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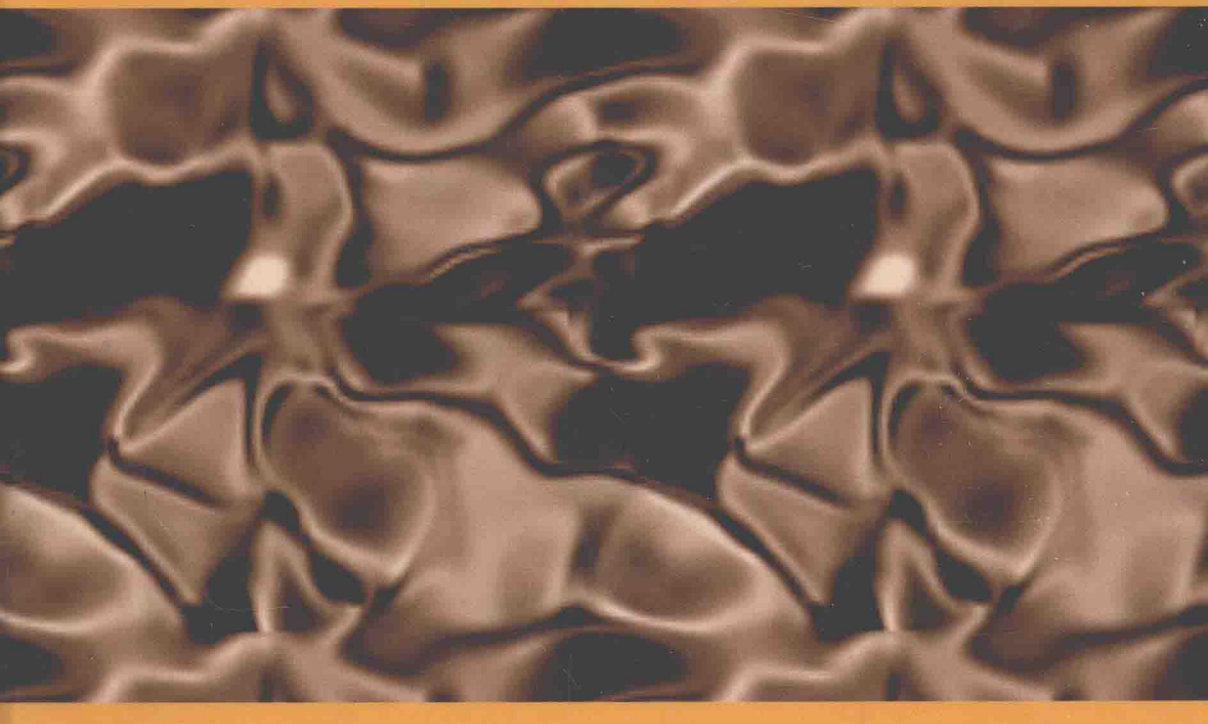
Economics of Health Law

VOLUME II

Edited by
Ronen Avraham, David A. Hyman
and **Charles M. Silver**



ECONOMIC APPROACHES TO LAW 47

Economics of Health Law
Volume II

Edited by

Ronen Avraham

Thomas Shelton Maxey Professor in Law
University of Texas School of Law, USA
and Visiting Professor of Law
Tel Aviv University, Israel

David A. Hyman

H. Ross and Helen Workman Chair in Law, Professor of Medicine
and Director, Epstein Program in Health Law and Policy
University of Illinois, USA

and

Charles M. Silver

Roy W. and Eugenia C. McDonald Endowed Chair in Civil Procedure
and Co-Director, Center on Lawyers, Civil Justice and the Media
University of Texas School of Law, USA

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Volume II

Economic Approaches to Law

Series Editors: Richard A. Posner
Judge, United States Court of Appeals for the Seventh Circuit and Senior Lecturer, University of Chicago Law School, USA

Francesco Parisi
Oppenheimer Wolff and Donnelly Professor of Law, University of Minnesota Law School, USA and Professor of Economics, University of Bologna, Italy

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CHAPTER 5

THE REGULATION OF MEDICAL PRODUCTS

ANUP MALANI AND
TOMAS PHILIPSON

IMPROVEMENTS in health have been a major component of overall gain in economic welfare in the last century (Cutler and Richardson 1998; Murphy and Topel 2006). Part of these health gains are attributable to medical research (Cutler and McClellan 2001; Murphy and Topel 2003; Lichtenberg 2003; Cutler et al. 2007). At the same time, the cost of health care has tripled in real terms since 1965 and now accounts for more than 17 percent of the gross domestic product (GDP). Evidence exists to suggest that a large share of this cost growth is driven by technological innovation (Newhouse 1992), including the cost of medical products such as drugs. The large role of innovation in explaining both improvements in health and health care cost growth suggests that it is important to understand the medical research and development (R&D) process and how it is regulated.

In virtually all developed countries and many developing countries, the government provides regulatory oversight over the quality of products generated by medical innovation. In the United States, this oversight is conducted by the US Food and Drug Administration (FDA), which regulates drugs, medical devices, biologics (products made from living organisms, such as vaccines and blood products), cosmetics, radiation-emitting electronic products, veterinary products, and foods. According to the FDA, the products it regulates account for more than one-fifth of US consumer spending. In the area of medical products, the agency reviews whether drugs and many devices are safe and effective both before and after they have been cleared for sale.

The manner in which the FDA regulates the quality of drugs and devices has a substantial impact on the cost of their development. The FDA requires that

companies conduct clinical trials to demonstrate that their medical products are safe and effective. These trials account for a large portion of the total development costs of these products (DiMasi et al. 2003; Adams and Brantner 2006). In addition, completion of trials does not guarantee that a product will be approved. This risk of nonapproval compounds the cost of product development (DiMasi et al. 2003).

Despite the central role of the FDA in regulating the quality and R&D costs of medical products, economists have conducted relatively little theoretical or empirical research on the efficiency of FDA policies. Ironically, if a product application were presented to the FDA with the scant amount of evidence that currently exists on the efficiency of the policies of the agency itself, such an application would likely be rejected on the basis of insufficient evidence. In this chapter, we synthesize and extend, in a nontechnical manner, recent research on the FDA. Our aim is to shed light on whether the policies of the agency itself are safe and effective when measured in terms of economic efficiency.

The first section provides an overview of the role of the FDA in regulating pharmaceutical drugs and medical devices. The second section surveys the existing efficiency rationales for government regulation of the information about and the quality of medical products and then canvasses the literature for empirical studies on the effects of FDA regulation on innovation and costs. The final section examines the growing role of tort law—specifically, products liability litigation—in supplementing FDA regulation of drug quality.

To understand the relationship of this chapter to others in this book, it is helpful to break government influence on medical product innovation into five parts. The first is the use of property rights over innovation to encourage investment in R&D. The second is direct government spending on R&D. The third is premarketing screening of new drugs and devices by the FDA. The fourth is postmarketing regulation of medical products by courts (and perhaps the FDA). The last is demand for medical products by government-run health insurance systems such as Medicare and Medicaid. This chapter focuses on the third and fourth categories; that is, the role of quality and safety regulation in directing innovation.

FDA Regulation of Drugs, Devices, and Biologics

Drugs

The US government began regulating drugs with the 1906 Food and Drug Act. That statute prohibited companies from selling misbranded or adulterated