

BIOMEDICAL RESEARCH AND THE LAW—
SELECTED ISSUES: THE PHARMACEUTICAL
INDUSTRY AND ITS RELATIONSHIP
WITH GOVERNMENT, ACADEMIA,
PHYSICIANS AND CONSUMERS

FOREWORD

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The articles in this issue developed from a conference entitled *Biomedical Research and the Law*, held at Hofstra University in the fall of 2006.¹ The conference explored conflicts of interest created by industry's support for biomedical research. Participants considered how to safeguard the integrity of research and the safety of drugs while encouraging the development of treatments for disease.

Industry now funds more pharmaceutical research in the United States than does the National Institutes of Health ("NIH").² Moreover, the proportion of funding contributed by the NIH has been diminishing.³ As a result, the influence of industry in how research is conducted and

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1. The full conference name was *Biomedical Research and the Law—Selected Issues: The Pharmaceutical Industry and its Relationship with Government, Academia, Physicians and Consumers*. It was held on October 4-5, 2006. We are appreciative to Hofstra University, Hofstra Law School, and the Hofstra Cultural Center, and to the law firm of Garfunkel, Wild & Travis, P.C. for supporting and sponsoring the conference from which the papers published in this issue developed. We owe a special debt to Natalie Datlof, Executive Director, and Athelene A. Collins, Associate Director for Project Development, of the Hofstra Cultural Center. Their hard work, intelligent planning, and commitment to the project contributed mightily to the success of the event. We are also grateful for the participation of North Shore-Long Island Jewish Health System in conference planning. Cindie Leigh and Kevin Shelton, Reference Librarians at Hofstra Law, provided invaluable assistance with bibliographical research. Finally, we are grateful to the editors of the *Law Review* for their part in transforming a conference into the symposium articles in this issue.

2. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 27-28 (2006) (comparing the approximately \$38 billion spent by industry in 2004 to the \$28.5 billion spent that year by the NIH for research).

3. WITHIN OUR GRASP—OR SLIPPING AWAY? ASSURING A NEW ERA OF SCIENTIFIC AND MEDICAL PROGRESS 1, 17 (2007), available at http://hms.harvard.edu/public/news/nih_funding.pdf (showing the impact of flat funding by the NIH from 2003-2007).

reported is steadily increasing. The articles in this issue reflect broad concern at that increase, in particular as regards clinical research, and in general as regards potential bias within industry, and conflicts of interest faced by institutions and individuals engaged in biomedical research and dependent on industry for financial support.

Public media have brought the concern of the confluence to the attention of the public through a series of dramatic stories. Two such stories frequently noted concern Vioxx and Paxil. Although studies suggested that Vioxx, an anti-pain and anti-inflammatory drug, carried a risk of coronary disease, the company that produced it, Merck, did not reveal that risk in a timely fashion.⁴ As a result, Merck faces tens of thousands of lawsuits by consumers claiming they suffered coronary episodes as a result of taking the drug.⁵ GlaxoSmithKline also faced liability because it recommended that Paxil, which it produced, be used in treating depression among children and adolescents, but did not timely reveal studies suggesting that the drug carried risks for young users.⁶ Both Vioxx and Paxil have focused public attention on industry's failure to disclose risks to patients and physicians.

The stories involving Vioxx and Paxil, and other drugs like them, raise difficult questions, including the following: Has funding by industry reduced or enhanced the information derived from pharmaceutical research? How does this funding affect the research itself, the researchers, academic institutions, government agencies, physicians, professional organizations, medical journals, and the public? How does the law assure the reliability of information derived from such research, and how does the law help the Food and Drug Administration ("FDA"), other governmental agencies, medical journals, institutional review boards, consumer organizations, academic institutions and the media to assure the reliability of research conclusions? Should changes be made to the response of the law to funding by the pharmaceutical industry of medical research?

4. Merck voluntarily withdrew the drug from the market in 2004. *See, e.g.*, Stephanie Saul, *Can Painkillers Recover?*, N.Y. TIMES, Aug. 20, 2005, at C1; Heather Timmons, *Arthritis Drugs Under Review by Europeans*, N.Y. TIMES, Oct. 25, 2004, at C9.

5. *See, e.g.*, Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749, 750 (2006) (pointing out that Merck is currently "the defendant in thousands of lawsuits accusing it of deceptively marketing a drug, Vioxx, that it knew to be dangerous in order to bolster its corporate bottom line").

6. Among other things, studies suggested that Paxil caused suicidal ideation in some young users. *See, e.g.*, Aisling V. O'Sullivan, Comment, *Walking a Fine Line: Are SSRIs Really Depression Wonder Drugs or Threats to Patient Safety?*, 26 PACE L. REV. 549, 568 (2006) (citing *New York Sues Glaxo over Paxil Test Data on Children*, CHI. TRIB., June 3, 2004, at C4; Gardiner Harris, *Spitzer Sues a Drug Maker, Saying It Hid Negative Data*, N.Y. TIMES, June 3, 2004, at A1).

The Hofstra conference provided a neutral forum for considering the questions above, as the papers published in this issue show. John Abramson (a physician who teaches primary care medicine),⁷ Ronald Green (a professor of religion),⁸ and Marvin Lipman (chief medical adviser of Consumers Union)⁹ suggest that pervasive marketing to physicians and consumers by the pharmaceutical industry undermines the integrity of medical information and the safety of drug use. Merrill Goozner (a journalist and health advocate),¹⁰ concerned about the extent of industry's control over the FDA, recommends a set of changes that would make the agency independent of industry support. Samuel Packer (an ophthalmologist)¹¹ and Janet Dolgin (a law professor)¹² each focus on the consequences of the social transformation of medicine and the conflict, in Packer's phrase, between "commercial interests" and "professional promise."¹³ Finally, both Chris Pascal (Director, Office of Research Integrity ("ORI"))¹⁴ and Congressman Maurice Hinchey (D-NY)¹⁵ provide perspectives from government insiders. Pascal details ORI's responsibility for ensuring that publicly funded research is untainted by fabrication, falsification and bias. Hinchey, describing the FDA as a "broken" agency, has proposed the creation of an independent Center for Drug Safety and Effectiveness within the FDA.

Virtually all of the articles noted explicitly assert, or implicitly presume, that the pharmaceutical industry and pharmaceutical research have yielded remarkable results that have increased life expectancy and eased the burden of illness (that, for example, AIDS has been transformed dramatically from a fatal disease to an infection controllable by medication). Thus, virtually all of the articles commend the value to society of pharmaceutical research, and detail the various concerns noted to preserve and enhance the productive synergy between academia,

7. John Abramson, *The Reliability of Our Medical Knowledge as a Product of Industry Relationships*, 35 HOFSTRA L. REV. 691 (2006).

8. Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749 (2006).

9. Marvin M. Lipman, *Bias in Direct-to-Consumer Advertising and Its Effect on Drug Safety*, 35 HOFSTRA L. REV. 761 (2006).

10. Merrill Goozner, *Conflicts of Interest in the Drug Industry's Relationship with the Government*, 35 HOFSTRA L. REV. 737 (2006).

11. Samuel Packer, *Medical Ethical Considerations in Collaborative Research*, 35 HOFSTRA L. REV. 771 (2006).

12. Janet L. Dolgin, *Debating Conflicts: Medicine, Commerce, and Contrasting Ethical Orders*, 35 HOFSTRA L. REV. 705 (2006).

13. Packer, *supra* note 11, at 786.

14. Chris B. Pascal, *The Office of Research Integrity: Experience and Authorities*, 35 HOFSTRA L. REV. 795 (2006).

15. Maurice Hinchey, *The Fight to Safeguard American Drug Safety in the Twenty-First Century*, 35 HOFSTRA L. REV. 685 (2006).

government, and the pharmaceutical industry.