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Institutional Corruption and the Pharmaceutical Policy

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INTRODUCTION

Institutional Corruption and the Pharmaceutical Policy

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Most institutions have a purpose, as seen by both by the members of the institution and by the rest of the society. Such is the case with the practice of medicine and the use of prescription drugs. Pharmaceutical firms develop and market medications used to cure or mitigate illness, prevent or reduce risk of medical problems, relieve symptoms, or reduce pain and suffering. Yet, today, the goals of pharmaceutical policy and medical practice are often undermined due to *institutional corruption* — that is, widespread or systemic practices, usually legal, that undermine an institution's objectives or integrity. Institutional corruption displaces some goals and compromises the attainment of others.

In this special issue of the *Journal of Law, Medicine & Ethics*, a symposium of authors investigates the corruption of pharmaceutical policy, each taking a different look at the sources of corruption, how it occurs, and what is corrupted. Institutional corruption can result from improper dependency (for money or for information), from financial incentives that are at odds with the needs of patients and public health, from market failure, or from marketing that has compromised medical practice.

We will see that the pharmaceutical industry's own purposes are often undermined. In addition, pharmaceutical industry funding of election campaigns and lobbying skews the legislative process that sets pharmaceutical policy. Moreover, certain practices have

corrupted medical research, the production of medical knowledge, the practice of medicine, drug safety, and the Food and Drug Administration's oversight of pharmaceutical marketing.

Pharmaceutical firms have found ways to influence — and often corrupt — medical research and publications, and key firms and organizations that affect physicians' clinical choices. These include: professional medical associations, continuing medical education programs, online professional networking groups, hospital administrators, insurers, organizations that create practice guidelines and diagnostic treatment categories, and patient advocacy organizations. These institutions in turn influence physicians in general and particularly influential physicians known as *key opinion leaders*.

As a result, practitioners may think they are using reliable information to engage in sound medical practice, while they are actually relying on misleading information; they may then prescribe drugs that are unnecessary or harmful to patients, or more costly than equivalent medications. At the same time, patients and the public may believe that patient advocacy organizations effectively represent their interests, while these organizations actually neglect those interests.

Overview of the Articles

The symposium begins with two articles on the concept of institutional corruption. Lawrence Lessig offers a careful definition and explanation of the idea ("Institutional Corruption Defined"). He is the right person to explain the term because his writing on the subject (particularly his book, *Republic Lost: How Money Corrupts Congress — and a Plan to Stop It*) and Dennis Thompson's book (*Ethics in Congress: From Indi-*

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vidual to Institutional Corruption), have inspired the work of the authors in this symposium.¹ Gregg Fields explores how Lessig and Thompson have analyzed institutional corruption of Congress and other governmental institutions and how their insights apply to pharmaceutical policy (“Parallel Problems: Applying Institutional Corruption Analysis of Congress to Big Pharma”). He shows that making analogies between the corruption of different institutions must be done carefully.

targeting campaign contributions to influential legislators and allies. In this way, the industry displaces the public’s voice in developing pharmaceutical policy. Jorgensen suggests that it is possible for citizens to mobilize, expand the scope of political conflict, and bring about significant change, although given the pharmaceutical industry’s economic and political resources, this will be very difficult. To illuminate what is at stake, he proposes a research agenda to uncover the mechanism of pharmaceutical industry influence.

Practitioners may think they are using reliable information to engage in sound medical practice while actually relying on misleading information and therefore prescribe drugs that are unnecessary or harmful to patients, or more costly than equivalent medications. At the same time, patients and the public may believe that patient advocacy organizations effectively represent their interests while these organizations actually neglect their interests.

With the concept of institutional corruption explained, the rest of the articles are organized into five topics: (1) systemic problems, (2) medical research, (3) medical knowledge and practice, (4) marketing, and (5) patient advocacy organizations. Many of the articles, however, address more than one topic; some important recurring themes will be discussed after the overview.

Systemic Problems

Certain problems in pharmaceutical policy are systemic. The source of the problem may be corruption of the legislative process, the production of medical knowledge, the structure of markets, economic incentives for firms, or a variety of other areas. Several articles in this symposium address pharmaceutical policy’s systemic problems. Solving these problems requires systemic reforms.

Paul Jorgensen asks why Congress does not pass legislation that would lower drug prices and improve public health (there have been several such proposals), but does enact laws that protect the profits of the pharmaceutical industry. He probes the links between current policy and the pharmaceutical industry’s political action through financing political campaigns and lobbying (“Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda”).² Jorgensen’s thesis is that the pharmaceutical industry has convinced legislators to define policy problems in ways that advance its interests. The industry reinforces this policy framework by selectively providing information to legislators, subsidizing their work, and

Turning from the political-legal context to the market in which firms operate, we find other systemic problems. Marc-André Gagnon explains that the current architecture of pharmaceutical markets has created a misalignment of financial incentives and public health that is a central cause of harmful practices (“Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health”).³ Firms have strong financial incentives to develop so-called *me-too drugs* — products which are minor variations of existing drugs — and to heavily market them in ways that exaggerate their benefits and fail to reveal their full risks; this is much safer than developing truly new drugs but is still enormously profitable. And again, it is not a special feature of any particular company, but a feature of the system in which they all operate. Gagnon explores three possible solutions to address these misaligned incentives: (1) increased financial penalties and criminal prosecution for illegal conduct; (2) taxes to discourage inappropriate promotion and other undesirable corporate activity; and (3) new forms of drug pricing, such as (a) pricing drugs based on their value as measured by their effects on health outcomes and (b) basing the price of a new drug on the price of a drug that produces comparable therapeutic benefits (a method known as reference-point drug pricing).

My own article in this section points out that the public improperly relies on pharmaceutical firms over the entire lifespan of a drug, from development of new drugs to post-marketing pharmacovigilance (“Five Un-Easy Pieces of Pharmaceutical Policy Reform”).⁴

The public improperly depends on drug firms to: (1) set priorities on drug research and development; (2) conduct clinical trials to test whether drugs are safe and effective; (3) decide what clinical trial data to disclose to the public; (4) monitor post-marketing drug safety; and (5) supply product information to physicians and to finance continuing medical education and other professional activities. Improper dependence on pharmaceutical firms in these areas compromises the integrity of pharmaceutical policy and should be addressed by system-wide reforms.

Donald W. Light, Joel Lexchin, and Jonathan J. Darrow argue that the pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they are tested, and how medical knowledge is created (“Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs”).⁵ Like Gagnon, they note the powerful business incentive to devote R&D to me-too drugs and then promote them to the hilt. Meanwhile, the industry’s political influence has long compromised both the legislation meant to protect the public from unsafe drugs and the role of physicians as independent advisors to patients. Starting in 1992, the Prescription Drug User Fee Acts made the Food and Drug Administration (FDA) dependent on funding from pharmaceutical firms, deepening its regulatory capture. Industry demanded more rapid reviews of applications to market new drugs and that resulted in what the authors call an epidemic of insufficiently tested drugs, many of which prove to have harmful and even fatal side effects that are undiscovered until they are in general use. To address these systemic problems, Light, Lexchin, and Darrow suggest measures to discourage R&D on drugs with few or no new clinical benefits; full public funding for all FDA activities; having a public agency choose who will conduct clinical trials to test new drugs rather than allowing manufacturers to control the process; the creation of a National Drug Safety Board; and independent FDA leadership.

Jennifer Miller argues for another type of systemic reform that taps market forces (“From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices through Accreditation, Certification, and Rating”).⁶ She suggests that we can develop accreditation, certification, or rating systems that reveal the ethical performance of the drug firms to purchasers, investors, employees, and regulators. Market forces would then create incentives for drug firms to improve their ethical conduct. Miller suggests that ratings of drug firms focus on four areas of stakeholder concern: (1) clinical trial design and management, (2) dissemination of clinical trial results, (3)

marketing practices, and (4) the accessibility of medicines. She also explains how system-level issues such as conflicts of interests and revolving door practices can compromise accreditation, certification, and rating systems.

Medical Research

Research on the effects of a new drug determines whether the FDA approves it or not. Subsequent research sometimes determines whether the FDA withdraws that approval. Physicians rely on both forms of research when prescribing drugs and when they develop practice guidelines; insurers rely on the same research to decide whether and how much to pay for a drug; and hospitals rely on it to decide whether to include a drug in their formularies. It is no small matter, then, that institutional corruption often compromises this research. Three articles in our symposium examine how such corruption can occur and what to do about it.

The standout example of institutional corruption in our time may have been the corruption of the auditing firms and rating agencies that should have nipped the subprime mortgage disaster in the bud rather than play a key role in bringing it to pass. One source of corruption was that financial firms had an incentive to manipulate data. Another was that auditors and rating agencies lacked incentives to detect the manipulation and sometimes even were financially dependent on the institutions they were supposed to oversee. With this in mind, Abigail Brown asks if the experience of firms that manipulated financial data yields lessons for developing policies to counter the manipulation of clinical research data by pharmaceutical firms and affiliated researchers (“Understanding Pharmaceutical Research Manipulation in the Context of Accounting Manipulation”).⁷

Brown recalls that several scandals ensued when pharmaceutical firms manipulated data from clinical trials that test their drugs. Company managers have strong financial incentives (in the form of stock options and bonuses) to get drugs approved and widely marketed — the quality of the drug being somewhat beside the point. The risk of manipulation multiplies because standards for how to report and interpret clinical data are ambiguous; often, so is the test data itself. (Genuine scientific uncertainties are one reason why individual and institutional honesty are so important.) In theory, manipulated data would have to pass through a tough gauntlet consisting of FDA reviewers and the journals that publish results of clinical trials. However, these guardians, like the financial auditors, often miss — or let pass — what they should catch. Brown suggests three ways to reduce the risk of data bias and

manipulating. To reduce publication bias, journals should review research protocols before a clinical trial starts and commit to publishing the protocol and findings whether the results are positive or negative. We should also encourage whistleblowers aware of misconduct to avail themselves of bounties offered by the Dodd-Frank Act. Finally, the government should subsidize insurance for pharmaceutical firms to cover the cost of clinical trials when the results are negative and the firm does not obtain FDA approval to market their drug.

Yet financial incentives are not always the source of the problem, according to Yuval Feldman, Rebecca Gauthier, and Troy Schuler, who argue that we need different strategies to deter unethical or illegal conduct depending on the context (“Curbing Misconduct in the Pharmaceutical Industry: Insights from Behavioral Ethics and the Behavioral Approach to Law”).⁸ Contrary to the assumptions underlying the dominant rational actor model, not all misconduct is the product of intentional rational behaviour designed to maximize profits. Some is due to automatic, intuitive, and unconscious decisions as a result of individual bias or blind spots, particularly among scientific researchers, who are typically motivated more by prestige and peer recognition than by financial gain.

When the research misconduct is motivated by good intentions, or is due to subconscious bias, the threat of sanctions is often ineffective. Sanctions may drive unethical conduct underground, making it harder to detect. Setting fines may make people believe that they are entitled to engage in the conduct if they pay the price. Nor is requiring disclosure of conflicts of interest a panacea because it can make people feel they have a moral license to act in their self-interest. What then is to be done? Feldman, Gauthier, and Schuler suggest that we change the work environment to make it harder for people to do wrong while believing they are acting ethically. Sometimes we should make researchers take explicit responsibility for their actions and decisions so that they cannot morally disengage. In other situations, we should delegate decisions about how to handle ambiguous results to independent parties.

While unethical behavior may stem from failures in individual morality or psychological blind spots, Garry C. Gray explains that they are performed through social interactions among individuals and groups. (“The Ethics of Pharmaceutical Research Funding: A Social Organization Approach”).⁹ The rise of pharmaceutical-firm-funded university research changes the social context of research, and along with it, the opportunities and constraints on researchers. Gray uses a case study of a medical school professor’s first

experience with pharmaceutical company-sponsored research in order to examine how funding arrangements can constrain research integrity. The case study reveals that there are conflicts between the norms of commercial firms and universities. Moreover, corporate funding can make researchers dependent on their sponsor and lead them to learn new ways behave and conduct research. Gray finds that individual researchers have to renegotiate concepts such as *academic independence*, and *research integrity*, that they previously took for granted. He argues that in order to counter institutional corruption and ensure the integrity of research, we need to examine the social organization of behavioral ethics among scientific researchers.

Medical Knowledge and Practice

It takes work for medical research — what scientists know — to become medical knowledge and practice — what doctors know and do. The path is long and indirect, and there are many opportunities for institutional corruption along the way.

Drug companies work hard to spread what they deem to be medical knowledge to help market their products. But they also play a role in creating that knowledge in a way that is biased toward their interests. Sergio Sismondo examines how pharmaceutical companies use physicians who are *key opinion leaders* (KOLs) to market drugs and how that affects the information about drugs available to physicians. (“Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won’t Cast Light on”).¹⁰ Firms develop close relations with KOLs to influence the information these well-regarded experts disseminate to their peers through talks, continuing education, medical journals, and media reports. A small number of drug firms thus have inordinate influence over how medical knowledge is produced, circulated, and consumed, and thereby influence the decisions made by physicians. Sismondo notes that the Physician Payment Sunshine Act aims to mitigate industry influence by disclosing pharmaceutical firm payments and gifts to physicians, but it does not reduce the pharmaceutical industry’s disproportionate influence over the production of knowledge. He therefore evaluates proposals to change the political economy of medical knowledge by separating pharmaceutical research and development from pharmaceutical marketing. One proposal would create an independent government agency to conduct clinical trials. Another proposal would divide the research and marketing functions that drug firms perform today between two types of firm: one would engage only in research and development and the other would purchase rights to manufacture and market drugs that

the FDA approves. A third, more modest option, is to restrict clinicians and researchers from giving talks (or engaging in other work) to market drugs.

Lisa Cosgrove and Emily Wheeler examine a disturbing instance of pharmaceutical company influence over medical knowledge: the creation of psychiatric diagnostic categories and treatment guidelines (“Drug Firms, Codification of Diagnostic Categories, and Bias in Clinical Guidelines”).¹¹ They explain that

because of flawed oversight of drug prescribing. Typical reform proposals, such as increased sanctions for manufacturers, might make the practice somewhat less common, but do not address its main causes or consequences. We need to track off-label prescriptions in order to know which patients are affected, to evaluate the risks and benefits, and to know when manufacturers are promoting the practice. Reimbursement rules should be changed so that manufacturers cannot

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the American Psychiatric Association (APA) and leading physician researchers have become financially dependant on drug firms. The APA receives millions of dollars from pharmaceutical companies for advertisements and grants. It publishes the *Diagnostic and Statistical Manual for Mental Disorders (DSM-5)*, which will generate millions this year alone. It is no coincidence that this manual relies on a biological disease model of mental illness that is not well supported by the evidence but that does promote the commercial agenda of drug firms. Many researchers have financial ties to drug firms even as they conduct clinical trials on those firms’ psychiatric medications and even as they develop the *DSM* categories and draft the practice guidelines that call for the use of these drugs and guarantee that insurers will pay for them. Are all these physicians on the take?¹² No. But conflicts of interest compromise the judgment of physicians who conduct and interpret studies, develop diagnostic categories, and draft practice guidelines. The authors conclude that medical schools need to educate clinicians about the bias in scientific literature to help address these problems and that organized psychiatry needs to wean itself from dependency on industry funding.

My own article in this section examines drug prescribing that is not supported by medical knowledge (“Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use”).¹³ Off-label drug use — prescribing drugs for uses that the FDA has not approved — can sometimes be justified but is typically not supported by substantial evidence of effectiveness or safety. It is, however, profitable for manufacturers. The practice thrives because pharmaceutical firms ignore the problem or encourage the practice and

profit from off-label sales. When off-label sales pass a critical threshold, manufacturers should also be required to pay for independent testing of the safety and effectiveness of off-label drug uses and for the FDA to review the evidence. Manufacturers should also finance, under FDA supervision, programs designed to warn physicians and the public about the risks of off-label drug use.

Marketing

In an ideal world, physicians would prescribe drugs based on knowledge of their effects, and not primarily due to pharmaceutical promotion. However, proposals to ban pharmaceutical marketing altogether are not likely to get far because the Supreme Court has held that the First Amendment protects advertising and other marketing as commercial speech. Moreover, since manufacturers sell drugs in a market economy, promotion is inevitable and some promotion is appropriate. Nevertheless, marketing is a source of institutional corruption — it turns institutions away from their purpose — when it manages to pass off false or misleading information as reliable medical knowledge and when it co-opts physicians and researchers into marketing activities.

A big part of the problem is that the medical community does not realize how outclassed it is. Sunita Sah and Adriane Fugh-Berman explain that most physicians consider themselves to be rational and objective, and consequently fail to recognize how susceptible they are to commercial influences due to self-serving bias, rationalization and cognitive dissonance (“Physicians under the Influence: Social Psychology and Industry Marketing Strategies”).¹⁴ Pharmaceutical

firms suffer from no such naivety. They are well aware of these human foibles and often apply principles of social psychology to influence physicians. The authors illustrate six psychological principles that pharmaceutical firms use to influence physicians and explain that a commitment to ethical behavior cannot eliminate subconscious bias (although most of us think it can, at least in our own case). Physicians need to be armed to resist industry influence. The authors advocate educating medical school faculty and students about the social psychology underlying manipulative marketing. They also argue that medical institutions should develop policies to deter physicians from accepting pharmaceutical firm gifts and to end the medical profession's improper dependence on industry funding, which most physicians do not find particularly disturbing. What is needed is not only new rules, but also new social norms within the medical profession.

Amy Snow Landa and Carl Elliott examine a new trend: online networks that enable doctors to share their concerns and ask colleagues for information in a secure environment without paying a subscription fee or being inundated by advertisements ("From Community to Commodity: The Ethics of Pharma-Funded Social Networking Sites for Physicians").¹⁵ Sounds wonderful, doesn't it? But the two most popular sites are also marketing tools for firms that want to track what physicians are thinking. One of those sites, Sermo — with over 100,000 physicians participating — also allows firms to disseminate messages to the physicians and to cultivate key opinion leaders. Sermo sells this access to clients that include global pharmaceutical companies, market research and consulting firms, and investors such as hedge funds. For a fee, these clients have access to tools for monitoring, analyzing, and soliciting physicians' opinions and are allowed to conduct awareness campaigns aimed at influencing physician sentiment about specific drugs and medical devices. Participating physicians may know this is happening, but here again, feel themselves immune to any pernicious influence. Landa and Elliott argue that the dual nature of these sites undermines their integrity as forums for exchanging medical opinion.

Patient Advocates

A comparatively new component of the U.S. health care system is *patient voice*. Up until the mid-20th century, medical care was dominated by physicians and other experts who were assumed to know and do what was best for their patients.¹⁶ But this changed as patients, research subjects, people with disabilities, women, and consumers began to collectively assert

their rights and seek greater control over decisions that affected their lives. One result has been the development of self-help groups, affinity groups, and associations through which patients and medical consumers advocate for their own interests. A key problem now is how to ensure that these groups represent the patients that they purport to serve; or in other words, how to protect these institutions from institutional corruption.

Susannah L. Rose finds the corruption may already be under way ("Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness").¹⁷ Many patient advocacy organizations (PAOs) accept funding from pharmaceutical firms in order to finance their activities, but dependency on that funding creates conflicts of interest that can bias PAO advocacy toward the interests of pharmaceutical donors. Rose notes that institutions are often interested in ensuring that they are trusted, but says that instead they need to focus on developing practices and policies to ensure that they remain trustworthy — in short, that they deserve to be trusted. PAOs could accomplish this by disclosing conflicts of interest, using conflict-of-interest oversight committees, separating the work of their fundraisers from the work of their managers and policymakers, limiting the amount of funding they accept from drug firms, and not allowing industry donors to specify how they will use the contributions they do accept.

Key Themes in the Articles

One of the benefits of looking at a subject from multiple perspectives is that underlying features reveal themselves through recurring themes. In the 16 articles that make up this symposium, you will be able to spot at least four such themes: (1) improper dependencies as a source of corruption; (2) misalignment of incentives and markets as a source of corruption; (3) marketing as a distortion of medical practice and ethics; and (4) the limits of financial disclosure as a remedy.

Improper Dependencies as a Source of Corruption

Key actors and organizations accommodate themselves to pharmaceutical firms that help pay their bills. Paul Jorgensen shows that legislators have become dependent on drug company campaign contributions and other resources and, rather than representing citizens, legislation often serve the interests of pharmaceutical firms.¹⁸ In a similar vein, Donald W. Light, Joel Lexchin, and Jonathan J. Darrow explain that the Prescription Drug User Fee Act makes the FDA financially dependent on industry user fees from reviewing

applications to market new drugs.¹⁹ As a result, the FDA focuses on rapidly reviewing new drug applications which displaces the FDA's original regulatory agenda: ensuring drug safety.

My overview of pharmaceutical policy reveals that improper dependence on drug firms systematically slants important policy choices in five key areas, start-

for drug firms are often misaligned with public policy goals so that firms can prosper without advancing the public's health. The articles by Donald W. Light, Joel Lexchin, and Jonathan J. Darrow and by Marc-André Gagnon, as well as my own article on pharmaceutical policy, all note that the pharmaceutical industry has a business model that relies on developing and aggres-

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ing with the development of new drugs and continuing through the monitoring of patient safety after drugs are marketed.²⁰ Others focus on dependence related to the production of knowledge and research. Sergio Sismondo argues that physicians and the public have become dependent on drug firms for the production of knowledge about drugs.²¹ Abigail Brown shows that dependence on drug firms to honestly report clinical trial results when they have incentives to manipulate data creates a moral hazard that needs to be addressed.²² Garry C. Gray's case study illustrates how dependence on corporate funding for research can challenge scientific norms of independence and research integrity.²³ Lisa Cosgrove and Emily Wheeler show that organized psychiatry has become financially dependent on pharmaceutical industry funding and that this has corrupted the development of psychiatric diagnostic categories and practice guidelines.²⁴

Pharmaceutical firms also create dependence to market their products. Sunita Sah and Adriane Fugh-Berman explore how gifts make physicians psychologically as well as financially dependent on pharmaceutical firms so that physicians will reciprocate by prescribing a particular drug.²⁵ Amy Snow Landa and Carl Elliott show that physician depends on online networks that are also used for marketing.²⁶ And it is not only physicians who can become dependent on pharmaceutical firm funding. Susannah L. Rose explores how patient advocacy group are financially dependent on pharmaceutical firms, which can bias an advocacy organization's policy stance and the services it provides.²⁷

Misalignment of Incentives and Markets as a Source of Corruption

In a market economy, firms are supposed to serve the public by responding to market demand and financial incentives. But in fact, the financial incentives

sively marketing incremental modifications of existing drugs (me-too drugs) that are not only more expensive without providing much more — or any more — benefit, but in some cases are even harmful.²⁸ In other words, current market incentives do not advance public health goals. My article on off-label uses shows that firms have a strong incentive to market drugs for uses that the FDA has not approved, even when there is a lack of significant evidence that such uses are safe or effective.²⁹ Misaligned incentives can encourage research fraud. Abigail Brown notes that the incentive for firms and managers to get drugs approved by the FDA can be so strong that it encourages manipulating research data.³⁰ However, as Yuval Feldman, Rebecca Gauthier, and Troy Schuler point out, not all research misconduct is due to financial incentives, so financial penalties cannot be our only deterrent.³¹

If misalignment of incentives is the root of the problem, we should change those incentives. Jennifer E. Miller suggests that we can improve the alignment between pharmaceutical firm incentives for profit and ethical corporate conduct through the use of accreditation, certification, and rating systems that evaluate corporate ethical performance.³² Public rating of a firm's ethical performance, she argues, can affect what consumers choose to buy, in which firms individuals invest, and where potential employees choose to work, and that will create incentives for firms to act ethically. And Gagnon suggests that changes in the way we reimburse drug firms can create stronger incentives to develop truly innovative drugs.

Marketing as a Source of Distortions of Medical Practice and Ethics

Several articles explain how drug marketing can corrupt medical practice, turning it against the ends of medicine. Sunita Sah and Adriane Fugh-Berman explore how sophisticated pharmaceutical market-

ing draws on knowledge of psychology and social science to sway physicians' decisions.³³ Sergio Sismondo examines how drug firms boost sales by targeting key opinion leaders and use them to control information.³⁴ My article on off-label prescribing shows that drug firms have an incentive to market drugs for uses that conflict with good medical practice.³⁵ Amy Snow Landa and Carl Elliott examine the use of online physician networks as marketing tools.³⁶ Articles by Marc-André Gagnon³⁷ and by Donald W. Light, Joel Lexchin, and Jonathan J. Darrow find that marketing priorities distort decisions about what R&D to conduct.³⁸

The Limits of Financial Disclosure as a Remedy

The conventional wisdom is that disclosure of financial ties is always desirable and is often sufficient to cure conflicts of interest, even though scholars have been pointing out the limits of disclosure for 25 years.³⁹ Several symposium authors discuss problems with disclosure. Sergio Sismondo argues that the Sunshine Act, which requires pharmaceutical firms to report payment and gifts to physicians, does not address key problems.⁴⁰ Lisa Cosgrove and Emily Wheeler say that disclosure of conflicts of interest is insufficient because it does not eliminate the bias created by those conflicts.⁴¹ Yuval Feldman, Rebecca Gauthier, and Troy Schuler argue that disclosure can make matters worse by creating moral license for individuals to pursue their self-interest even when it is inappropriate.⁴² Susannah L. Rose finds that disclosure of drug company funding to patient advocacy organizations can be beneficial, but she acknowledges its limitations.⁴³

The Path to Reform

No doubt some readers — maybe even many — will disagree with the analysis in a few of these articles or in the conclusions that they draw. Yet I hope that these articles stimulate your thinking, and provoke those of you who disagree with our proposals to think of something better.

This symposium makes clear the need for careful thinking about how to improve the situation. Yet, one of the hallmarks of the kinds of dependency we describe is that proposed reforms will meet with opposition from all sides. Pharmaceutical companies will fight hard for their right to spread their wealth around to their own benefit, and so will the many institutions that rely on their share of that wealth. So many of our suggestions for reform will not be implemented any time soon, however helpful they might be if they were.

Light, Lexchin, and Darrow observe that none of their reform proposals will be implemented “until third-party payers, politicians, and the people decide

they want to stop paying so much for so many drugs of little value and then for treating the millions harmed by those drugs.” I hope that our collective efforts will publicize these issues and convince people that it is time to stop the institutional corruption of pharmaceutical policy.

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References

1. L. Lessig, *Republic, Lost: How Money Corrupts Congress – and a Plan to Stop It* (New York: Twelve, 2011); D. F. Thompson, *Ethics in Congress: From Individual to Institutional Corruption* (Washington, D.C.: The Brookings Institution, 1995); D. F. Thompson, “Two Concepts of Corruption: Making Campaigns Safe for Democracy,” *George Washington Law Review* 73, no. 5 & 6 (2005): 1036-1069. For other work related to institutional corruption, see the web page of the Lab at the Edmond J. Safra Center for Ethics, which has links to working papers, blogs, and information about research of Lab Fellows: <<http://www.ethics.harvard.edu/lab>> (last visited July 29, 2013).
2. P. D. Jorgensen, “Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 553-555.
3. M.-A. Gagnon, “Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 571-580.
4. M. A. Rodwin, “Five Un-Easy Pieces to Pharmaceutical Policy Reform,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 581-589.
5. D. W. Light, J. Lexchin, J. J. Darrow, “Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 590-600.
6. J. E. Miller, “From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices through Accreditation, Certification, & Rating,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 601-610.
7. A. Brown, “Understanding Pharmaceutical Research Manipulation in the Context of Accounting Manipulation,” *Journal of Law, Medicine, & Ethics* 41, no. 3 (2013): 611-619.
8. Y. Feldman, R. Gauthier, and T. Schuler, “Curbing Misconduct in the Pharmaceutical Industry: Insights from Behavioral Ethics and the Behavioral Approach to Law,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 620-628.
9. G. C. Gray, “The Ethics of Pharmaceutical Research Funding: A Social Organization Approach,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 629-634.
10. S. Sismondo, “Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 635-643.
11. L. Cosgrove and E. Wheeler, “Drug Firms, Codification of Diagnostic Categories and Bias in Clinical Guidelines,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 644-653.
12. J. Kassirer, *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health* (Oxford University Press, 2005).
13. M. A. Rodwin, “Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use,” *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 654-664.

14. S. Sah and A. Fugh-Berman, "Physicians under the Influence: Social Psychology and Industry Marketing Strategies," *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 665-672.
 15. A. S. Landa and C. Elliott, "From Community to Commodity: The Ethics of Pharma-Funded Social Networking Sites for Physicians," *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 673-679.
 16. M. A. Rodwin, "Patient Accountability and Quality of Care: Lessons from Medical Consumerism and the Patients' Rights, Women's Health and Disability Rights Movements," *American Journal of Law and Medicine* 20, nos. 1 & 2 (1994): 147-167; M. A. Rodwin, "Exit and Voice in American Health Care," *Michigan Journal of Law Reform* 32, no. 4 (1999): 1041-1067.
 17. S. L. Rose, "Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness," *Journal of Law, Medicine & Ethics* 41, no. 3 (2013): 680-687.
 18. P. D. Jorgensen, "Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda," *Journal of Law, Medicine & Ethics* 14, no. 3 (2013): 561-570.
 19. See Light, Lexchin, and Darrow, *supra* note 5.
 20. See Rodwin, *supra* note 4.
 21. See Sismondo, *supra* note 10.
 22. See Brown, *supra* note 7.
 23. See Gray, *supra* note 9.
 24. See Cosgrove and Wheeler, *supra* note 11.
 25. See Sah and Fugh-Berman, *supra* note 14.
 26. See Landa and Elliott, *supra* note 15.
 27. See Rose, *supra* note 17.
 28. See Light, Lexchin, and Darrow, *supra* note 5; Gagnon, *supra* note 3; Rodwin, *supra* note 4.
 29. See Rodwin, *supra* note 13.
 30. See Brown, *supra* note 7.
 31. See Feldman, Gauthier, and Schuler, *supra* note 8.
 32. See Miller, *supra* note 6.
 33. See Sah and Fugh-Berman, *supra* note 14.
 34. See Sismondo, *supra* note 10.
 35. See Rodwin, *supra* note 13.
 36. See Landa and Elliott, *supra* note 15.
 37. See Gagnon, *supra* note 3.
 38. See Light, Lexchin, and Darrow, *supra* note 5.
 39. M. A. Rodwin, "Conflicts of Interest: The Limitations of Disclosure," *New England Journal of Medicine* 321, no. 20 (1989): 1405-1408. See also, M. A. Rodwin, *Medicine, Money and Morals: Physicians' Conflicts of Interest* (New York: Oxford University Press, 1993): at 213-219; M. A. Rodwin, *Conflicts of Interest and the Future of Medicine: The United States, France and Japan* (New York: Oxford University Press, 2011): at 214-219.
 40. See Sismondo, *supra* note 10.
 41. See Cosgrove and Wheeler, *supra* note 11.
 42. See Feldman, Gauthier, and Schuler, *supra* note 8.
 43. See Rose, *supra* note 17.
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