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Introduction—Pharmaceutical Innovation and Cost: An American Dilemma

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The four papers which follow, presented during an interdisciplinary symposium at the University of Chicago, respond to an atmosphere of growing public dissatisfaction with the pharmaceutical industry. The industry's problems include the rising cost of drugs, the slowing rate of innovation, concerns about the FDA's ability to effectively regulate the safety and efficacy of drugs, and the impact of the recently passed prescription drug benefit legislation. The past year has seen a flood of new books cataloguing these problems, including Marcia Angell's *The Truth About the Drug Companies: How They Deceive Us and What To Do About It*,¹ Jerry Avorn's *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*,² Jerome Kassirer's *On the Take: How America's Complicity with Big Business Can Endanger Your Health*,³ and John Abramson's *Overdosed America: The Broken Promise of American Medicine*.⁴ Thus, despite a century of progress in developing safe and effective drugs that improve the length and quality of life, we are left with a fundamental dissatisfaction over the costs of medications and the rate of new drug development and innovation.

In November 2004, the University of Chicago's MacLean Center for Clinical Medical Ethics, John M. Olin Program in Law and Economics at the Law School, Committee on Clinical Pharmacology and Pharmacogenomics, and

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1. MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004).

2. JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* (2004).

3. JEROME P. KASSIRER, *ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH* (2004).

4. JOHN ABRAMSON, *OVERDOSED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE* (2004).

Harris Graduate School of Public Policy Studies convened scholars from different disciplines to discuss these and related issues. The conference, titled "Pharmaceutical Innovation and Cost: An American Dilemma," was held at the Law School. A series of papers on innovation and regulation were presented at the conference, some of which were selected for publication in this volume.

The first paper in the series, *The Problem of New Uses* by Professor Rebecca Eisenberg,⁵ outlines the challenges our legal system faces when balancing the social cost of data and product exclusivity against providing adequate incentives for further research. In particular, she examines the need to promote corporate research into new uses of existing drugs at a time when drug companies fear negative results that call their drugs' safety into question (e.g. Cox-2 inhibitors) and the prospect of generic manufacturers free-riding on data from new trials. Eisenberg concludes that the best system would combine public disclosure of data with extended product exclusivity, an intent she believes the FDA should read into existing legislation. Professor Richard A. Epstein's paper, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*,⁶ criticizes the FDA for a paternalistic regulatory approach that privileges the safety of all potential drug users over informed individual choice. Epstein claims that the FDA has strayed from its primary mission of protecting consumers against impure substances and fraud. Epstein further argues that patients, not regulatory agencies, are in the best position to assess what risks are acceptable, and that the FDA's attempt to police the drug market solely through upstream regulation shows indifference to the opportunity cost of denying treatment to patients whose individual cost-benefit calculation counsels use of moderately risky drugs.

Both Eisenberg and Epstein emphasize the economies of information at play in the market for prescription drugs. The two final pieces, which examine aspects of pharmaceutical advertising, provide additional perspectives on this theme. The paper by Marshall Chin analyzes the way patients acquire information about drugs in the burgeoning era of direct-to-consumer advertising (DTCA).⁷ The period when patients received almost all of their information about which drugs to take from their physicians has now passed. Although his paper, *The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids*, concludes that DTCA is appropriate, Dr. Chin contends patients

5. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 211 (2005).

6. Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 235 (2005).

7. Marshall Chin, *The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids*, 5 YALE J. HEALTH POL'Y L. & ETHICS 265 (2005).

must diversify into other sources of information, including decision aids and clinician guidance, to make optimal choices. In their paper *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, Puneet Manchanda and Elisabeth Honka look at the relationship between detailing (informational sales pitches by drug company sales representatives to physicians) and physician prescribing behavior.⁸ The authors aggregate data from numerous empirical studies of detailing's impact on physician behavior and conclude that detailing's impact is most significant early in a drug's life cycle, but then declines as physicians gain access to other sources of information about the drug.

At a time when the pharmaceutical industry finds itself the focus of tremendous public attention, we hope that these papers offer some insight into how the industry can best fulfill its promise of safe, innovative, and moderately-priced drugs.

8. Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y L. & ETHICS 279 (2005).

