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Foreword: Academic-Industry Collaborations in the Clinic

Michael J. Malinowski

Louisiana State University Law Center, mjmalin@lsu.edu

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FOREWORD:

ACADEMIC-INDUSTRY COLLABORATIONS IN THE CLINIC

The “genetics revolution” has reached the clinic.¹ Consequentially, clinical research has been infused with unprecedented innovation and potential for improving human health.² However, the maturation of contemporary biomedical research also has advanced an entanglement of ethical and regulatory complications associated with intense academic-industry collaboration, competition, and commercialization.³ Critics and many concerned participants claim that the life science communities and policy makers have launched this genetic revolution in science, and brought research into an era of academic-industry alliances, without first establishing sufficient safeguards to ensure the protection of human subjects and the integrity of research.⁴ In response to this concern and related controversies which have captured media attention,⁵ the

1. For identification of the drug development pipeline, see <http://www.phrma.org> (last visited Aug. 23, 2001) (site of the Pharmaceutical Researchers and Manufacturers of America (PhRMA), the world’s leading pharmaceutical trade organization); <http://www.bio.org> (last visited Aug. 23, 2001) (site of the Biotechnology Industry Organization (BIO), the world’s leading biotechnology industry trade organization); <http://www.clinicaltrials.gov> (last visited Aug. 23, 2001) (details on approximately 5,500 mostly government-funded clinical trials); <http://cancertrials.nci.nih.gov> (last visited Aug. 23, 2001) (the National Cancer Institute’s clinical trial listing); <http://www.actis.org> (last visited Aug. 23, 2001) (the AIDS clinical trial information service (ACTIS)); <http://www.centerwatch.com> (last visited Aug. 23, 2001) (one of the earliest and the most comprehensive private sites); <http://www.emergingmed.com> (last visited Aug. 23, 2001) (privately-funded cancer trials; under expansion to cover other diseases); <http://www.veritasmedicine.com> (last visited Aug. 23, 2001) (lists trials and standard treatments for numerous diseases); <http://www.americasdoctor.com> (last visited Aug. 23, 2001) (trials in various disease categories, excluding cancer); and <http://www.acurian.com> (last visited Aug. 23, 2001) (developing lists of trials in numerous disease categories).

2. See generally *supra* note 1.

3. See Press Release, Department of Health and Human Services, Secretary Shalala Bolsters Protections for Human Research Subjects (May 23, 2000) [hereinafter DHHS Press Release], available at <http://www.hhs.gov/news/press/2000pres/20000523.html>. See also Elizabeth A. Boyd & Lisa A. Bero, *Assessing Faculty Financial Relationships With Industry: A Case Study*, 284 JAMA 2209 (2000); Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203 (2000); Catherine D. DeAngelis, *Conflict of Interest and the Public Trust*, 284 JAMA 2237 (2000). See generally David Korn, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234 (2000).

4. See, e.g., DHHS Press Release, *supra* note 3 (addressing the need to bolster protections for human subjects); Donna Shalala, *Protecting Research Subjects—What Must Be Done*, 343 NEW ENG. J. MED. 808 (2000).

5. The incident which has captured the most attention is the circumstances surrounding the death of Jesse Gelsinger, an 18-year-old gene-therapy subject in a protocol approved by the University of Pennsylvania. See *Gelsinger v. Trustees of the Univ. of Pa.*, Case No. 000901885 (Ct. Com. Pl., Phila. County, filed Sept. 18, 2000), at <http://www.sskrplaw.com/links/healthcare2.html>

United States (including the government, industry, and academia sectors), is reassessing the soundness of its regulatory regimes to protect human subjects and research integrity.⁶ Consequentially, fundamental reform is being contemplated in the midst of an extraordinary amount of important, ongoing clinical research.⁷

On March 15, 2001, approximately 200 representatives from the biomedical industry, the medical community, government agencies, and multiple disciplines in academia gathered at the Widener University School of Law's Delaware campus to advance critical thinking about this pressing topic. This effort was a shared undertaking by the *Widener Law Symposium Journal* and the Widener Health Law Institute in cooperation with the American Bar Association, Delaware Bar Association, Pennsylvania Bar Association, Pennsylvania Biotechnology Association, and with the financial sponsorship of Centocor, Inc. and Eckert Seamans Cherin & Mellott, LLC.

The primary objective of the conference was to bridge legal academia with the life science and medical communities and to create a forum that could make a meaningful "real world" contribution through pragmatic discussion and by raising awareness. This issue of the *Widener Law Symposium Journal* contains a collection of written contributions originating from and complementing the lively and informative conference proceedings.

(last visited Aug. 23, 2001); Thomas Petzinger Jr., *Yes, Technology Seems to Change Almost Daily. But Some Trends are Likely to Remain in Force for a Long Time*, WALL ST. J., Jan. 1, 2000, at R12.

6. The Department of Health & Human Services (DHHS), Office of the Secretary, hosted a forum on August 15-16, 2000, entitled "Human Subject Protection and Financial Conflict of Interest." This forum also was sponsored by the National Institutes of Health (NIH), Centers for Disease Control (CDC), and Food & Drug Administration (FDA). See Agenda, Human Subject Protection and Financial Conflicts of Interest Conference (Aug. 15, 2000), at <http://ohrp.osoph.dhhs.gov/coi/agenda.htm>. Subsequently, NIH undertook "visits" to recipient institutions throughout the country to see first-hand how they are dealing with conflicts of interest. See Patrick Healy, *Harvard Forum Eyes Oversight of Biomedical Research*, BOSTON GLOBE, July 21, 2000, at A13. More significantly, the FDA issued guidance to assist industry in dealing with potential conflicts of interests. FOOD & DRUG ADMIN., DEPT HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (2001), at <http://www.fda.gov/oc/guidance/financialdis.html> (last visited Sept. 4, 2001). Along these same lines, representatives from several of the nation's top medical schools (Harvard, Baylor College of Medicine, Columbia University, Johns Hopkins University, the University of Pennsylvania, the University of Washington, Washington University, Yale University, and the University of California at San Francisco and Los Angeles) have jointly drafted proposed conflict of interest guidelines that require researchers to disclose any financial interests they have in studies involving patients. See Carey Goldberg, *Medical Schools Offer Rules on Doctors' Conflict of Interest*, N.Y. TIMES, Feb. 8, 2001, at A23. Several Professional Societies, including the American Society of Human Genetics, have done the same. See AMER. SOC'Y OF GENE THERAPY (ASGT), POLICY OF THE AMERICAN SOCIETY OF GENE THERAPY ON FINANCIAL CONFLICT OF INTEREST IN CLINICAL RESEARCH (2000), at <http://www.asgt.org/policy/index.html> (last visited Sept. 4, 2001).

7. See generally *supra* note 1.

The issue begins with two overview pieces. First, in *Financial Conflicts of Interest: How are we Managing?*,⁸ Erica Rose surveys a multitude of fundamental issues introduced by financial conflicts of interest, including how conflicts of interest arise and attempts to identify and manage them. Second, in *Globalization of Interests and Clinical Research: An Overview of Trends and Issues*,⁹ Timothy Caulfield surveys the trends of globalization and commercialization in clinical research relating to the issue of conflicts of interest. Caulfield sets forth several proposals, including the need to create research policy and Institutional Review Board structures to minimize conflicts and reduce the threat of forum shopping introduced by globalization.¹⁰

The next four contributions focus on the roles and obligations of institutions, individual researchers, and involved physicians. In *Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*,¹¹ I focus on the impact of biotechnology and the genetics revolution on clinical research and the resulting issue of institutional conflicts of interest. I conclude that the issue of conflicts of interest transcends, and requires reforms to, the regulatory regimes for both technology transfer and human subject protections.¹² I introduce several proposals for reform, the foremost being to write uniform, workable, and enforceable federal conflicts of interest standards directly into federal technology transfer policy.¹³

Pilar Ossorio and Janet Fleetwood address the roles and responsibilities of clinical researchers. Ossorio's contribution, entitled *Pills, Bills and Shills: Physician-Researcher's Conflicts of Interest*, is a primer on research, emphasizing the multifaceted nature and, consequentially, the varied roles of, and influences upon, physician-researchers.¹⁴ Ossorio offers suggestions to minimize and manage conflicts of interest, including the involvement of third parties in the consent process¹⁵ and institutional policies for professional advancement which prioritize research quality over quantity.¹⁶ Ossorio emphasizes the importance of disclosure and institutional oversight.¹⁷

8. Erica Rose, *Financial Conflicts of Interest: How are we Managing?*, 8 WIDENER L. SYMP. J. 1 (2001).

9. Timothy Caulfield, *Globalization of Interests and Clinical Research: An Overview of Trends and Issues*, 8 WIDENER L. SYMP. J. 31 (2001).

10. *See id.*

11. Michael J. Malinowski, *Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 WIDENER L. SYMP. J. 47 (2001).

12. *See id.*

13. *See id.* at 69-70.

14. Pilar N. Ossorio, *Pills, Bills and Shills: Physician-Researcher's Conflicts of Interest*, 8 WIDENER L. SYMP. J. 75 (2001).

15. *See id.* at 96-97.

16. *Id.* at 97.

17. *Id.* at 100.

In *Conflicts of Interest in Clinical Research: Advocating for Patient-Subjects*, Janet Fleetwood focuses on the doctor-patient relationship and the obligations to patient-subjects. Fleetwood attributes the ongoing nature of the conflicts of interest problem to three major factors: complications to the consent process attributable to the doctor-patient relationship, lack of sufficient subject-patient knowledge, and inadequate ongoing oversight by IRBs.¹⁸ She concludes that conflict of interest policies have done little to inform or protect patients.¹⁹

The series of symposium articles concludes with a comprehensive treatment by Patricia Kuszler, entitled *Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*.²⁰ Kuszler surveys a broad range of conflicts issues, financial and non-financial, in basic research and the delivery of care as well as in clinical research. Kuszler concludes that, “conflicts of interest, both financial and non-financial are now deeply embedded in the fabric of biomedical research”²¹ and, consequentially, “the traditional boundaries and values differential between the market and the ivory tower of academia are blurred, if not completely obliterated.”²²

In addition to these pieces originating from the conference proceedings, this issue includes a book review by William Charles Lucas of Cynthia Robbins-Roth’s book, *FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY*.²³ In reviewing *FROM ALCHEMY TO IPO*,²⁴ a best-selling “industry insider’s” account of the biotechnology sector, Lucas draws heavily from his own experience as the Vice President and Associate General Counsel of Pharmacia and former Vice President and General Counsel of Zeneca Pharmaceuticals. Lucas concludes that “the book . . . provide[s] the potential investor with a helpful compendium of due diligence concerns and enough background to begin to understand this very complex industry.”²⁵

Michael J. Malinowski
Faculty Chair

18. Janet Fleetwood, *Conflicts of Interest in Clinical Research: Advocating for Patient-Subjects*, 8 WIDENER L. SYMP. J. 105, 105-06 (2001).

19. *See id.* at 106.

20. Patricia C. Kuszler, *Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*, 8 WIDENER L. SYMP. J. 115 (2001).

21. *Id.* at 152.

22. *Id.*

23. William Charles Lucas, *From Alchemy to IPO: The Business of Biotechnology*, 8 WIDENER L. SYMP. J. 153 (2001) (book review).

24. CYNTHIA ROBBINS-ROTH, *FROM ALCHEMY TO IPO* (2000).

25. *See* Lucas, *supra* note 23, at 155.