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Symposium Articles

SYMPOSIUM

Dangerous Liaisons? Industry Relations with Health Professionals

Guest Edited by
Robert M. Sade

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*Letter from
the Editor*

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INTRODUCTION: Dangerous Liaisons? Industry Relations with Health Professionals

Robert M. Sade

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Altruism and Self Interest in Medical Decision Making

Paul H. Rubin

We seem to prefer that medicine and medical care be provided through altruistic motives. Even the pharmaceutical industry justifies its behavior in terms of altruistic purposes. But economists have known since Adam Smith that self-interested behavior can create large and growing social benefits. This is true for medical care as well as for other goods. First, I consider specifically the case of pharmaceutical promotion, both to physicians and to consumers. I argue that such promotion is highly beneficial to patients and leads to health improvements. I consider some criticisms of promotion, and show that they are misguided. I then provide some evolutionary explanations for our erroneous beliefs about medical care.

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Better Regulation of Industry- Sponsored Clinical Trials Is Long Overdue

Matthew Wynia and David Boren

Regulating clinical trials for testing new drugs is fraught with risk. Misregulation can slow development of innovative and useful new drugs, but in other ways misregulation can foster trials that are inefficient and unethical, driven by commercial rather than scientific ends, and that can harm patients. In this paper, we argue not for more but for better regulation, based on the goal of rapidly producing innovative and safe products that represent significant advances in medical care. Data on industry-funded, late-stage clinical trials demonstrate an urgent need for dramatic changes in how these trials are designed, conducted, and analyzed. On the one hand, current patent rules can dissuade development of innovative new products with smaller markets and press trial designers to create positive results too rapidly. But at the same time, numerous studies show that when the pharmaceutical industry sponsors clinical trials, the results are systematically biased in favor of the sponsor's product, often to the detriment of patients and the public. The reasons for this bias are both complex and unavoidable, and the ways in which clinical trial design, conduct, and reporting can be inappropriately influenced are so varied and nuanced, that efforts

to manage this conflict of interest and prevent harms are inevitably unsuccessful. Instead, we conclude such conflict should be avoided and a strong firewall should exist between drug developers and the final stages of clinical testing in humans. All financial support for phase III clinical trials should pass through a public-private partnership organization — perhaps tied to a broader clinical effectiveness research enterprise — which would be charged with designing, funding, and monitoring late-stage human clinical trials of new pharmaceutical products.

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More Regulation of Industry- Supported Biomedical Research: Are We Asking the Right Questions?

*Sigrid Fry-Revere and
David Bjorn Malmstrom*

Industry-sponsored biomedical research is under the microscope. In an attempt to achieve just results in extraordinary cases, critics are suggesting regulations that would pervert the U.S. clinical trial process. However, the arguments made to justify such regulation are weak at best. All the proposals to regulate industry sponsorship of clinical trials that we surveyed (over a hundred articles and ten books, most written in the past decade) suffer from some form of fallacious reasoning. In the interest of advocating sound policy, this article points out some of the most common reasoning errors found in the literature on financial conflicts of interest in clinical trials.

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Drug Reps Off Campus! Promoting Moral Purity by Suppressing Commercial Speech

Lance K. Stell

In the name of restoring professionalism, an influential group of physician-educators have urged academic medical centers to take the lead in purging the house of medicine of the conflicts of interest created by industry's marketing. I argue that this revivalist movement is misguided, uses "conflict of interest" as an epithet, creates counter-productive incentives, and fails the duty to prepare physicians for ethical engagement with their commercial partners in patient care.

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DTC Advertising Harms Patients and Should Be Tightly Regulated

Peter Lurie

Like all interventions in health care, direct-to-consumer (DTC) advertising should be evaluated by comparing its risks to its benefits, in the context of the available or potentially available alternatives. The objective, of course, is to realize any unique benefits while minimizing the risks. On balance, the adverse effects of DTC advertising outweigh the still-undemonstrated benefits of the advertising.

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Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence?

Howard Brody

Presently, the pharmaceutical industry funds about half of the costs of continuing medical education (CME) programs in the U.S. This contributes to the ethical problems that pervade the relationship between medicine and the pharmaceutical industry: trustworthiness and conflicts of interest. The problems are exacerbated by rationalizations prevalent on both sides that deny the ethical concerns. Commercialism and commercial bias are highly visible at large CME gatherings, and available data, while scanty, back up the view that physician attendees' subsequent prescribing practices are influenced by the commercial message. The industry believes that it will recoup \$3.56 in increased sales for every dollar that it invests in CME. New guidelines instituted by the Accreditation Council for Continuing Medical Education (ACCME) in 2004 may succeed in reducing excessive commercial influence, especially since the Department of Health and Human Services has also warned the industry of possible anti-kickback violations if firewalls are not erected between CME funding and marketing of drugs. Critics counter that early indicators of improvement are lacking.

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The Ethical Health Lawyer: An Empirical Assessment of Moral Decision Making

Joshua E. Perry, Ilene N. Moore, Bruce Barry, Ellen Wright Clayton, and Amanda R. Carrico

Writing in 1999, legal ethics scholar Brad Wendel noted that "[v]ery little empirical work has been done on the moral decision making of lawyers." Indeed, since the mid-1990s, few empirical studies have attempted to explore how attorneys deliberate about ethical dilemmas they encounter in their practice. Moreover, while past research has explored some of the ethical issues confronting lawyers practicing in certain specific areas of practice, no published data exists probing the moral mind of health care lawyers. As signaled by the creation of a regular column "devoted to ethical issues arising in the practice of health law" in the *Journal of Law, Medicine & Ethics*, the time to address the empirical gap in the professional ethics literature is now. Accordingly, this article presents data collected from 120 health care lawyers. Presenting

this population with a number of hypothetical scenarios relating to how they would respond when confronting an ethical dilemma without an obvious solution or when facing a situation in which their personal values were in tension with their professional obligations, this article represents a first step toward better understanding how lawyers who practice in health care settings understand and resolve the moral discomfort they encounter in their professional lives.

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Off-Label Prescribing: A Call for Heightened Professional and Government Oversight

Rebecca Dresser and Joel Frader

Under current U.S. law, physicians may prescribe drugs and devices in situations not covered on the label approved by the Food and Drug Administration. Those supporting this system say that requiring FDA approval for off-label uses would unnecessarily impede the delivery of benefits to patients. Patients do benefit from off-label prescribing that is supported by sound scientific and medical evidence. In the absence of such evidence, however, off-label prescribing can expose patients to risky and ineffective treatments. The medical community and federal authorities should more actively promote patients' interests in receiving beneficial off-label treatments. To exercise responsible self-regulation, members of the medical community must determine whether available evidence justifies specific off-label uses and must promote information-gathering when the evidence is inadequate. Physicians should also discuss with patients the uncertainties accompanying off-label uses. Federal authorities should more closely monitor the effects of off-label prescribing and adopt other measures to reduce harm and enhance benefits produced by off-label prescribing.

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Futility Clarified

Eric Chwang

Futility is easily defined as uselessness. The mistaken appearance that it cannot be defined is explained by difficulties applying it to particular cases. This latter problem is a major goal of clinical training and cannot be solved in a pithy statement.

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Data and Safety Monitoring Boards: Some Enduring Questions

Charles J. Kowalski and Jan L. Hewett

Data Safety and Monitoring Boards (DSMBs) have been referred to as a "growth industry," and this trend continues to be fueled by recent FDA guidance and the NIH's requirement that DSMBs be employed in virtually all phase III clinical trials. The widening role of DSMBs has been sporadically questioned on ethical grounds, but growth has continued, despite the fact that many of the questions endure, unanswered, save for repeated references to safeguarding the scientific integrity of trials. This may be about to change. The recently appointed director of the Office for Human Research Protections (OHRP), Jerry Menikoff, is on record as regarding current practices — where consent forms often promise what the DSMB has been assembled to specifically not provide —

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Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

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Developing Oversight Approaches to Nanobiotechnology: The Lessons of History

A Symposium
Guest Edited by
Susan M. Wolf,
Gurumurthy
Ramachandran,
Jennifer Kuzma, and
Jordan Paradise

as constituting fraudulent behavior. That is, a subject may inherently rely on, to their detriment, information that has been misrepresented in the consent document. In this paper, we assemble some of the enduring questions and top them off with Menikoff's tour de force to present what we hope will be a compelling argument to require that consent forms fairly represent what the DSMB will do — and not do — with trial data as they accumulate. We argue that DSMBs should be used only in rare circumstances, and question the practice of precluding principal investigators from DSMB membership, but our main thrust is to ensure that DSMBs, when used at all, are properly described in trial consent forms.

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