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David Orentlicher

University of Nevada, Las Vegas -- William S. Boyd School of Law

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INTRODUCTION

Insights from a National Conference: “Conflicts of Interest in the Practice of Medicine”

Aaron S. Kesselheim and David Orentlicher

The practice of medicine is indelibly intertwined with the personal interests of the people and institutions delivering the care. Doctors and hospital executives worry about the physical and mental health of their patients, but they also worry about the financial health of their families and institutions. For-profit pharmaceutical and medical device companies seek to develop important new medical technologies, but also have a responsibility to their shareholders.¹ Conflicts of interest are inevitable and pervasive in our health care system. And while they can promote better patient care, they also can compromise patient well-being. When surgeons are rewarded with royalties for their innovative devices, they are more likely to develop better devices, but they also may favor their own devices over alternative and better options.²

Financial conflicts may be the most common and troubling kinds of conflicts of interest, but other conflicts are important as well. For example, the pursuit of professional recognition may divert the attention of health care providers from serving the interests of their patients.³

In the past, fee-for-service reimbursement for individual doctors represented the dominant source of financial conflicts,⁴ and it still plays a major role in the problem of conflicts.⁵ But changes in health care organization have multiplied the kinds of conflicts of interest. The era of the solo or even small group practitioner is nearing its close; physicians now commonly

practice in large partnerships, often spanning specialties and offering an increasingly broad range of services such as laboratory and radiological studies and dispensation of prescription drugs. These complex practice groups may make care delivery more convenient and effective for patients, but these arrangements have also been associated with overutilization and excessive costs.⁶ Mergers of solo hospitals into health care systems have raised controversy by offering increasingly sophisticated and cutting-edge services — at high cost to patients and payers — without always having supporting evidence of the efficacy of these procedures.⁷

Conflicts are common as well in medical research. Pharmaceutical and medical device manufacturers frequently partner with academic medical centers, researchers, and physicians to develop and test products intended to improve patient management. Many important therapies have resulted from these partnerships. However recent studies have shown that sources of financial support in biomedical research can unduly influence the design of studies and the reporting of the study results.⁸ In the past decade, numerous drug and device manufacturers have been investigated for promoting their products for indications lacking evidence of efficacy, behavior that is driven at least in part by the potential for large revenues from these uses.⁹

As these examples show, policymakers must take conflicts of interest seriously and draw the best balance between their benefits and harms. Conflicts cannot and should not be eliminated, but they need to be identified and managed. Otherwise, they risk compromising, rather than enhancing, the quality of our health care system.

Aaron S. Kesselheim, M.D., J.D., M.P.H., is an Assistant Professor of Medicine at Harvard Medical School Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. **David Orentlicher, M.D., J.D.,** is the Samuel R. Rosen Professor and Co-Director of the Hall Center for Law and Health at Indiana University Robert H. McKinney School of Law.

Defining Conflicts of Interest

According to Dennis Thompson, the phrase “conflict of interest” refers to a set of conditions in which professional judgment concerning a primary interest is vulnerable to undue influence by a secondary interest.¹⁰ Few would deny that a driving interest of practitioners, researchers, and hospitals is providing effective health care to patients. However, the secondary interest arising from financial and other personal interests can affect how that care is provided. Even when personal interests do not actually exert any

medical center environments. Finally, we identified a range of ideas for moving forward to address conflicts of interest in medical practice arising from the diverse points of view represented at the conference. This journal issue represents one intended output of the conference, and features scholarly works emerging from the remarks of some of the key participants.

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influence, perceptions that such an influence could exist can be a powerful force that reduces confidence in a health care provider or institution.¹¹

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Held in October 2011, the conference proceeded in three main parts. First, we reviewed the issue of whether conflicts of interest matter in medical practice, including an evaluation of the current state of the evidence and knowledge about the various barriers to reform. Second, we discussed how principles of conflict of interest management are applied to some of the most complicated questions in medical practice, such as delivery of innovative care using medical devices and balancing financial relationships within academic

Pittsburgh Health Sciences, and by the University of Pittsburgh School of Law. Outstanding support also was provided by Ted Hutchinson and Katie Johnson at ASLME and from the conference advisory committee comprising Eric Campbell, Steven Joffe, Bernard Lo, George Loewenstein, Alan Meisel, Kevin Outterson, and William Sage.

Addressing Conflicts of Interest in Medicine

Numerous ideas have been offered that intend to address conflicts of interest in medicine that arise out of the personal interests of health care researchers and providers. Most of the attention has focused on financial relationships, and some experts have advocated separating medical practice and commercialization with the goal of eliminating the relationships that cause conflicts of interest. As former *New England Journal of Medicine* editor Arnold Relman put it, “Physicians should not accept the industrialization of medical care, but should work instead toward major reforms that will restore the health care system to its proper role as a social service that society provides to all.”¹² Industry advocates have decried efforts to focus attention on financial relationships, calling efforts to regulate conflicts of interest “a pejorative, framing bias” that seeks to “eliminate, reduce, mini-

mize or disclose, rather than proliferate, increase and maximize."¹³

Available data expose the flaws in both of these arguments. As Bernard Lo points out in his article,¹⁴ partnerships between pharmaceutical companies and academic researchers have led to the development of innovative and important drugs. However, it is impossible to ignore the negative outcomes from conflicts of interest. Lo also provides a comprehensive review of evidence showing that conflicts of interest can lead to biased evaluations of study drugs on the part of researchers and the for-profit companies sponsoring them. In many cases, the biased evaluations resulted in patient harm.

But while financial relationships can lead to harmful outcomes, eliminating them completely is essentially impossible.¹⁵ Therefore, we must navigate in the middle. How do we decide which financial relationships are permissible and which are not? For those relationships that are permissible, what kinds of safeguards are needed to protect against undue influence from the conflicts of interest that arise? For example, is it sufficient for physicians to disclose permissible conflicts to their patients, or are other steps needed?

Addressing these considerations, a number of important themes were developed during the conference:

1. Conflicts of interest really do matter.

While some might argue that financial considerations do not influence physician decision making, the evidence shows otherwise. In the systematic review performed by Christopher Robertson, et al.,¹⁶ numerous studies provide good reason to believe that conflicts matter. For example, after physicians purchase an MRI scanner for their practice, they prescribe more scans. In addition, orthopedic surgeons who buy an ownership stake in a hospital perform more complicated, more expensive operations and fewer less complicated, less expensive operations. And physician-owners of ambulatory surgery centers tend to refer Medicaid patients to the hospital for care while referring patients with private insurance or Medicare coverage to their own center.

Robertson and colleagues also showed how conflicts influence the performance and outcomes of medical research. When a company funds a study of one of its own products, research and substantial experience show that the study is more likely to support use of the product in question. Thus, patients may be

harmed before the bias in the original research can be identified and corrected.

In addition to financial conflicts, nonfinancial conflicts also matter. As Richard Saver explains,¹⁷ recent attention to financial relationships and the conflicts they create may lead policymakers to assume that in the absence of these monetary connections, conflicts of interest cannot exist. However, Thompson's definition of conflicts of interest makes no reference to the source of the conflict – indeed, personal or political interests also can constitute the secondary interest. Saver provides evidence of the impact of these nonfinancial conflicts and describes how lack of recognition of their effects creates negative spillover that also weakens financial conflicts regulation.

2. Experts and institutions have been placing too great a weight on disclosure as a remedy for conflicts of interest.

The most common response to medical conflicts of interest is disclosure. Most medical journals now require financial disclosure statements,¹⁸ a growing number of academic medical centers require central reporting of faculty members' financial relationships,¹⁹ and the Affordable Care Act includes a sunshine provision that will require reporting and public disclosure of all industry payments to physicians by 2014.²⁰

However, as Sunita Sah discusses,²¹ disclosure has perils of its own. Disclosure of conflicts of interest may place too much of the burden on the subject of the disclosure to police conflicts. Physicians reading their colleagues' disclosure statements in medical journals may disregard the disclosure, or paradoxically assign greater weight to the recommendations by assuming that multiple relationships are a sign of expertise. Disclosure can also make physicians more willing to place themselves in conflicted positions. Once a conflict has been disclosed, some physicians reason, they have met their ethical obligations and therefore are free to be in the conflicted position. Finally, patients may not properly respond to the existence of a financial relationship when deciding whether it should affect their choice of physician or their willingness to agree to their physicians' recommendations. In her article, Sah describes studies showing that while patients worry when their physicians have conflicts, they also are reluctant to act on their concerns for fear that their physicians will recognize that they do not fully trust the physicians.

3. It is not clear how much we should rely on professional self-regulation and how much we should rely on legal regulation of financial relationships in medicine.

Professional regulations are easier than laws to revise, and they reinforce a culture of accountability and professional responsibility. Robert Steinbrook and Bernard Lo describe one area of professional self-regulation by examining in-depth how medical journal editors evaluate and try to regulate the existence of financial relationships among the authors of the articles they publish.²² Medical journals fulfill a central role in the health care system as the primary forum for critical evaluation and dissemination of knowledge. Thus, editors are often at the front lines of financial disclosure controversies. Slowly, medical journals have been adopting regulatory practices such as full disclosure reporting (often in lengthy on-line supplements) and exclusion of authors or reviewers with financial relationships from certain article types. Steinbrook and Lo provide suggestions for additional regulatory steps.

But professional self-regulation has its limits. It is difficult for any profession to police itself adequately. Accordingly, it is common for legislators, courts or governmental agencies to supplement professional self-regulation with extrinsic regulation. For example, Kate Greenwood and colleagues describe a process of externally-organized training and compliance programs for physician-scientists, and conclude that such requirements could help promote a culture of openness and greater understand of the importance of accounting for potentially conflicting relationships.²³

However, legal regulation has drawbacks too. It can become too complicated and generate unintended consequences.²⁴ As Lo observes, complying with conflicts of interest paperwork can be cumbersome and time-consuming. Physicians also may have to spend a good deal of time explaining the value of their financial relationships to suspicious patients or reporters. With such burdens, physicians may find it desirable to forego even beneficial financial relationships. Regulation can have other unintended consequences. As mentioned above, Sah found that disclosure can make physicians more willing to place themselves in conflicted positions.

4. It may not be appropriate to place the "burden of proof" on those seeking greater oversight of financial relationships.

It is generally assumed that proponents of regulation should demonstrate the value of their proposed regulations before they are imposed on physicians or industry. But it may make more sense to require opponents of such regulation to prove that a regulation would be harmful before it is rejected. This is particularly salient as more and more studies provide very good reason to believe that conflicts of interest can compromise the quality of medical research and the judgment of physicians.

There are other good reasons to place the burden of proof on opponents of oversight of conflicts. Because of their access to funding and relevant data, industry is much more able than others to secure evidence on the benefits and burdens of conflicts. We need better data on the benefits and harms of different types of conflicts, and of proposed remedies, before we can reliably assess their impact. Another important reason for placing the burden of proof on industry lies in the fact that industry has created the conflicts problem. It therefore should have greater responsibility to limit harms from its creation. In his article, Marc Rodwin examines how the emphasis of conflict of interest regulation too often falls on physicians rather than on the drug and device companies that often create and dictate these financial relationships.²⁵ Perhaps society could best address the conflicts of interest dilemmas by reducing corrupting practices at those institutions.

Next Steps

The Pittsburgh conference was designed to promote better understanding of conflicts of interest, greater discussion of the problems that conflicts cause in health care delivery, and more effective measures to manage conflicts. As conference organizers, we hope that the attendees, as well as the ASLME and the Highmark Foundation, were inspired to continue to push for sensible policies and reforms in this area to ensure that patients realize more of the benefits and fewer of the harms from financial relationships that are inevitable in the U.S. health care system.

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