-up licensing rights to use the invention.

[4] *Id.* at 32.

[5] Pub. L. No. 96-517, 94 Stat. 3015-28 (1980) (codified as amended at 35 U.S.C. §§200-212, 301-307).

[6] *Id.*

Chapter 6 – The Anticommons:

- **Chapter Summary**: In this chapter Epstein discusses the theory of the anticommons as it relates to the pharmaceutical industry.
- **Chapter Discussion**: The theory of the anticommons dictates that the "rich profusion of patents has created an 'anitcommons' which will retard the pace of biomedical innovation." [7] In that regard, when an individual patents an invention, he is taking something away from the commons. Consequently, some have suggested in response to the dilemma of the anticommons that our patent system should include a mandatory royalty system, which would both protect the inventor and allow access for the public. However, the author notes that a voluntary licensing system would be a more effective method of dealing with the anticommons. Moreover, according to Epstein, the pharmaceutical industry has been able to deal with the problem of the anticommons as demonstrated by the continued innovation of new drugs.

Chapter 7 – The Single Monopoly: Current Patent Limitations:

- **Chapter Summary**: In this chapter, the author discusses how the current patent system limits monopolies over drugs and medical devices.
- **Chapter Discussion**: While a patent gives the patentee a monopoly over the new drug, the patent system itself has several barriers which mitigate the development of such monopolies. In *O'Reilly v. Morse*, the Supreme Court ruled that a patent does not give an inventor the

[7] EPSTEIN, *supra* note 2, at 48.

exclusive control of all aspects of a particular field. [8] A patent only gives an individual control over his specific invention. Moreover, the requirements of patent registration such as nonobviousness, novelty, etc., which apply to new drugs and medical devices, also limit the possibility of monopolies. Lastly the author discusses the Hatch-Waxman Act which allows for the development and sale of the generic drugs as a means of limiting monopoly control over drugs. [9]

Chapter 8 – Rate Regulation: An Unneeded Swap:

- **Chapter Summary**: In this chapter, the author discusses different proposals for price control imposed on the pharmaceutical industry.
- **Chapter Discussion**: According to the author, any attempt to control prices will limit the development of new drugs. Due to the fact the pharmaceutical products are created at a fixed cost, any attempt to regulate that cost would result in reducing allocations for research and development of subsequent drugs. Several unsuccessful legislative attempts such as the Greater Access to Affordable Pharmaceuticals Act of 2001 and the Pharmaceutical Market Access and Drug Safety Act of 2004 sought to impose rate regulation on the pharmaceutical industry.[10] Accordingly, the author found that such attempts would have been either ineffective or counterproductive to the development of new drugs.

[8] O'Reilly v. Morse, 56 U.S. 62 (1854).

[9] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as 21 U.S.C. §355; 34 U.S.C. §§156, 271).

[10] Greater Access to Affordable Pharmaceuticals Act, S. 812, 107th Cong. (2001); Pharmaceutical Market Access and Drug Safety Act, S.2328 108th Cong. (2004).

Chapter 9 - Patent Purchases: A Second Swap:

- **Chapter Summary**: In this chapter, the author discusses the suggestion that the government should purchase pharmaceutical patents either through voluntary or compulsory purchases.
- **Chapter Discussion**: In an attempt to mitigate the monopolies of pharmaceutical patents, some have suggested that the government should purchase drug patents. However the problem with both voluntarily and compulsorily sales is that it is not clear which patents would be purchased. The government could not afford to buy every patent. Moreover it is not clear who would pay for the research and development for drugs that are not purchased. Likewise, under a patent purchase scheme, it is not clear who would be financially responsible for promoting the drugs. Moreover, it is almost impossible to determine what the price of a drug should be. Until demand for the drug is determined, the price for the patent is indeterminable. In addition, the government would risk purchasing patents for drugs that become obsolete. For example, the author discusses the anthrax scare following 9/11. Under the purchase scheme, the government would have purchased the patent for ciprofloxacin (a drug used to treat anthrax exposure) to control the rate of production. Since the anthrax scare never truly materialized, the government would have wasted money to purchase the patent at an inflated rate.

Chapter 10 – Socialization of R&D: The Final Swap:

- **Chapter Summary**: In this chapter the author critiques the proposal to socialize the research and development of new drugs.
- **Chapter Discussion**: In this chapter, Epstein discusses the proposal by Peter Stein and Ernst Valery that shifts responsibility for research and development of new drugs to the

government. According to the author, such a proposal does not take into account the actual cost of research and development (R&D). Likewise, the proposal does not take into account the fact the NIH does not have the necessary experience or infrastructure to develop drugs in the same fashion as the private sector. Lastly, there is the problem with oversight of clinical trials. Currently the FDA has the responsibility of oversight, however if the NIH was responsible for the creation of new drugs, it could create a conflict of interest by having one government agency oversee the clinical trials of another government agency.

Chapter 11 – The Steady Expansion of FDA Power:

- **Chapter Summary**: In this chapter the author gives a brief overview of the FDA.
- **Chapter Discussion**: According to the author, even if a drug meets the requirements for patent protection, the FDA still has the power to restrict its sale. The FDA has two main responsibilities. First, the FDA is responsible for determining which drugs are safe to be sold. Second, the FDA has the responsibility to determine whether a drug should be withdrawn from the market. While the purpose of the FDA is to protect the general population from unsafe drugs, many critics have stated that the FDA has been ineffective in this regard.

Chapter 12 – FDA Versus the Individual: Upstream or Downstream Decision Making:

- **Chapter Summary**: In this chapter the author discusses who should be responsible for deciding whether a particular drug should be withdrawn. Moreover, the author identifies the types of errors which the FDA is seeking to mitigate by controlling which drugs are on the market.

- **Chapter Discussion**: Epstein identifies two groups of people who have the ability to decide whether or not the use of a drug should be discontinued. Decisions made by the FDA are classified as "upstream" decisions and decisions made by the individual user and his doctor are considered "downstream" decisions. For example, when the FDA issues a blanket warning against the use of antidepressants by children, the author considers such a determination an "upstream" decision.[11] The theory behind placing this power with the FDA is that consumers do not have the sophistication to make informed decisions regarding their health. The author counteracts this assumption by stating that with the aid of a personal physician, there is no reason why the individual cannot make decisions regarding his own health without the interference of the FDA.

  The author identifies two types of errors which motivate decisions by the FDA. Type 1 errors occur when a drug that should not be on the market causes visible harm to the consumer. Type 2 errors occur when individuals cannot benefit from a drug that is kept off the market. According to the author, the FDA is only motivated by Type 1 errors. Because the FDA wants to minimize occurrences where drugs cause injury to the public, they are at times so over cautious that they inevitably cause injury to those individuals who would benefit from the drugs. Accordingly Epstein states that "the ban should be the last resort, not the first option." [12]

[11] EPSTEIN, *supra* note 2, at 114-15.

[12] *Id.* at 123.

Chapter 13 – Drug Withdraw: Too Much, Too Soon:

- **Chapter Summary**: In this chapter the author discusses what happens when a drug is withdrawn. Moreover, he introduces what occurred with Vioxx.
- **Chapter Discussion**: Similar to its power to restrict what drugs are allowed on the market, the FDA has the ability to withdraw dugs that had been previously approved. On September 30, 2004, Merck Pharmaceuticals removed Vioxx from the market because 3.5 percent of patients suffered a heart attack after using the drug. Due to the pressure by some, the FDA was forced to consider whether Vioxx should be banned from the market. Shortly thereafter on February 18, 2005, the FDA voted to not ban Vioxx in a vote of 17 to 15.

Chapter 14 – Getting the Drugs to the Market:

- **Chapter Summary**: In this chapter, the author discusses the marketing of pharmaceuticals and the possible controversies that arise from such marketing.
- **Chapter Discussion**: One of the greatest complaints waged against the pharmaceutical industry is how the industry markets their products. The cost of marketing far exceeds the cost of R&D of new drugs. However, the author suggests that without marketing, there is no way for a company to cover the cost of developing a new drug. Moreover, he states that the amount of money spent on marketing is not too high because if it was, drug companies would have reduced their spending. Like any other business, a drug company would not spend more money than necessary because that would be a waste of resources. While some criticize direct advertising to physicians in the forms of vacation retreats, free samples, dinners, etc., Epstein does not believe that this is a problem. According to Epstein, the more detailed and accurate the information provided to the physicians, the better off the consumer

will be. To that regard, Epstein states "I want my physician to squeeze in an extra round of golf if it improves my own prospects for long term care." [13]

Chapter 15 – Deceptive Marketing:

- **Chapter Summary**: In this chapter the author discusses deceptive marketing of drugs and medical devices.
- **Chapter Discussion**: According to the author, most deceptive marketing comes in the form of either an understatement of the risks involved with a particular drug or the overstated benefit of a drug. However, the effect of misrepresentation can be minimized by doctors who read and study the appropriate literature and warnings before prescribing the drug to their patients. In addition, the Federal Trade Commission (FTC) has the power to enjoin or fine companies who engage in false and misleading advertising. However, even if a company uses deceptive marketing, the author notes that the consumer still has the burden of showing that they had used the drug and that drug had caused his injury in order to receive damages as a result of litigation.

Chapter 16 – Tort Preliminaries:

- **Chapter Summary**: In this chapter the author discusses tort and contract liability in pharmaceutical cases. In addition, this chapter gives more information regarding the background of the Vioxx litigation.
- **Chapter Discussion**: According to the author, an injury that is caused by drugs cannot be regulated by contract law. Even though there are contractual disclaimers on all drugs, such

[13] *Id.* at 157.

waivers would not insulate the pharmaceutical company from liability if a person is injured by the drug. However, the author does not necessarily think that these disclaimers should be powerless. To that regard, the author notes "this is paternalism with a vengeance…remove freedom of contract, and low and behold, people are not free." [14] As for tort liability, the author notes several difficulties that arise under tort liability. Specifically, he states that because judgments in drug cases are potentially very high, some individuals may be inclined to lie about how they used the drug or if they used the drug at all. In regards to Vioxx, the author states that thousands of lawsuits were brought against Merck, all of which must answer the threshold question of whether the decedent actually used Vioxx. The first suit against Merck was brought by Carol Ernst for the death of her husband Robert who had died from cardiac arrhythmia secondary to coronary atherosclerosis. [15]

Chapter 17 – Product Liability for Prescription Drugs: Manufacturing and Design Cases:

- **Chapter Summary**: In this chapter the author gives a brief overview of the differences between manufacturing and design defects.
- **Chapter Discussion**: According to the author there are three types of defects: design defects, manufacturing defects and warning defects. In this chapter, the author discusses the first two types of defects. A manufacturing defect is one which is caused by an error in the fabrication of the product. A company cannot disclaim or warn against such defects. A design defect is where the design of the product has made that product unsafe and that an alternative design was available. Both design and manufacturing defects are generally not an

[14] *Id.* at 189.

[15] Ernst v. Merck & Co., No. 19961 (Tex. D. Ct., 23rd Jud. D. Aug. 19, 2006).

issue in regards to pharmaceuticals. Accordingly, the author states that in pharmaceutical cases, the defect in question is one of warnings.

Chapter 18 – The Main Event: Misrepresentation, Overpromotion, and Duty to Warm:

- **Chapter Summary**: In this chapter, the author discusses the issues relating to warning defects, misinformation and incomplete information. In addition, the author further discusses the Vioxx litigation.
- **Chapter Discussion**: Issues relating to information transfer can be organized in two categories. The first deals with misstatements and misrepresentations in communication that takes place between the drug company, the physician and the consumer. The second category deals with information that is distributed with the drug to the patient and his doctor. In regards to the Vioxx litigation, Merck did not tell either consumers or doctors of the cardiac related side effects of the drug. However, even if there was misrepresentation, the author notes that the plaintiff must still show that the decedent would have taken a different course of action had he known of such risks. Likewise, the plaintiff is required to show that there was a causal connection between the decedent's use of the drug and his death. Lastly, the author discusses several proposals to deal with cases of warning defects such as creating a no fault system, a new Federal system to prosecute pharmaceutical companies and new rules relating to warnings.

Conclusion – Socialized Medicine:

- **Chapter Summary**: The author concludes the book in this chapter.

- **Chapter Discussion**: In this chapter, the author concludes by stating that we should "remove those numerous obstacles that needlessly retard pharmaceutical innovation." [16] Accordingly, he states that the public should not automatically disagree with the objective of the pharmaceutical industry because such an adversarial position has had negative repercussions in the development of new drugs.

[16] EPSTEIN, *supra* note 2, at 240.