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Book Reviews

# Inside the FDA - The business and politics behind the drugs we take and the food we eat

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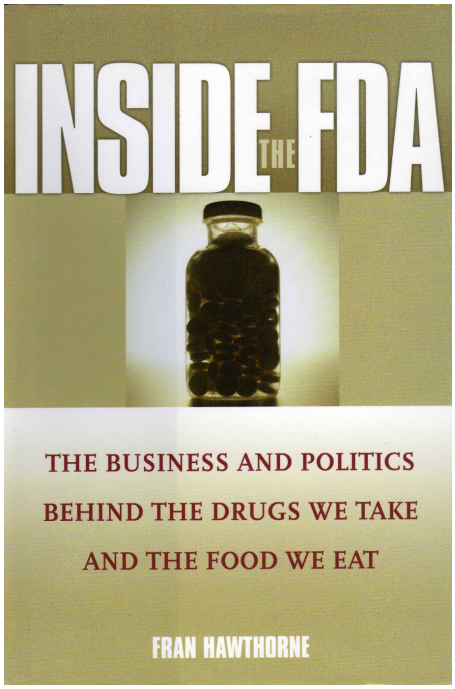
The work contains an introduction and fifteen chapters (1: Case Study: Chasing Cancer; 2: Beyond Science; 3: The First 100 Years; 4: "You Don't Know Which Agency Is in Charge"; 5: Truckloads of Paper; 6: Case Study: The Return of Thalidomide; 7: How Picky Is the FDA?; 8: How Powerful Is Industry?; 9: Case Study: The Death of Monica George; 10: When Consumers Get Angry; 11: A Political Pawn; 12: FDA and DNA; 13: The FDA Meets Madison Avenue; 14: Frivolous Drugs? 15: The Next 100 Years) written in a journalistic style, faithful to the author's formal profession, concerning the role of the planet's foremost food and drug regulatory agency *The Food & Drug Administration* (FDA) of the United States of America, founded in 1906. Given that the work was published in 2005, there was a clear intention on the author's part to mark the agency's centenary.

The chapters deal with a range of themes, though these are overwhelmingly focused on the question of medications with just scattered references to foods over the course of the book. Adopting case studies in some chapters, the book mixes facts with opinions, the latter obtained from the statements of various specialists, including analysts from the agency itself who worked on the dossiers relating to a number of specific drugs. At the end of the work, the author thankfully includes an item 'Notes' that explains numerous sources.

The introduction provides an original account of a demonstration that took place in 2004, in Bethesda, Maryland, USA, held by relatives of people harmed or killed by the use of medications. The book's opening includes emotional accounts that highlight the known risks of using drugs improperly, especially various cases linked

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to neuroactive drugs. Chapter 1 describes the complex authorization process undertaken by a company wanting to deposit a dossier to conduct clinical trials with a new anti-cancer agent originating from academic research in a non-industrial environment. This illustrative topic is revisited briefly in the final paragraphs. The costs of these studies are documented and shown to represent a severe limitation on the capacity of this small company to push forward its research. Chapters 2 and 3 examine the scientific infrastructure deployed by the agency to ground its decisions on issues relating to drugs and foods. The latter chapter provides an overview of key events during the first hundred years of the agency's existence, highlighting the legal frameworks in existence. Chapter 4 discusses the impact of the rise in the *Salmonella enteritidis* microorganism on the health of the American population consuming fast foods and questions the forms in which these foods are regulated. Chapter 5 looks at the enormous volume of dossiers involved in the regulatory process, noting that their sheer scale means that the examiners cannot always produce an effective analysis. The dossiers relating to the investigational new drug application (IND) process, indispensable for conducting clinical trials on human beings, describe in depth the trials performed on laboratory animals, the procedures for obtaining and preparing trial samples, as well as the proposal of protocols for the desired clinical trial. The examination of these protocols for the realization of clinical trials represents a crucial stage in the process of analysis, demanding examiners with expertise. Here the author cites the use of placebos as one of the main issues and, as an example, examines atorvastatin, the third statin to be introduced on the US market in 1996. It is worth noting that throughout the work, the author employs the trade name of the drugs! Chapter 6 contains the largest amount of historical documentation. The trajectory of thalidomide is documented without sufficient description of the role of the FDA itself at the time of its discovery when authorization for its use in the US was not granted, thereby protecting pregnant American women from the tragic effects of this medication, originally indicated for nausea. Indeed, in this chapter the drug is called by its generic name, but when reference is made to the new use, the author again turns to the trade name used by a US company. The chapter exemplifies the importance of the scientific role performed by some researchers in recognizing the pharmacological properties of thalidomide in relation to the action of tumour necrosis factor-alpha (TNF-α), discovered through its use in the treatment of the inflammatory process found in people with leprosy. The author mentions, albeit very briefly, Brazil's contribution to the rebirth of thalidomide when the drug was employed in the country to cure leprosy. Its potential use in certain types of cancer, such as multiple myeloma, led a US company to request a license from the FDA. Chapter 7 describes some of the criteria used by the agency when authorizing certain drugs and comments, with examples, on its relationship to the pharmaceutical industry. The chapter also describes the episode involving the withdrawal from the market of an important prostaglandin-endoperoxide synthase 2 inhibitor, a drug also known as COX-2, marketed by Merck. Chapter 8 discusses the role of the pharmaceutical industry in discovering drugs. Innumerable examples illustrate the power of this industrial sector and its organizational capacity, as well the political influence it exerts. Chapter 9 recounts the episode of the death of a 64-year old retired nurse, attributed to the use of a medication. Chapter 10 surveys arguments demonstrating the importance and influence of public opinion on the regulatory framework of the controlling government agencies. Chapter 11 provides arguments summarizing political aspects of the agency's action in US's biparty social organization. Chapter 12 describes the relationship between researchers and scientists and the agency, emphasizing the distinct scientific disciplines, especially the biological and medical sciences. The agency's interactions with specialists from the US National Institute of Health (NIH), also located in Bethesda, a neighbour of the FDA, exemplifies the multidisciplinary view of issues related to medications. Chapter 13 focuses on the advertising produced by pharmaceutical companies to sell their products to the public. The author cites various figures for the expenditure made by this industrial sector on advertising, noting that some companies spend more than US$ 100 million/year on marketing a single medication. Some of the statements recorded have a clearly populist appeal. Indeed in some passages of the book the author allows herself to be led by superficial arguments to make rather tenuous conclusions, for example when she looks to justify a higher therapeutic profile for a particular medication rather than another from the same therapeutic class with a different price, merely relying on the reports of patients who used one and the other without linking these uses to all the real conditions involved. Chapter 14 comments on the crisis in innovation affecting the pharmaceutical industry, especially in the United States. Based on figures relating to the new chemical entities (NCE) that represent real innovations, approved by the US agency each year, the author notes the fall in the capacity to invent truly innovative new drugs. Strategies used by industrial pharmaceutical laboratories to overcome this situation are described, such as developing therapeutic copies (e.g. me-toos) or new associations, extending the patent protection time for their components, or asserting their therapeutic benefits per-se in the deposited documents. In this chapter the author records various opinions on the need to improve the quality of this information, including the description of the results of comparative use of classical drugs and the innovations claimed. The final chapter outlines the prospects for future decades, including some considerations on the price of various innovative drugs in the US market, considered the most expensive in the world. The author also discusses the prices of innovative drug treatments in different countries, concluding that Americans pay much more than other nationalities, even those of nearby countries such as Canada. Bioterrorism and the importance of preventing attacks through continual actions involving the regulatory government agencies are also examined. The price of medications, the related

ethical issues, the effects of tobacco consumption on the health of populations and the diet of US citizens are all covered in the final comments to this chapter.

Reading the 308 pages of *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat* by journalist Fran Hawthorne is an agreeable experience given its elegant style and represents a good choice for anyone wishing to know more about the role of the main government regulatory agency of food and drugs in the United States.