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Foreword

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FOREWORD

JESSE A. GOLDNER*

On Friday, March 20, 2012, the Saint Louis University Center for Health Law Studies and the *Journal of Health Law & Policy* hosted the 24th annual Health Law Symposium entitled *Drugs and Money*. The genesis of this year's Symposium program, in some respects, is a lengthy one. In 1982, a small group of law faculty at Saint Louis University,¹ over lunch at the law school's beloved watering hole (Humphrey's), sketched out on a napkin (actually rediscovered a few years ago) the outline for what soon became the School of Law's Center for Health Law Studies. This year has been dedicated to a celebration of the Center's 30th anniversary. Activities included a reception for alumni and other friends of the Center attended by over 200 people, held at the United States Supreme Court, and a 30th anniversary conference, keynoted by Paul Starr, Professor of Sociology and Public Affairs and Stuart Professor of Communications and Public Affairs at Princeton University. The conference also celebrated the 30th anniversary of Dr. Starr's classic study, *The Social Transformation of American Medicine*,² as well as the publication of his more recent book *Remedy and Reaction: The Peculiar American Struggle over Health Care Reform*.³ The scholarship arising out of that conference will be published in Volume 6, Issue 2 of this Journal.

The Symposium that served as the basis for the scholarship presented here was yet another anniversary year activity and came about largely due to a chance discussion during the 2010-2011 academic year between

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1. Sandra Johnson, now Tenet Professor of Law and Ethics, Emerita at Saint Louis University; Michael Wolff, currently Distinguished Professor of Law and Co-Director of the Center for the Interdisciplinary Study of Law at Saint Louis University; Nicolas Terry, currently Hall Render Professor and Co-Director of the William S. and Christine S. Hall Center for Law and Health at Indiana University Indianapolis; and myself.

2. PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982).

3. PAUL STARR, *REMEDY AND REACTION: THE PECULIAR AMERICAN STRUGGLE OVER HEALTH CARE REFORM* (2011).

Professor Thomas (Tim) Greaney⁴ and Marc Rodwin. The conversation included the possibility of devoting a Symposium to the topic of conflicts of interest in healthcare — a topic on which, as noted below, Marc is one of the country's leading authorities. As we began to identify suitable principal speakers for the program, over time the topic for the Symposium morphed somewhat to focus more specifically on issues related to the pharmaceutical industry and more broadly on financial issues in general. Hence its apt title. Center faculty, and in particular Tim Greaney's,⁵ fingerprints can be seen in the conceptualization of the program. Also, special thanks are owed to Professor Rob Gatter, co-director of the Center, who, in addition to helping identify commentators, keeps the rest of us on course. In addition, Amy Sanders, Esq., Assistant Director of the Center, and Cheryl Cooper, the Center's Program Coordinator, were responsible for the various logistics involved in putting on the Symposium.

Certainly, this is neither the first nor likely the last Health Law Symposium to cover topics related to healthcare financing and/or the pharmaceutical industry. Symposium programs that touched on these issues over the last two decades include: *Implementing Health Reform Fairness, Accountability and Competition* (2011), *Medicare: After the Medicare Modernization Act* (2007), *From Risk to Ruin: Shifting the Cost of Health Care to Consumers* (2005), *Taking the Pulse of Medicaid* (2000), *Medical Necessity: Fraud, False Claims and Managed Care* (1998), *Antitrust and Health Care: Current Antitrust Issues for the Health Care Reform* (1994), and *Legal and Ethical Controls on Biomedical Research: Seeking Consent, Avoiding Condescension* (1993). Even prior to these formal, live symposia, the *Saint Louis University Law Journal* published a series of issues at least once and sometimes twice each academic year, beginning with a 1978 *Health Law Review*, that included a number of articles devoted to health law topics.

4. Tim is currently the Chester A. Myers Professor of Law at Saint Louis University and serves as co-director of the Center for Health Law Studies.

5. This year's Symposium in some respects relates back to Tim's joining the faculty in 1987. In 1986, the four of us who originally created the Center of Health Law Studies on that napkin came to a growing recognition that the future of health law seemed likely to include numerous issues related to money. None of us could honestly claim significant expertise in financial issues related to the provision of health care. Tim applied for a faculty position to teach in the business associations area and, fortuitously, had spent ten years at the U.S. Department of Justice in Washington D.C. in its Antitrust Division as a trial attorney, and then as the assistant chief in charge of antitrust matters in health care. He has spent nearly twenty-five years as an academic examining the evolution of the health care industry, and financing in particular, and is a vocal advocate for reforming the health care system and protecting consumers.

The first contribution to this Symposium is Professor Robert Field's *How the Government Created and Sustains the Private Pharmaceutical Industry*.⁶ Professor Field holds a joint appointment as Professor of Law at the Earle Mack School of Law as well as Professor of Health Management and Policy at the School of Public Health at Drexel University. In addition, he is a lecturer in healthcare management at the Wharton School of the University of Pennsylvania and serves as an adjunct senior fellow of the University of Pennsylvania's Leonard Davis Institute of Health Economics. Professor Field is the author of *Health Care Regulation in America: Complexity, Confrontation and Compromise*,⁷ an overview of the government's oversight of healthcare, and he writes a regular blog focusing on health policy for the *Philadelphia Inquirer*. He has a Ph.D. in psychology from Boston University, and he holds a M.P.H. from the Harvard School of Public Health, a J.D. from Columbia Law School, and a Bachelor's degree from Harvard College.

Professor Field takes us through the complex world of interrelationships of various players surrounding the development, regulation, and distribution of pharmaceuticals. As he notes early in his paper, "[t]he path has countless twists and turns. . . ." In doing so, he paints a picture of the incredible financial success of pharmaceutical manufacturing and the various factors that have contributed to it, particularly the role of research and development. He then proceeds to explore in great detail the role of "public biomedical research," particularly the National Institutes of Health (NIH) and its various programs, as well as other forms of governmental support for the pharmaceutical industry. His discussion of the NIH includes a description of what it does, its history, and its phenomenal growth, and how it has served as an "instigator" of private drug development. Looking to its future role, he describes the significance of its Human Genome Project, what that program has already produced, and how it augurs a future of "personalized medicine." NIH's recently created National Center for Advancing Translation Sciences, Field observes, has the potential to create conditions that would allow the competitive market to bring genomic therapies to patients.

Other forms of government support for the pharmaceutical industry exist in ways that many may not immediately identify. For example, it is clear that through various programs including Medicare and Medicaid, (and I would add, other government programs such as Tricare and the VA system) the government is the nation's largest payor for pharmaceuticals. The history of

6. Robert I. Field, *How the Government Created and Sustains the Pharmaceutical Industry*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 11 (2012).

7. ROBERT I. FIELD, *HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE* (2007).

the federal Food and Drug Administration (FDA) that has created a sense of trust by the American population in approved drugs and devices, also plays a significant role. The history of that agency's growth as well as some of its problems and limitations also is traced. Various pieces of federal legislation apart from those relating to the programs already noted similarly have proven to be of significance. Thus, Field notes and describes the influence of the Hatch-Waxman Act in reshaping the market for generic drugs, the Orphan Drug Act that has led to medications for rare diseases, and government efforts through legislation to encourage clinical trials on the previously largely ignored pediatric population. Of course, federal tax policy and the entire patent system have both been extremely influential in nurturing private drug development.

Professor Field proceeds to offer two case studies of what he describes as "medical miracles" to demonstrate how the various aspects of government support for pharmaceutical research that he described have operated in practice. He paints a useful picture of both the development of statins to reduce cholesterol levels and prevent heart attacks, strokes, and other cardiology related problems and the development of Taxol, the best-selling cancer drug.

Field concludes by arguing that we must be cognizant of the fact that whatever we may say about the pharmaceutical industry and its successes, "the greatest producer of that knowledge by far has been the United States government." Without the government support he describes, the industry very likely would be "a shadow of its present self." He suggests that while we often think of a "free-market" private sector, that market in this industry does not exist because the government stepped aside. Rather, its success has very much been a product of government involvement throughout the industry.

The sole non-lawyer contribution to the contents of the Symposium was provided by Jeremy Sugarman, M.D., M.P.H., M.A., the Harvey M. Meyerhoff Professor of Bioethics and Medicine, professor of medicine, professor of Health Policy and Management, and deputy director for medicine of the Berman Institute of Bioethics at the Johns Hopkins University. Dr. Sugarman has particular expertise in the application of empirical methods and evidence-based standards for the evaluation and analysis of bioethical issues. He is the author of over 200 articles, reviews and book chapters. He has also edited or co-edited four books: *Beyond Consent: Seeking Justice in Research*;⁸ *Ethics of Research with Human Subjects: Selected Policies and Resources*;⁹ *20 Common Problems: Ethics in*

8. JEFFERY P. KAHN ET AL., *BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH* (1998).

9. JEREMY SUGARMAN, *ETHICS OF RESEARCH WITH HUMAN SUBJECTS: SELECTED POLICIES AND RESOURCES* (1998).

Primary Care,¹⁰ and *Methods in Medical Ethics*,¹¹ and serves as an editor or is on the editorial board of several academic journals.

Dr. Sugarman has served as senior policy and research analyst for the White House Advisory Committee on Human Radiation Experiments, consultant to the National Bioethics Advisory Commission, and Senior Advisor to the Presidential Commission for the Study of Bioethical Issues. He is an elected member of the American Society of Clinical Investigation and the Institute of Medicine, as well as a fellow of the American Association for the Advancement of Science, the American College of Physicians, and the Hastings Center.

Dr. Sugarman's essay, *Data, Policies and Conflicts of Interest in Research*,¹² begins by noting that little has been known about the process of disclosure of conflicts of interest (COI): specifically, what, when, where and how such information should be disclosed and the results of such disclosure on the willingness of potential participants to agree to participate in research. He proceeds to describe the Conflict of Interest Notification Study (COINS), on which he was the senior author.

Funded by NIH, the study reviewed COI policies and received input from a variety of stakeholders involved in COI, concluding that providing information to study coordinators about financial interests and offering education and training to them "would facilitate the disclosure of financial interests to potential research participants during the informed consent process." The study developed both model disclosure language and scales on which trust in medical researchers could be measured. Using an internet-based and phone-based survey and employing five different types of financial interest disclosures, the study concluded that the sole difference in trust between the five was that respondents "consistently viewed a researcher owning equity less favorably than a researcher receiving per capita payments." The study also determined that disclosure alone was an inadequate method of managing such conflicts, that other tools also needed to be used, and that, in particular, greater attention needed to be paid to the issue of how per capita payments for research were determined and used.

Study personnel then wanted to conduct a randomized study of the various empirically developed approaches to disclosing financial COI in an actual large scale clinical trial. Sugarman's article proceeds to describe some of the challenges they successfully faced. They then identified an institutional review board (IRB) willing to collaborate, but none of the

10. JEREMY SUGARMAN, *20 COMMON PROBLEMS: ETHICS IN PRIMARY CARE* (2000).

11. JEREMY SUGARMAN & DANIEL P. SULMASY, *METHODS IN MEDICAL ETHICS* (2d ed. 2010).

12. Jeremy Sugarman, *Data, Policies and Conflicts of Interest in Research*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 69 (2012).

industry sponsors they approached were willing to do so, citing “corporate fiduciary obligations,” and fears that drawing attention to the COI issue “was seen to be risky.” The effort then had to be abandoned. They also wished to conduct a study of non-financial conflicts of interest using a qualitative methodology, but were unable to obtain funding for it.

Kathleen M. Boozang, the final principal presenter at the Symposium, is Professor of Law at Seton Hall University in New Jersey. She also serves as its Associate Dean for Academic Advancement and Director of its Center for Religiously Affiliated Nonprofit Corporations and Professor of Law. She previously served as Vice Provost of the University. The founder of Seton Hall’s health law program, she has dedicated much of her career to nonprofit governance issues with a special focus on religiously-sponsored hospitals. In the last several years, however, she has expanded her research and teaching to explore the legal and policy issues related to the global pharmaceutical and medtech industries, many of which make New Jersey their headquarters.

Professor Boozang serves on the Board of Directors of the American Health Lawyers Association. She is a Fellow of The Hastings Center and the American Bar Foundation and a member of the American Law Institute and is a past editor-in-chief of the *Journal of Law, Medicine & Ethics*. She is past president of the American Society of Law, Medicine & Ethics and previously sat on the Advisory Board of the *Journal of Health Law*.

Some months after the 2012 Symposium took place in St. Louis, the country learned of the tragedy involving the New England Compounding Center (NECC), a Massachusetts pharmaceutical compounding operation that, rather than producing tailor-made drugs for individual patients as the law permitted, had become a significant drug maker. Its products were distributed in all fifty states and it supplied even prestigious hospitals with tainted batches of steroids used in spinal injections. The steroids now have been connected to an outbreak of fungal meningitis. A recent report indicated that the drugs killed some 32 people, infected 400 and exposed approximately 14,000 people. An account of that tragedy now sits as a prologue to Professor Boozang’s article, *Responsible Corporate Officer Doctrine: When is Falling Down on the Job a Crime?*¹³ It provides an unusually poignant example for the thesis of the piece.

Professor Boozang concludes the FDA’s strategic deployment of the Responsible Corporate Officer Doctrine (RCO) (sometimes known as the Park Doctrine) is quite appropriate, despite various attacks on its use. There are situations, she argues, that criminal responsibility should be placed on

13. Kathleen M. Boozang, *Responsible Corporate Officer Doctrine: When is Falling Down on the Job a Crime?*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 77 (2012).

the owners and top executives of such laboratory ventures, despite the fact that the government may be unable to establish criminal intent or precise knowledge of the conditions of the laboratories by those owners and top executives. Under the RCO Doctrine, the Department of Health and Human Services Office of the Inspector General (OIG) presumes that if there has been a RCO Doctrine conviction there is a presumption of federal health program debarment.

In addition to focusing on fraud and abuse in the drug and device manufacturing sector, she notes that government agencies also have been focusing on both the inappropriate use and harmful effects of some of the industry's products. But, as with many of the broader initiatives, she posits that the efforts there have largely been unsuccessful. Given that the government is the largest purchaser of these products in the United States, such unwarranted use has served to increase healthcare costs. In her article, Professor Boozang describes how the relationship between patent laws and the FDA approval process creates a variety of perverse marketing incentives. At the same time, laws governing company directors' exercise of their fiduciary duties have failed to persuade them to assure that the companies strictly follow the law. The standard of review for the duty of care for directors and officers has come to be one of gross negligence. This, coupled with the business judgment rule has resulted in an extraordinarily low risk of liability for breaches of their fiduciary duties of care and loyalty.

Moreover, given that the companies' products are so critical to the health and welfare of individuals throughout the world, it has become "almost impossible to criminally prosecute life science companies because convictions would bar them from contracting with most nations' governments, which would thereby deny their citizenry access to (potentially) essential medicines." Part of the problem, Boozang notes, is that consequently they have become "too big to nail," akin to the "too big to fail" theories posited with respect to the financial services industry a few years ago.

She proceeds to review the facts of two situations in which the RCO Doctrine was applied: that of Purdue Pharma's marketing of OxyContin and Synthes' marketing of bone cements used for spinal infusions. Both cases ultimately resulted in misdemeanor convictions and prison sentences for individual defendants. As a consequence, the FDA announced that it would increase its use of misdemeanor prosecutions against responsible corporate officials. These might well occur in circumstances which could result in debarment from participation in government health care programs in the face of arguments that such a result was inappropriate. The FDA published guidance for determining when a case would be forwarded to the Department of Justice for a Park Doctrine Prosecution, listing a variety of

factors to be considered. The OIG likewise has a guidance for when exclusion authority should be exercised.

Professor Boozang concludes by suggesting that it may be possible that the NECC adulterated steroid situation would be an appropriate one for the use of the Doctrine. She addresses a number of questions about the propriety of its application in various situations. Noting that the Doctrine should be and has been used sparingly, she concludes that a suitable key to minimizing the inappropriate and sometimes harmful effects of life science companies' behavior is for management and corporate officers to create a proper ethos within the company. When that does not occur, the absence of a finding of scienter by officers and directors ought not necessarily bar their criminal liability, nor consequent exclusions when it is clear that the environment they establish fails to meet the necessary standard.

Marc A. Rodwin is Professor of Law at Suffolk University Law School, after having previously taught at Indiana, Tufts, and Brandeis Universities. He is the author of *Conflicts of Interest and the Future of Medicine: The United States, France and Japan*¹⁴ and *Medicine, Money & Morals: Physicians' Conflicts of Interest*.¹⁵

Professor Rodwin has been a visiting faculty member or scholar at several universities in France and Japan, and has lectured on issues related to conflicts of interest in seven foreign countries and at more than a half dozen American universities. His research has been supported by the German Marshal Fund, and the Robert Wood Johnson Foundation among others, and he has held a Pew Health Policy Doctoral Fellowship as well as a Fulbright Commission Fellowship.

Rodwin's contribution to the Symposium, *Independent Clinical Trials that Test Drugs: The Neglected Reform*,¹⁶ posits that the current role played by drug manufacturers in the conduct of clinical trials amounts to a significant COI that must be remedied. This is due to the extent to which they design and control trials to test safety and efficacy in an effort to have the Food and Drug Administration (FDA) approve the marketing of the drug. He argues that existing "regulation . . . [has] failed to eliminate bias, flawed practice and fraud," despite efforts by public officials to remedy the situation. Instead, as his title suggests, he argues for a new paradigm which would entirely eliminate pharmaceutical influence in the conduct of such trials.

14. MARC A. RODWIN, *CONFLICTS OF INTEREST AND THE FUTURE OF MEDICINE: THE UNITED STATES, FRANCE AND JAPAN* (2001).

15. MARC A. RODWIN, *MEDICINE, MONEY & MORALS: PHYSICIANS' CONFLICTS OF INTEREST* (1995).

16. Marc A. Rodwin, *Independent Clinical Trials that Test Drugs: The Neglected Reform*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 113 (2012).

In the introductory section, the article reviews a half dozen options available for the way these trials are and can be constructed on a continuum between maximum manufacturer control to maximum government control, and the extent to which each addresses COIs. He specifically details how each of them could be altered in an effort to increase control over such conflicts. He proceeds to provide a historical context for U.S. drug regulation, particularly in the very minimal way as it relates to COI. These included a variety of milestones, often precipitated by scandals: prohibition of marketing of dangerous or improperly labeled products, requirements that drugs be shown to be effective as well as safe, other restrictions on promotional materials, increased restrictions and prescriptions on how trials would be conducted including the use of phased testing, and requirements on how approved medications would be manufactured and marketing would be approved.

Rodwin then proceeds to discuss relatively current proposals for entirely independent testing of drugs through the use of a new institute within NIH or some other government center to conduct clinical trials. He describes a variety of studies that have emerged demonstrating how company-funded studies produce publication biases and efforts by drug firms to prohibit researchers from publishing studies showing unfavorable results. Studies also document how study design, subject selection, methodology, questions posed, and results reported indicate further biases. He also details a variety of efforts both by Congress and the FDA itself between 1960 and 1980 to improve the situation. Ultimately, the conclusion that must be reached after reviewing these efforts is that reform should begin with independent testing of new drug applications. Rodwin notes that this is the most feasible solution because the FDA seemingly already has the power to modify its existing regulations in this area. Another proposal mentioned, requiring drug firms to finance post-marketing studies and ordering the withdrawal of approved drugs for failing to do so adequately, would require an expansion of existing FDA authority. Similarly, the FDA has no authority to require independent testing of approved drugs when a sponsor designs a trial to show that a drug is more effective, safer, or cost-effective than competing drugs, non-drug therapies, or an approved drug's possible benefits for new uses.

During the Symposium, a number of respondents provided commentary on the principal presentations. Efthimios Parasidis, J.D., M.B.E., Assistant Professor of Law at Saint Louis University, responded to Professor Field's paper. Both James DuBois, Ph.D, D.Sc., the Hubert Mäder Endowed Professor and Director of Bander Center for Medical Business Ethics and The Albert Gnaegi Center for Health Care Ethics at Saint Louis University, and Raymond C. Tait, Ph.D., Vice President for Research at Saint Louis University and Professor in its Department of Neurology & Psychiatry, addressed Jeremy Sugarman's talk. John Munich, J.D. a partner in the law

firm of Stinson Morrison Hecker LLP, who previously served as an Assistant United States Attorney for the District of Columbia (1991-93) and later as Deputy Attorney General for the State of Missouri, prosecuting healthcare fraud cases, replied to Kathleen Boozang's presentation, as did Heather McCollum, J.D., M.H.A., P.M.P., a Manager at Polaris Management Partners, a consulting firm for life sciences companies. Stuart Kim, J.D., Senior Regulatory Counsel, Pharmaceuticals at Covidien, a medical device and pharmaceutical manufacturing company, and I responded to Marc Rodwin's paper.

Those who attended the Symposium learned a great deal from the presentations. The editors of this *Journal* and I trust that you will enjoy the additional unique contributions of the fully fleshed out papers presented here.