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In the Interest of Patients:
Recommendations for Physician Financial Relationships and Clinical Decision Making

Report of the Task Force on Financial Conflicts of Interest in Clinical Care

June 2010

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Introduction

Partnerships among academic medical centers, their physicians and scientists, and the pharmaceutical, device, and biotechnology industries are essential to capture the fruits of biomedical research for the benefit of the public and to assure continued advancements in the prevention, diagnosis, and treatment of disease. These partnerships lie at the heart of the innovation process and represent a powerful force for constructive collaboration to the ultimate benefit of society at large. The benefits realized by these partnerships validate the wisdom of public policies that have encouraged them for years.[1]

Examples of these relationships often involve the development of new drugs and devices. Discoveries in the basic science laboratories of academic medicine are licensed to companies for development, testing, and marketing. Faculty physicians and scientists who make patentable inventions can be compensated with royalties as can the academic institutions where the inventions were made. Other relationships include consulting, when faculty physicians, consistent with policies of their institutions, may enter into personal consulting agreements with companies to work in various phases of research or development projects that would not normally be undertaken in their academic roles. These individually based agreements produce personal income for physicians and scientists.

Regardless of how financial interests are derived, when physicians and their institutions have interests in the products of companies that are used in connection with the actual care of patients in academic medical centers and elsewhere ("related interests"), the interests can conflict with or be perceived as conflicting with the primacy of the interests of patients. It is imperative that the possibility or perception of conflict between these interests be advertently examined and appropriately evaluated to ensure that academic medicine in all of its missions is fundamentally dedicated to the welfare of patients and the improvement of public health.[1]

To this end, the "Report of the Task Force on Conflicts of Interest in Clinical Care" represents the third and final portion of the Association of American Medical College's (AAMC) conflict of interest policy initiatives. Its two previous task forces, the Task Force on Industry Funding of Medical Education and the joint AAMC-Association of American Universities Advisory Committee on Financial Conflicts of Interest in Clinical Research, developed recommendations aimed at guiding the academic medical community in dealing with these challenging personal and institutional financial relationships in the education and research settings.

However, academic medical centers also have a critical additional mission, the delivery of medical care to patients. The presence of individual or institutional financial interests in the patient care setting may create real or perceived bias in clinical decision making and may distort the values of medical professionalism.

[1] The Bayh-Dole Act of 1980, 35 U.S.C. § 200-212. Available at: http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf. Accessed May 2010.

The interests of the patient are at stake, as is the trust of the public. Moreover, when personal financial interests conflict with clinical care activities, there is the potential for a negative and lasting influence on the development of professionalism in medical students and other trainees.

In its two previous reports, the AAMC had addressed many issues that are relevant to the clinical care setting, even though they were contained in its recommendations concerning the education and research mission areas, including strong recommendations concerning gifts, drug samples, speakers bureau participation, ghostwriting, and the like. However, in order that the principles guiding the AAMC's two previous reports could be explicitly and comprehensively extended to physicians' interactions with their patients, the AAMC charged a task force on conflicts of interest in clinical care with examining existing policies and practices in clinical care and with making recommendations to guide the academic medical community in addressing conflicts of interest in this setting, beyond those that had already been issued. Though the task force was charged with addressing clinical conflicts of interests only in academic medicine, it believes that the principles that have guided its work and that shape its report are applicable generally to the practice of medicine.

Chapter 1

Medical Professionalism and Conflicts of Interest

Medical professionalism and the special responsibility of academic medicine in developing professionalism were addressed "Industry Funding of Medical Education: Report of an AAMC Task Force," published by the AAMC in 2008. That report provides context and content for the work of the task force on conflicts of interest in clinical care.

> Professionalism lies at the heart of medicine, and inculcating the values associated with it in future generations of physicians is a primary responsibility of academic medicine… Only through a conscientious review of current practice and its implications can each medical center respond appropriately to the challenges of deciding how best to meet the highest standards of professionalism while preserving the valuable interactions between academic medicine and industry that are consistent with their shared goal of improving the health of the public.
>
> From the many efforts to define "profession," "professional," and "professionalism" in the medical and social science literatures, a broad consensus has emerged. A profession is a collectivity of practitioners who are trained in expert knowledge generally not available to their clients or to the wider public. This endows them with a special power and obligation to practice and advance this knowledge responsibly. Frequently, the basis of this knowledge is scientific, as in the case of the practice of medicine. Professionals are also responsible for training future generations of practitioners. In varying degrees professionals are self-regulating, abiding by the ethics of their profession. Thus, physicians are expected to employ independent, objective judgment in their decisions, based on their understanding of best practices and the best interests of their patients, and not act out of personal self-interest or at the behest of interested others. Professionalism implies a set of ethical standards and motivations on the part of individual practitioners. Among medicine's ethical principles are autonomy, objectivity, altruism, and the avoidance of conflicts of interest.[2]

However, several contextual realities of modern medicine can seriously compromise medical professionalism.

Financial Conflicts of Interest and Physician Compensation for Clinical Care[3]

Physicians and other health care professionals have traditionally sought to highlight the altruistic nature of their work while downplaying the influence of financial considerations on their activities. Yet the conflict is apparent and is an intrinsic part of the American practice of medicine. Physicians must often

[2] Association of American Medical Colleges. Industry Funding of Medical Education:: Report of an AAMC Task Force. Washington, DC: Association of American Medical Colleges; 2008:3.

[3] The task force is indebted to Kendal Williams, MD, MPH, Brian Leas, MS, MA, and Gretchen Kuntz, MSLIS, University of Pennsylvania Health System, Center for Evidence Based Practice, for their contributions to this section and for their contribution of Appendix A to this report, summarizing the research in this area.

respond to the expectations and requirements of external payers and purchasers, while simultaneously ensuring the financial viability of their own practice and providing high-quality patient care. The U.S. medical system is increasingly driven by payment methodologies.

While the focus of this task force is on the effect on medical professionalism of certain physician relationships with the pharmaceutical, device, and biotechnology industries, the fundamental impact that payment mechanisms have on clinical decision processes must be recognized. Although the evidence is neither extensive nor conclusive, it is clearly suggestive of ethical challenges. Thus any effort to address conflicts of interest in clinical care should begin with an acknowledgment of this contextual reality in the search for solutions.

Multiple models of physician compensation now exist, and some explicitly attempt to influence physician behavior in targeted directions. The most common mechanisms in use include fee-for-service, managed care, salaried arrangements, and the rapidly growing pay-for-performance movement. Each of these approaches may have an impact on physician decision making in substantive ways, and ethical dilemmas as well as conflicts of interest are inevitable in these circumstances.

Specifically, associations have been reported between compensation mechanisms and resource utilization that may imply some erosion of medical professionalism.[4] Physicians treating patients insured by capitated systems appear more likely than those in fee-for-service models to restrict the volume of diagnostic services, referrals, and office visits. Unfortunately, the evidence does not clarify whether physician responses to these different systems are motivated significantly by personal financial considerations. Yet physicians have long expressed concerns about the impact managed care has on patient care, clinical autonomy, and practice income. The evidence, though, does not support clear conclusions.

The research on recently emerging quality incentive programs[5] is even less decisive. While these programs grow in number and scope, they remain too new to generate strong evidence of their impact. Physicians remain skeptical of the effects pay-for-performance efforts will have on medical care, concerns that mirror those voiced about managed care.

A related concern arises from private physician ownership of expensive technology (e.g., MRIs) and care sites (e.g., specialty hospitals, ambulatory surgery centers) to which they refer patients. Physician ownership of medical infrastructure presents very direct and substantial opportunities for financial, legal, and ethical conflicts to emerge. Legal standards, though important, are not determinative of the extent of the implications of these relationships. They do not define standards of professionalism.

[4] See Appendix A. Williams, K, et al, Physician Compensation and Medical Professionalism, 2009, for a summary of the research in this area.
[5] Ibid.

A maze of federal laws has been enacted to prevent some of these conflicts. The so-called Stark laws[6] generally prohibit "physicians from referring Medicare or Medicaid beneficiaries to entities for "designated health services" if the physicians or their immediate family members have ownership or investment interests in the entities or have compensation arrangements with the entities" unless they meet an exception.[7] However, the exceptions permit limited facility and equipment ownership.

Though the Centers for Medicare and Medicaid Services now require that physician ownership or investment in a hospital be disclosed to patients,[8] such arrangements may independently pose the risk of direct and substantial threats to professionalism. Research[9] in this area has shown that ownership is associated with higher rates of self-referral and overall utilization. However, alternative explanations that highlight quality, satisfaction, and convenience may also help to account for these findings.

Academic medical centers must be aware of how their own compensation mechanisms can unduly influence physician behavior and thus conflict with the interests of patients. They have the responsibility to develop compensation plans based on incentives that are consistent with the values of medical professionalism and that reflect the primacy of the interests of patients.

Financial Conflicts of Interest in Clinical Care and Physicians' Relationships with Industry

The second contextual reality that may compromise the values of medical professionalism is that advances in medicine depend on a constructive partnership between academic medicine and the pharmaceutical, device, and biotechnology industries. At the same time some of these interactions have been shown to produce both potential and actual conflicts of interest, especially when the relationships have the capacity to generate financial gain for physicians and their institutions and influence professional behavior.[10]

These relationships exist throughout the medical profession in the United States. Though this report is focused on conflicts of interest in clinical care and is the product of, and is directed to, academic medicine, the entire medical profession shares the responsibility for upholding the values of medical professionalism.

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6 42 USC 1395nn.

7 42 USC 1395nn and 42 USC 1396b(s).

8 http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf.

9 See Appendix A. Williams, K, et al, Physician Compensation and Medical Professionalism, 2009, for a summary of the research in this area.

10 See e.g., Orlowski JP, and Wateska L. The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch. Chest. 1992;102:270-3. Chren MM, and Landefeld CS. Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary. JAMA. 1994;271:684-9.

Chew LD, O'Young TS, Hazlet TK, et al. A physician survey of the effect of drug sample availability on physicians' behavior. J Gen Intern Med. 2000;15:478-83.

Symm B, Averitt M, Forjuoh SN, et al. Effects of using free sample medications on the prescribing practices of family physicians. J Am Board Fam Med. 2006;19(5):443-449.

Adair RF and Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J Med. 2005;118:881-884.

Boltri JM, Gordon ER, and Vogel RL. Effect of antihypertensive samples on physician prescribing patterns. Fam Med. 2002;34:7231.

The medical profession is the public face of medicine, and the degree to which all of its components accept the responsibility for addressing potential conflicts that may result from its relationships with industry is directly related to the maintenance of public trust in the integrity of medical decision making.

The psychological research on how financial interests can distort decision making has been summarized as follows:[11]

> This research shows that when individuals stand to gain by reaching a particular conclusion, they tend to unconsciously and unintentionally weigh evidence in a biased fashion that favors that conclusion. Furthermore, the process of weighing evidence can happen beneath the individual's level of awareness, such that a biased individual will sincerely claim objectivity. Application of this research to medical conflicts of interest suggests that physicians who strive to maintain objectivity and policy makers who seek to limit the negative effects of physician-industry interaction face a number of challenges. This research explains how even well-intentioned individuals can succumb to conflicts of interest and why the effects of conflicts of interest are so insidious and difficult to combat.[12]

The AAMC Task Force on Industry Funding of Medical Education observed on these points:

> These commonplace patterns of interaction can create conflicts for the affected physicians, and therefore for their institutions, between their duty to exercise independent medical decision making in the best interest of their patients and the biasing influence of personal gifts and other favors on their decisions.[13] Many practitioner-recipients assert that they are not influenced by gifts, payments, and favors, and that they can act in their own economic self-interest as well as altruistically towards patients. However, the link between self-interest and the erosion of altruism has been demonstrated by multiple studies.[14]
>
> Supplementing the robust psychosocial evidence regarding the effect of gifts on physician decision making, recent neurobiological studies document that inherent biological processes cause individuals to respond reciprocally—and typically unconsciously—to relationships that involve even simple gifts, sponsorships, or the development of personal relationships.[15, 16] Although the neurobiology is still an emerging area of scientific discovery, and studies have not yet been performed on physician-industry interactions and

[11] Dana J. How Psychological Research Can Inform Policies for Dealing with Conflict of Interest in Medicine. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009:358-359.

[12] Ibid.

[13] Marco CA, Moskop JC, Solomon RC, et al. Gifts to physicians from the pharmaceutical industry: An ethical analysis. Ann Emerg Med. 2006;48(5):513–521.

[14] Wazana A. Physicians and the pharmaceutical industry, is a gift ever just a gift? JAMA. 2000;283(3):373-80.

[15] Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit. The Scientific Basis of Influence and Reciprocity: A Symposium. Washington, DC: Association of American Medical Colleges; 2007. Available at: www.aamc.org/reciprocity. Accessed May 2010.

[16] Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. JAMA. 2003;290(2):252-255.

decision making, studies suggest that the neurobiological processes that engage the brain's reward and decision-making circuitry can operate below the detection and overt control of higher cognition. Thus, although strong motivation and altruistic intent exist in most physician-industry interactions, the intention may be unwittingly undermined when innate reciprocity mechanisms are engaged.

These studies reinforce the necessity for multifaceted solutions to interdict biasing influences.[17]

The Special Responsibility of Professional Medical Societies as Mentors

Specialty societies and professional medical associations play a critical role in the development and inculcation of standards of professionalism. They serve as conveners, arbiters, and educators of society members and as powerful sources of the specialty's standards and ethics. Recent commentary has documented the extensive reliance by many medical specialty societies and associations on industry funding.[18] Such funding takes many forms, including both restricted and unrestricted educational grants, revenues from sponsorships of meetings and industry exhibitions at meetings, industry advertising in society journals, and funding of the development of clinical practice guidelines.

Professional societies' activities are directly relevant to conflicts of interest in clinical care, given the role of many specialty societies in continuing medical education and in the development of clinical practice guidelines. Behaviors that are common at professional society meetings, including gifts, industry "satellite" receptions, and thinly veiled sponsorships of professional activities reverberate throughout the profession. These are the settings for appropriate standards of professionalism to be modeled for those who are new to the profession and for those for whom standards need reinforcing. The influence of these behaviors is profound and extensive.

The prevalence of industry funding that surrounds professional society activities is now receiving appropriate critical review. Some believe that transparency of funding sources is an adequate response. Others believe that much more rigorous standards represent the solution, for example, a ban on industry funding in the development of practice guidelines.[19] Whatever the balance struck, societies must explicitly recognize the influence of their own "hidden curricula" on the professionalism of the clinician.

The Task Force strongly supports the efforts of those professional societies that have or are developing new or revised standards for their own conflicts of interest. Such policies, or their absence, have profound influence on the inculcation of the highest standards of medical professionalism.

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[17] Association of American Medical Colleges. Industry Funding of Medical Education: Report of an AAMC Task Force. Washington, DC: Association of American Medical Colleges; 2008:4-5.

[18] Rothman DJ, McDonald WJ, Berkowitz CD, et al. Professional Medical Associations and Their Relationships With Industry. A Proposal for Controlling Conflict of Interest. JAMA. 2009;301(13):1367-1372.

[19] IOM (Institute of Medicine). Conflict of Interest and Development of Clinical Practice Guidelines. *Conflict of Interest in Medical Research, Education, and Practice.* Washington, DC: The National Academies Press; 2009:189-215.

Chapter 2

Academic Medicine and Conflicts of Interest in Clinical Care

The Special Responsibility of Academic Medicine as Mentor

Because the transmission of both professional expertise and the values associated with professionalism formally begins with academic medicine, the institutions themselves and their physicians have a special responsibility to model the policies, practices, and behaviors that represent the highest standards of professionalism, including the clinical care of patients. Ultimately, this is what defines the culture of American medicine, that is, the principles of professionalism that are modeled and inculcated in the formative training years in medical schools and teaching hospitals.

> Within the experience of students, but outside the courses lies the "hidden curriculum," the students' exposure to what we *actually* do in our day-to-day work with patients and one another – not what we say *should* be done when we stand behind podiums in lecture halls. It is this modeling, not only by the faculty but by the residents, that constitutes the most powerful influence on students' understanding of professionalism in medicine.[20]

In addition to the influence that faculty and resident physicians have on students, including how their related financial interests are addressed, the manner in which academic medical centers themselves address their own myriad relationships with industry is critically important, from receipt of philanthropy from industry to accruing royalties as a consequence of the licensing of inventions made at the medical center.

> To preserve high standards of professionalism, both individual and institutional "circuit breakers" are necessary. A focus on individual commitment to professionalism is necessary but not sufficient; the constant tension between altruism and self-interest must also be acknowledged and addressed in institutional policies and practices.[21]

This acknowledgment has special relevance for the perceived or actual conflicts of interest of institutional leaders and officials. Especially for those serving in direct leadership roles for faculty physicians (division chiefs and department chairs), addressing conflicts of interest is critically necessary. These are the individuals who frequently set the standards for prescribing or use of products as well as standards for purchasing decisions. Institutional expectations regarding the identification and management or elimination of these officials' conflicts should be clearly communicated and effectively enforced as components of institutional policies on conflicts of interest.

[20] Inui T. S. A Flag in the Wind: Educating for Professionalism in Medicine. Washington, DC: Association of American Medical Colleges; 2003:16.

[21] Association of American Medical Colleges. Industry Funding of Medical Education: Report of an AAMC Task Force. Washington, DC: Association of American Medical Colleges; 2008:5.

Identifying Conflicts in Clinical Care

The AAMC has not previously offered an explicit definition of a conflict of interest in clinical practice, and for the purposes of this report, endorses and adopts the definition offered by the Institute of Medicine in its Conflicts of Interest in Medical Research, Education, and Practice.[22] "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[23] A *clinical* practice conflict of interest thus occurs when a secondary financial interest creates the risk that the primary duty to the patient and the delivery of optimal care will be unduly influenced by personal financial interests of the care provider or care provider institution. Institutional financial conflicts of interest similarly should not interfere with the delivery of the most appropriate care and best use of patient care resources.

Academic medical centers should explicitly address, through a well-defined and publicized institutional process, conflicts of interest in clinical care resulting from physician-related financial interests as well as those conflicts that result from the institution's financial interests in products prescribed for its patients.

Though many academic medical centers have detailed, explicit policies governing conflicts of interest in research[24] as well as ones that ban or sharply restrict pharmaceutical and device company gifts, speakers bureaus, travel, ghostwriting, and the like, only a small number of academic medical centers have, to date, adopted policies explicitly defining and addressing conflicts of interest in clinical care. Many of these policies' provisions represent good models for other institutions seeking to put policies in place. For example, Washington University School of Medicine's Policy on Conflicts of Interest in Clinical Care provides that the School of Medicine:

> "considers a potential conflict of interest to exist when a Washington University treating physician or health professional (or his/her immediate family member) has a material financial relationship with a commercial health care company, and the physician or health professional is in a position to affect a patient's decision and/or consent to the use of that manufacturer's, distributor's or entity's product.[25]

This policy defines a "financial relationship" as:

> any relationship in which a . . . faculty member (or his/her immediate family member) has received, or is expected to receive, cash or something of value, including but not limited to consulting fees, advisory board payments,

[22] IOM (Institute of Medicine). Conflict of Interest and Development of Clinical Practice Guidelines. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009:189-215.

[23] IOM (Institute of Medicine). Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009:46.

[24] Ehringhaus S, Korn D. U.S. Medical School Policies on Individual Financial Conflicts of Interest. Results of an AAMC Survey. Washington, DC: Association of American Medical Colleges; 2004.

[25] See http://wuphysicians.wustl.edu/page.aspx?pageID=249&NavID=4. Note: Ancillary equipment is not covered.

> product evaluation payments, royalties, intellectual property rights, honoraria, ownership interests (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), educational payments, unrestricted grant awards, or other financial benefit, from a company, person or entity that produces, manufactures or distributes a medical device, implant, pharmaceutical or other medical care related product that is recommended or prescribed to Washington University patients.[26]

Whatever the particular definitions used, three principal types of individual related financial interests should be included in the definition and receive special attention: payments for services, royalties, and ownership interests. They have the most significant potential to create the secondary interests that can result in conflict between the duty owed to the patient and the personal financial stake and can inject bias into the decision making relating to the patient's care.

Because there may be a direct link between royalties and the use of a patented item and income to the inventor, royalties should get special treatment in clinical conflicts of interest policies, specifically those derived by the institution or its physicians from sales of drugs, devices, or diagnostics used at that institution. Although there are serious practical limitations on restricting royalty payments to physician inventors and their institutions beyond initial licensing transactions, one institution indicates that it does not receive royalties on the sale of items invented at the institution that are prescribed for their patients.[27] Another prohibits physicians from collecting royalties on products that they prescribe for their patients.[28] Both recognize the special problem of directly benefiting from the use of a particular drug or device that itself generates income to the prescribing physician/institution where the item was invented. Still another institution's policy requires that licensees not pay royalties derived from the sales of a particular drug or device to that institution, unless a committee has reviewed and approved a mechanism under which all such royalties will be donated to a specific charity.[29]

Payments to physicians for their personal consulting and other outside services for companies whose products and services are used in their clinical practices should also be singled out for special attention. One institution addresses consulting as follows:

> Physicians who provide services to commercial companies should receive reasonable compensation for their services. However, to avoid the appearance of an improper inducement, Washington University physicians

[26] Ibid.

[27] Mayo Clinic Conflict of Interest Policy; February 9, 2009: 12. Available at: http://www.mayoclinic.org/governance/pdfs/conflict-of-interest-mc.pdf. Accessed May 2010.

[28] Washington University Policy on Conflicts of Interest in Clinical Care; March 16, 2006. Available at: http://wuphysicians.wustl.edu/page.aspx?pageID=249. Accessed May 2010.

[29] See http://www.partners.org/vendor/InterimPolicyStatement.pdf.

who collaborate or otherwise provide services to commercial companies shall comply with the following:

a. Ensure that collaborations are performed pursuant to a written agreement or memorandum that is established in advance with a description of the expected deliverables.

b. Maintain documentation of the compensation received and the services provided, including reasonable estimates of the time and effort committed to providing the services.

c. Ensure that compensation is based on, and commensurate with, the provision of tangible services and not on the decision to use a specific device, implant, or drug in a patient.[30]

Finally, ownership interests (e.g., stock, stock options, other ownership interests but excluding certain diversified mutual funds) are typically covered in policies explicitly encompassing conflicts of interest in clinical care. They should be included within the definition of those financial interests that must be disclosed and evaluated. A distinction may be made between ownership interests in publicly traded companies and those in privately held companies, for purposes of triggering evaluation by a conflicts of interest official or committee. Especially in the case of start-up companies, ownership interests of any value may need formal evaluation for conflict, as opposed to interests in large, publicly traded companies, where the use of the product may have no material effect on the value of the ownership interest, unless it is above some significance threshold.

However relevant financial interests are defined, in the case of clinical care, physicians should be required to report to their institutions on an annual basis; so-called transactional reporting is difficult to implement in the clinical care setting. Annual reports (and their updates when interests change during a reporting period) should include the identification of their personal financial interests that are related to their clinical practices. This does not mean the academic medical center cannot examine other financial interests of its physicians, but the question places an appropriate responsibility on physicians initially and advertently to identify those personal financial interests that in their judgment relate to their practices.

The Question of a Threshold

A question often arises regarding whether there is some de minimis value or threshold below in which it is not relevant to report and/or examine such relationships. There are at least three different points at which the issue of a

[30] See http://wuphysicians.wustl.edu/page.aspx?pageID=249.

threshold should be considered: first, what physicians should report to their institutions; second, the dollar point at which institutional review and evaluation mechanisms are brought to bear on reported interests; and third, the level at which financial interests of physicians are disclosed to patients.

The initial threshold to establish is the dollar value of related financial interests that a physician should be required to report to his or her institution. Some institutions have adopted a zero threshold, on the theory that the institution should determine for itself what is relevant for it to consider as potential or actual conflicts of interest. Others set a higher reporting threshold, with de minimis values varying across institutions, in an effort to reduce the reporting burden on faculty physicians and institutional reporting mechanisms.

The second threshold that must be established is the dollar level at which institutional review and evaluation machinery should occur. Institutions that have enacted explicit policies or practices in the clinical area vary in their responses to this question, with the thresholds ranging from $5,000 to $25,000. In the research context, there has been a threshold adopted for PHS-funded research of more than $10,000 income or more than $10,000 stock plus more than 5 percent ownership interest,[31] though a lower threshold is currently under review.[32] There is no sure answer or consensus position regarding the point at which the institutional review and evaluation threshold should routinely take place for conflicts involving clinical care.

Despite the absence of definitive guidance, the task force believes that the establishment of some de minimis for institutional review and evaluation is necessary. No de mimimis standard would result in a huge volume of disclosures to evaluate and would diminish an institution's ability to focus on those conflicts with the most potential to inject bias into the relationships with patients. Although arguably bias can be introduced in any of these relationships,[33] at some point (as is already the standard in the research context[34]) a de minimis standard should be used below which institutional resources would not be committed to evaluation and management because the possibility of bias is sufficiently small not to threaten the integrity of decision making.

The third threshold to consider is the point at which the institutional machinery requires that disclosure to the patient is necessary in connection with management of an identified conflict of interest. However, this variety of disclosure necessarily is preceded by a decision that a specific financial interest of a physician could be related to the care of his or her particular patients and

[31] 60 FR 35815, 42 CFR 50 (1995).

[32] 75 FR 28688 (2010).

[33] Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit. *The Scientific Basis of Influence and Reciprocity: A Symposium.* Washington, DC: Association of American Medical Colleges; 2007. Available at: https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=215&cfid=1&cftoken=41A38533-BA0B-BEBF-379F4FACC6FC63DF. Accessed May 2010.

[34] 60 FR 35815, 42 CFR 50 (1995).

thus should be revealed to those patients when the interest is implicated. This disclosure is one mechanism (but frequently not the only one) that can be employed to address or manage the potential that a financial interest could conflict with the interests of the patient. The threshold at which the decision is made by an institution to disclose a particular potential conflict to a patient may or may not be the same point at which related interests are required to be evaluated by the institution. Moreover, this third disclosure threshold does not necessarily have to be established in dollar terms. Other possibilities include whether the clinical care to be provided is routinely provided as standard of care or represents a departure from established patterns.

Disclosure to Patients

In the academic research context where institutional thresholds have been routinely established for many years (at least for PHS-funded research), once an institutional determination is made that a particular financial interest constitutes a potential conflict of interest in research, disclosure is commonly required as a necessary but frequently insufficient method of management. This includes disclosure to research colleagues, research staff, human subjects participating in the research project, reviewers of the research, funders of the research, and in connection with professional and scientific presentations. As indicated earlier, a very small number of academic medical centers are now evaluating these reported financial interests in the context of their physicians' clinical practice and are disclosing the existence of identified potential conflicts to individual patients as well as to colleagues and supervisors as the need is determined.[35]

Little is known about the effects of disclosure of conflicts of interest on patients, but researchers have studied the effects of disclosure of researchers' related interests to potential research participants. In this process, six possible goals for disclosing researchers' financial relationships to potential research participants have been suggested:[36] promoting informed decision making, respecting participants' right to know, establishing or maintaining trust, minimizing risk of legal liability, deterring troubling financial relationships, and protecting research participants' welfare. These goals for disclosure of potential conflicts of interest may also be viewed as applicable in the clinical care context.

One study[37] used a hypothetical clinical trial to examine the effects of financial disclosures on attitudes of participants toward clinical trials. The importance attributed by participants to disclosure of the researcher's financial information

[35] See e.g., Mayo Clinic Conflict of Interest Policy at: http://www.mayoclinic.org/governance/pdfs/conflict-of-interest-mc.pdf and Washington University Conflict of Interest Policy at: http://wuphysicians.wustl.edu/page.aspx?pageID=249.

[36] Weinfurt, KP, Hall MA, King NMP, et al. Disclosure of financial relationships to participants in clinical research. New England Journal of Medicine. 2009;361:916-921.

[37] Weinfurt, KP, Hall MA, Dinan MA, et al. Effects of disclosing financial interests on attitudes toward clinical research. J Gen Intern Med. 2008;23(6):860-866.

varied, but most "assigned far less importance to information regarding financial interests than to other information about the trial." "[T]rust in medical researchers and institutions was substantially affected by the type of financial interest disclosed. The disclosures made over one-third of respondents less trusting of researchers and institutions, although they led to greater trust for some respondents."[38]

Another study examined what potential research participants want to know about financial interests, their capacity to understand disclosed information, and their reaction to disclosures. The results suggested that most people wanted to know about financial interests, even though it might not have affected their participation.[39] They also suggested "that some people may not have the baseline understanding necessary to judge the risks posed by financial interests, calling into question whether simple disclosure to prospective research participants is an effective strategy, standing alone, for managing conflicts of interest in research."[40]

> "[I]f the goal of disclosing financial interests is to allow the research subject to assess the risk of harm, either to self or to science, our data present several cautions. Consistent with research about informed consent and consumer disclosure practices in other medical and nonmedical arenas, there are high barriers to achieving the goals of rational decision-making models. On balance, those charged with protecting research participants should consider what might be a realistic goal of disclosing to potential research participants. Our data suggest that allowing potential research participants to weigh the risks of financial interests might not be as realistic a goal as the more general goal of honoring patients' right to know and avoiding harms to trust if they learn of undisclosed incentives at a later time."[41]

In different contexts, experimental studies in psychology suggest the potential for unintended consequences from disclosure of conflicts of interest. For example, two groups of studies of disclosure by individuals in an advice-giving role suggested that disclosure of conflicts of interest benefitted the interests of those giving the advice but adversely affected the interests of those to whom the disclosure was made.[42] Studies of journal readers indicate that disclosure of an author's financial interests may cause readers to believe the research to be less credible.[43, 44] The IOM report summarizes this research.[45]

Among the few studies undertaken on physician disclosure to patients, one

[38] Ibid.

[39] Weinfurt, KP, Friedman JY, Allsbrook JS, et al. Views of potential research participants on financial conflicts of interest: barriers and opportunities for effective disclosure. J Gen Intern Med. 2006;21(9):901-906.

[40] Ibid, 904.

[41] Ibid, 905.

[42] Cain D, Loewenstein G, and Moore D. The dirt on coming clean: the perverse effects of disclosing conflicts of interest. Journal of Legal Studies. 2005;34:1-25.

[43] Chaudhry S, Schroter S, Smith R, et al. Does declaration of competing interests affect readers' perceptions? A randomized trial. British Medical Journal. 2002;325(7377):1392.

[44] Schroter S, Morris J, Chaudhry S, et al. Does the type of competing interest statement affect readers' perceptions of the credibility of research? Randomized trial. British Medical Journal. 2004;328(7442):742-743.

[45] Dana J. How Psychological Research Can Inform Policies for Dealing with Conflict of Interest in Medicine. *Conflict of Interest in Medical Research, Education, and Practice.* Washington: The National Academies Press; 2009:358-374.

study suggests that patients were "more likely than their physicians to believe that acceptance of pharmaceutical gifts may influence prescribing behavior... and patients tended to find gifts less appropriate than did their physicians."[46] In another study, about half of the patients expressed interest in the financial incentives the patients' health plan imposed on its physicians, but others did not want to know about them, despite the finding that many patients believe that certain kinds of payment methods could adversely affect their care.[47]

A recent newspaper survey examined the issue of physician financial ties to drug/device industries from the patient's standpoint.[48]

- Sixty-eight percent of respondents support legislation that would require public disclosure of financial relationships between physicians and industry.
- Seventy-eight percent believed that accepting gifts from the pharmaceutical industry influences their doctors' prescribing habits.
- Only 34 percent said they would be likely to ask their doctors about potentially troubling financial ties.

> The IOM, in its "Report on Conflicts of Interest in Medical Research, Education, and Practice" addresses by omission the issue of *physician* disclosure of related interests to patients. The recommendations in its chapter on Conflicts of Interest and Medical Practice explicitly do "not mention physician disclosure [by physicians] of financial relationships to patients. Patients could obtain that information, however, if the U.S. Congress were to require companies to disclose payments to physicians and place that information on a searchable public database. This option would avoid the interpersonal complexities involved with patients directly requesting or physicians directly providing such information. Patients and their families would need to be informed about the database, possibly through the use of brochures or notices in medical offices. Studies of patient use of the database would be a potential topic for the research agenda recommended..." in the report.[49]

In this complex landscape, it is difficult to find a sure pathway. Much more research is clearly necessary, as the IOM report recommends.[50] At a minimum, the research suggests that the research participant and the patient are interested in being informed of financial interests, which is consistent with the patient's right to know as a value. The task force recommends that institutions should inform patients of the existence of their providers' financial relationships that

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46 Gibbons RV, Landry FJ, Blouch DL, et al. A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts. J Gen Intern Med. 1998;13:153.
47 Kao AC, Zaslavsky AM, Green DC, et al. Physician incentives and disclosure of payment methods to patients. J Gen Intern Med. 2001;16(3):184.
48 Ibby Caputo. Probing Doctors' Ties to Industry. *The Washington Post.* August 18, 2009. Available at: http://www.washingtonpost.com/wp-dyn/content/article/2009/08/17/AR2009081702090.html. Accessed May 2010.

49 IOM (Institute of Medicine). Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009:187.
50 IOM (Institute of Medicine). Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009.

have been determined to be significant and should make additional information about those relationships readily available to patients. The task force strongly believes that in this process, the physician himself or herself should normally be required personally to make the disclosure to the patient and document the disclosure in the medical record.

Management of Conflicts in Clinical Care

As indicated in the previous section, procedures should be adopted by medical centers that call for explicit evaluation of relevant financial relationships by a duly appointed institutional official or committee whose purpose is to evaluate the information reported and to determine if there is a significant conflict of interest in clinical care and, if so, to manage it or determine that it should be eliminated. One institution's policy provides a list of possible management strategies for particular conflicts, depending on the degree of the potential conflict:

a. Verbal disclosure to patient with documentation of disclosure in medical record

b. Corroboration by colleague of any prescription involving a product from the commercial entity

c. Corroboration by colleague documented in the medical record of any prescription involving a product from the commercial entity

d. Appointment of an oversight committee to monitor practice patterns

e. Transfer of patient care to another colleague

f. Cessation or modification of relationship with a commercial entity, if necessary[51]

The importance of management strategies being tailored to fit the exigencies of particular clinical situations cannot be overstated. The decisions regarding which strategies are appropriate are best left to institutional oversight officials or committees based on both policy provisions and individual circumstances.

The manner in which an institution monitors and enforces its own policies sends a strong message to those affected about whether or not the institution takes seriously the matters addressed in the policies. Clear provisions about consequences of failure to follow policy requirements are necessary elements of conflicts of interest policies. One institution's policy[52] frames potential remedial

[51] See http://www.mayoclinic.org/governance/pdfs/conflict-of-interest-mc.pdf. 13.
[52] See http://wuphysicians.wustl.edu/page.aspx?pageID=249.

actions it may take if a conflict has not been resolved in accordance with its policy:

i) Suspend the faculty member's clinical privileges

ii) Withdraw professional liability insurance coverage for the faculty member

iii) Reduce the faculty member's salary or bonus, and/or

iv) Take other actions as appropriate.

Some of the most devastating publicity about medical conflicts of interest has centered less on the failure to adopt policies than on the failure to implement them effectively and/or the failure to follow them. Academic medicine and physicians associated with academic medicine have the responsibility to demonstrate that they can effectively self-regulate conflicts of interest with industry in all missions of academic medicine, through adoption of policies, management of conflicts, and monitoring and compliance with policy provisions.

Chapter 3

Transparency and Academic Medicine

Beyond requiring reports of physicians' related financial interests, beyond setting thresholds and establishing evaluation mechanisms, and beyond managing identified conflicts of interest including disclosure to patients, another responsibility lies. That responsibility involves transparency of financial interests generally to the health care-seeking public. A critical junction of shared responsibility for professionalism lies in the imperative for transparency in relationships among academic medicine, physicians, and industry. Ultimately, the public needs the tools with which to understand the forces that may have an impact, positive and negative, on the care they seek. By embracing this public transparency, physicians and their institutions can minimize distrust and concern regarding relationships with industry; take steps to minimize those relationships that have the capacity for inappropriate influence; and expand opportunities for open, principled collaborations. The nature and extent of a physician's relationships with industry are among the many pieces of information that one might consider in making appropriate health care decisions.

An understanding of these relationships begins with an awareness of them, and awareness depends on the relationships' being transparent. Two sectors have the information necessary to take the initial step towards transparency by revealing these relationships: physicians and their medical centers who have financial interests in and relationships with pharmaceutical, device, and biotechnology companies, as well as with specialty hospitals [hereinafter "related interests"], and the companies with which these related interests exist.

Making information available to the public about physicians' financial relationships with industry (not just those determined to be conflicts of interest) is embraced by some regulatory authorities,[53] Congress,[54] some states,[55] some companies (voluntarily or through legal processes[56]), and a

[53] See The Medicare Payment Advisory Commission (MedPAC). Public reporting of physicians' financial relationships. Report to the Congress: Medicare Payment Policy. Washington, DC. MedPAC; 2009:313-343. Available at: http://www.medpac.gov/documents/Mar09_EntireReport.pdf. Accessed May 2010.

[54] Pub.L.No. 111-148, 2010.

[55] District of Columbia Code Ann. 48-833.01 – 48-833.09. Available at: http://hrla.doh.dc.gov/hrla/frames.asp?doc=/hrla/lib/hrla/pharmacylaw.pdf, Accessed May 2010. State of Maine. Rev. Stat. Ann. tit. 22, 2698-A, Available at: http://www.mainelegislature.org/legis/statutes/22/title22sec2698-A.html. Accessed May 2010. State of West Virginia. Code 5A-3C-13. Available at: http://law.justia.com/westvirginia/codes/05a/wvc5a-3c- 13.html. Accessed May 2010. State of Minnesota. Minnesota statutes: health, chapter 151, pharmacy, 151.47 wholesale drug distributor licensing requirements, January 2006. Available at: http://www.revisor.leg.state.mn.us/data/revisor/statutes/2005/151/47.html. Accessed May 2010. State of Vermont. Vermont statutes online: Title 33, human services, chapter 19, medical assistance, 33 VSA § 2005: pharmaceutical marketers, January 2006. Available at: http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2008/acts/ACT080.htm. Accessed May 2010.

[56] See e.g., Johnson LA. Pfizer to disclose payments to doctors next year, Associated Press, February 10, 2009. Available at: http://www.msnbc.msn.com/id/29105875/. Accessed May 2010. Carey B. Drug maker to report fees to doctors, New York Times, September 24, 2008:A18. Available at: http://www.nytimes.com/2008/09/25/health/policy/25drug.html. Accessed May 2010. Medtronic to voluntarily disclose payments to U.S. physicians. Medtronic, February 2009. Available at: http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1235482300024&lang=en_US. Accessed May 2010. Edwards Lifesciences to disclose financial relationships with U.S. physicians. Edwards Lifesciences, December 2008. Available at: http://www.edwards.com/newsroom/nr20081223.htm. Accessed May 2010. AstraZeneca to disclose compensation to U.S. doctors. AstraZeneca, May 2009. Available at: http://www.astrazeneca-us.com/?itemId=5957808. Accessed May 2010. Lilly set to become first pharmaceutical research company to disclose physician payments. Eli Lilly, September 2008. Available at: http://newsroom.lilly.com/releasedetail.cfm?releaseid=336444. Accessed May 2010. Arnold M. GSK vows to disclose payments to docs; details to come. Medical Marketing & Media. Available at: http://www.mmm-online.com/gsk-vows-to-disclose-payments-to-docs-details-to-come/article/119918/. Accessed May 2010.

very small but growing number of academic medical centers.[57] It is achieved through public Web sites that reveal all of a physician's financial interests in a particular company (in the case of company-based sites), all companies' financial relationships with physicians (The Patient Protection and Affordable Care Act of 2010[58]), or all financial interests in related companies (in the case of the academic medical centers, usually with some de minimis threshold).[59]

These Web sites do not purport to provide information on those related interests that have been judged to be potential financial conflicts of interest in a particular situation (such as the implantation by a particular physician of a specific medical device in which the physician has a related interest).

Instead, the Web sites are aimed at disclosure of all physicians' related interests, with few exceptions. Many interests disclosed through these Web sites have no relation at all to the clinical practice experiences or other professional activities of particular physicians, nor are they conflicts of interest. They can be easily misunderstood or misused to suggest that all disclosed financial interests are relevant to all activities and constitute conflicts of interest. Others believe the Web sites are useful and important components of overall faculty profiles. At a minimum, they provide a window on the types of connectors that exist between industry and physicians and a prompt, at least for some of the health care-seeking public, to seek additional information.

Maximizing the Utility of Public Disclosure Web sites to Achieve Transparency[60]

Unfortunately, none of these Web sites is like any other. This lack of uniformity will confuse patients and the general public who are arguably the intended recipients of the disclosed information.

An example illustrates the dilemma. A company reports on its Web site that it paid a particular physician $22,000 for consulting during the fiscal year ending June 30. The academic medical center employing the physician discloses that he or she received $18,000 from that company for the same time period. The media exposes the discrepancy. Further scrutiny reveals that the company included reimbursement for travel, hotel, and meals in its disclosure, while the medical center did not. By the time it is clarified, the reputations of the physician, the employing medical center, and the company may be impugned, when the only issue was incongruity. Opportunities for more discrepancies increase if the two disclosures cover different 12-month periods.

Differences in disclosure categories and time frames used in these public disclosure systems present major problems for all stakeholders striving for

[57] See e.g., Cleveland Clinic disclosure Web page and Stanford disclosure Web page found at: http://my.clevelandclinic.org/about/overview/integrity.aspx and http://med.stanford.edu/profiles, respectively.

[58] Pub.L.No. 111-148, 2010.

[59] See e.g. Cleveland Clinic disclosure Web page and Stanford disclosure Web page found at: http://my.clevelandclinic.org/about/overview/integrity.aspx and http://med.stanford.edu/profiles, respectively.

[60] The task force is indebted to Guy Chisolm, PhD, and Maya Wolpert, The Cleveland Clinic, for their contributions to this section and for their contribution of Appendix B to this report.

transparency. First, misunderstandings are inevitable, and energy will need to be devoted to clarifying apparently inconsistent information. It is imperative that there be established uniform standards of disclosure in terms of definitions of categories of information to be disclosed and the time periods that disclosures cover. Categories across disclosure systems should be as nearly uniform as possible to reduce confusion and inadvertent discrepancies, and disclosures should be based on the most recently ended calendar year, not a distinct fiscal year or other 12-month period, or alternatively, make very clear what time period is being used. There are numerous benefits to adopting uniformity in public disclosure of industry financial ties, principally minimizing confusion and maximizing the possibility of public understanding.

Further, most of the disclosure mechanisms that exist, or that have been announced, display these relationships in isolation from a fuller picture of the physician, including education, expertise, professional employment, responsibilities, and commitments. When information on a physician's related interests is meant to help people make more informed choices about health care and to understand sources of potential influence, presenting the interests in isolation from the physician's professional context makes it appear that all of these relationships are at best problematic and at worst proven sources of inappropriate influence, when in fact no such judgments have been made about any interests. In the absence of broader context, there is no real opportunity for patients or the public to evaluate what the information means in relation to the entirety of the physician's professional activities. Ideally, sites should provide information about the potential benefits and value of appropriately structured related interests.

There is widespread agreement that transparency is an essential component in addressing physician-industry relationships. With respect to public Web sites on physicians' related interests, the accuracy, freedom from inconsistency, and ease of understanding of the information disclosed will determine whether this format for achieving transparency has any real value.

A template has been developed that represents one model for such a disclosure system. It is provided in Appendix B for consideration by those offering or planning to offer public disclosure systems.

As a caveat, the task force notes that disclosure Web site hosted by academic institutions represent an enormous commitment of institutional resources, which some suggest could be put to better uses. Many institutions do not have the means to establish such Web sites. Other options are also available. For example, one institution offers to its patients via clear signage at each of its clinics and hospitals to make information available about the patients' physicians. Requests can be made by mail, email, or telephone. A personalized response is sent to each patient who requests information about his or her physicians.[61]

[61] See e.g., University of Wisconsin School of Medicine and Public Health found at: http://www.med.wisc.edu/news-events/news/uw-madison-strengthens-policies-governing-relationships-with-health-care-industry/334. Accessed May 2010.

Chapter 4

Promoting Public Understanding

Efforts at transparency and management of conflicts of interest can only be successful if the nature of the relationships with industry and the purposes and content of disclosures are understood. The meaning and consequences of disclosures are difficult to assess even for people knowledgeable in the field, and research on the topic, particularly on disclosures to patients, is scant. Hence, transparency alone can rarely be an effective or sufficient response to the potential for conflicts of interest arising as a consequence of physician-industry relationships or medical center-industry relationships. Moreover, disclosure itself may have significant consequences.

The IOM frames two possible effects of disclosure of physicians' related interests in the following way:

> "Disclosure should have beneficial consequences if it leads physicians to avoid gifts, the use of industry-controlled presentations, and other relationships that create a risk of compromising their decisions and their professional independence. It could also have harmful consequences if physicians or researchers react by avoiding relationships that promote important societal goals and that are accompanied by adequate measures to protect objective judgment."[62]

This possibility notwithstanding, media attention to financial relationships between physicians and industry has largely focused on revelations of inappropriate influence and significant failures to disclose and manage these relationships, and the justifiable clamor for accurate disclosure drowns out efforts at providing a broader base of understanding.

Because the relationships that foster discovery and innovation and improve the health of the public frequently take place among the academic medical community's physicians and scientists, the academic medical community must take active responsibility for better educating the public about physician-industry relationships, along with their basis, value, challenges, pitfalls, and management. Information presented in various public disclosure Web sites and in targeted disclosures of related interests is often interpreted by information mediators; that is, the press, public interest groups, researchers, and patient groups, among others. This process is essential to public understanding of all perspectives on these difficult issues.

However, the voice of the academic medical community has been muted by widely publicized instances of failures of transparency and understanding. Although the community has made great strides in taking responsibility

[62] IOM (Institute of Medicine). Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009:67-68.

for managing its relationships with industry and in correcting evidence of deviations from appropriate standards, it must find its voice and explain in clear, compelling terms why relationships between physicians and industry exist. It must also define acceptable relationships for clinicians to undertake. It is important for the public to understand that substantial efforts have been undertaken by academic institutions, national associations, and professional and scientific organizations in developing and implementing appropriate standards of conduct and transparency.

Finally, the community should take the lead in asserting that protection of patients and promotion of patient understanding should lie at the heart of all of the systems that purport to address conflicts of interest. This means that efforts at transparency in the clinical context, whether by public Web sites or face-to-face discussions with patients, are informed by, and responsive to, needs as expressed primarily by patients. Framing disclosures in patient-centric ways does not change the need for full and complete revelation of facts relating to particular conflicts for the benefit of the public at large or of specific subsets, such as readers of scientific journals. It enhances transparency by heightening its utility to those with the greatest stake in the matter.

Chapter 5

Recommendations

1. **The principles articulated in this report are applicable to the medical profession, including but not limited to academic medicine.** Though the task force was charged with addressing clinical conflicts of interests only in academic medicine, it believes that the principles that have guided its work and that shape its report are applicable generally to the practice of medicine.

2. **Compensation mechanisms of academic medical centers should be aligned with the best interests of patients.** All academic medical centers should evaluate their own compensation systems in order to determine whether or not the bases for compensation and reward adversely influence physician behavior and conflict with the best interest of patients. Medical centers have the responsibility to develop compensation plans that are based on incentives that are consistent with the values of medical professionalism and reflect the primacy of the patient's best interests.

3. **Medical societies should set standards of addressing their own relationships with industry.** Professional societies must explicitly recognize the influence of their own "hidden curriculum" on the professionalism of the clinician. The task force strongly supports the efforts of those professional societies that have or are developing new or revised standards for their own conflicts of interest. Such policies, or their absence, have profound influence on the inculcation of the highest standards of medical professionalism.

4. **Academic medical centers should address their physicians' financial relationships with industry in the context of the clinical care they deliver.**

    a. All academic medical centers should address potential clinical conflicts of interest by establishing mechanisms to identify physician-industry financial relationships and evaluate their potential for biasing the clinical practice of physicians and to eliminate, limit, or manage those that appear to represent a risk of bias.

    b. The identification of these financial relationships should include the receipt of, or rights to receive, royalties by physicians, consulting or other services for industry by physicians, and physicians' ownership interest in related companies.

    c. The institutions should set thresholds for physician reporting to their institutions and for institutional evaluation mechanisms to assess the reported interests.

    d. Each medical center should also determine under what circumstances an individual physician's financial interest relating to particular drugs being prescribed or devices being used on a particular patient are such that they should be disclosed to the patient as well as the means for disclosure to the patient.

e. Clinical conflicts of interest policies should include provisions for consequences for failures to adhere to them.

5. **Academic medical centers should address institutional financial relationships with industry in the context of the clinical care they deliver.** The task force recommends that institutions should explicitly address conflicts of interest in clinical care that could result from their own financial relationships with industry involving products prescribed for or used in the treatment of its patients, or from the personal financial interests of their officials, including officials with immediate and direct responsibility for faculty.

6. **Academic medical centers should disclose the industry ties of their physicians to their patient communities as one method, though not the exclusive method, of managing actual and perceived conflicts of interest in clinical care.**

   a. The task force recommends that all academic medical centers make available to their patient communities and the public information regarding (i) the industry relationships of their individual physicians by whatever means each institution deems appropriate to articulate clearly the existence of these relationships; (ii) the value to society of such relationships; and (iii) a description of the institution's efforts to mitigate bias resulting from such relationships.

   b. Efforts should be made by Academic medical centers to use uniform standards and definitions of categories of disclosure for those interests that are determined to be conflicts so that patients can better understand information across care-giving sources.

   c. No single mechanism of disclosure (for example, Web sites or informational brochures) is recommended over others. Institutions should decide based on the needs of their patient communities how most effectively to communicate the realities of physician-industry relationships.

7. **Academic medical centers should involve their patient communities in determining the manner in which financial relationships of its physicians and of the institution itself should be made available to patients.**

   a. Academic medical centers should take full responsibility for helping patients understand the benefits, risks, and management of bias resulting from the financial relationships of its physicians with industry.

   b. The task force strongly supports the IOM's call for more research on conflicts of interest and the manner in which they should be addressed[63] but at the least, medical centers should involve their patient community in determining what information is useful to them as well as in how it is presented to specific patient communities.

[63] IOM (Institute of Medicine). Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009.

APPENDIX A

Physician Compensation and Medical Professionalism

An Evidence Review from the UPHS Center for Evidence Based Practice
October 2009

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BACKGROUND

The interaction between potential physician conflicts of interest and medical professionalism is of significant and growing concern to healthcare leaders, public policy makers, and the academic medicine community. Physicians and other health care professionals have traditionally sought to highlight the altruistic nature of their work while downplaying the influence of financial considerations on their activities. A growing body of research, however, raises questions about the impact of compensation and financial incentives on the practice of medicine. Recent Congressional inquiries into possible physician misconduct, scandals surrounding several widely used pharmaceuticals and their related clinical trials, and widespread public concern over health care costs have also led to increased concern about the role of money in medicine.

Much of the current debate and research focuses on conflicts of interest generated by interaction between healthcare providers and the primary industries that produce healthcare goods, including pharmaceuticals, medical devices, and related products. These relationships, while worthy of attention, are not the only important sources of potential financial conflicts and resulting challenges to medical professionalism. The mechanisms by which physicians are compensated in the routine course of providing care systematize incentives and disincentives, and may also create significant conflicts. Multiple models of physician compensation now exist, and some explicitly attempt to influence physician behavior in targeted directions. The most common mechanisms in use include fee for service, managed care, salaried arrangements, and the rapidly growing pay for performance movement. Each of these approaches may impact physician decision making in substantive ways, and create unique sources of ethical and financial conflicts. A related concern arises from private physician ownership of expensive technology (e.g., MRIs) and care sites (e.g., specialty hospitals, ambulatory surgery centers). These arrangements, although subject to legal and regulatory constraints, pose the risk of direct and substantial threats to professionalism.

This review presents a survey and summary of the literature exploring the potential impact of physician compensation arrangements on conflicts of interest and medical professionalism.

METHODS

The nature of the topic necessitated a review strategy that differed from conventional evidence reviews in some respects. A traditional evidence review produced by the Center for Evidence Based Practice is built through an iterative process of refining the most relevant MeSH terms in OVID Medline, and then applying necessary limitations to better focus the search. However, this strategy did not generate an appropriate body of literature to inform the current project. More than ten separate searches were attempted that connected varied terms related to compensation, such as reimbursement, capitation, managed care, and pay for performance, with outcomes oriented terms, such as professionalism, ethics, conflicts of interest, and quality. Unfortunately, these efforts consistently failed to provide enough specificity or sensitivity to permit analysis. The diverse nature of the research on this topic, and Medline's primary focus on biomedical sciences, probably account for these difficulties.

Alternative search strategies were therefore employed. A few key articles and prominent researchers related to each compensation mechanism were identified through narrow keyword-based searches, and a snowballing process was then adopted. Article bibliographies were scanned for additional sources, and Medline's "find citing articles" and "find similar articles" functions were frequently used. In addition to Medline, a keyword search of the healthcare business literature was conducted to capture perspectives not usually included in the medical literature. This process yielded approximately one hundred articles which were manually reviewed for relevance. 31 articles and 4 government reports were identified that offer significant and diverse insights into the impact of compensation on professionalism, and form the source data for this analysis.

Two important limitations were applied to the search. First, articles prior to 1990 were not sought. The marked changed in healthcare financing over the past twenty years are of particular significance to the research question, and the two

mechanisms that generate the most substantive debate – managed care and pay for performance – evolved in both form and as research subjects since 1990 (and since 2000, for the latter.) Research performed prior to that year was therefore expected to be dated. Second, studies were excluded if they did not involve an assessment of compensation in the United States. Several articles were identified that explored payment in Canada and Europe, but they were not included unless they also incorporated American physicians. The cumulative differences between the United States and other countries in almost every aspect of healthcare financing, delivery, physician autonomy, regulation, patient-physician communication, and general culture make it difficult to apply lessons from abroad to American healthcare.

EVIDENCE REVIEW

The overall body of literature is not very broad or robust. Although several payment mechanisms exist, few studies compare and assess the impact of multiple compensation models. Most research examines a single type of system.

The impact of compensation arrangements on physician behavior can be framed by a variety of outcomes. The most common outcomes assessed in the literature are:

- physician practice patterns, such as utilization of services and referrals
- physician self-reported attitudes, usually regarding autonomy, and
- quality of care, as defined by various process or outcome metrics

The development of the literature over the past twenty years reflects the historical evolution of health care payment schemes. Throughout the 1990's a body of research accumulated that focused on the managed care model. Some comparative studies of managed care versus fee for service also began to emerge. As the new millennium gave rise to widespread experimentation and adoption of quality incentives, a new literature focused on pay for performance approaches gained prominence. Most of the studies evaluated for this report assess either managed care stimuli or pay for performance projects. Physician ownership of specialty hospitals, ambulatory surgery centers, and imaging technology has also been addressed in the literature and received attention from the Medicare Payment Advisory Commission. These issues will be addressed as well. Finally, very little research focused on physician salary arrangements.

SYSTEMATIC REVIEWS

Two systematic reviews were identified which address physician compensation.

- A Cochrane Review (1) assessed how capitation, fee for service, salary, and mixed payment systems impact primary care physician behavior. They found four randomized controlled trials or other controlled studies, which included 640 physicians. The main outcome evaluated was utilization of healthcare services, and they determined that fee for service systems, compared with capitation, resulted in more patient visits to both primary care and specialty physicians, more diagnostic services, and fewer hospital referrals. While these results are not surprising and may imply possible conflicts of interest, the authors cautioned that the evidence is insufficient to support any strong conclusions.
- Another review (2) assessed a broader range of studies. Eight randomized controlled trials were included along with 81 additional studies with varying designs (i.e. nonrandom controlled studies, observational studies, and pilot studies.) Utilization was the key outcome, and the findings were similar to the Cochrane review: physicians in capitated systems provide a lower volume of services to patients than those in fee for service environments. The authors concluded, however, that the body of evidence was very limited.

PRIMARY STUDIES

Comparative Studies

Two studies directly compared different types of payment mechanisms.

- One study (3) comprised cross sectional surveys of physicians operating in closed-model systems (staff or group model HMOs) and open-model systems (where no exclusive payment arrangement existed.) The surveys were conducted in 1986 and replicated in 1997. Physician satisfaction, which was defined to include perceived personal autonomy, was the primary outcome. The study found that physicians in closed-model systems reported a greater sense of autonomy than those in open-models, and physicians in 1997 were less satisfied than they were in 1986 in almost every area measured by the survey. Satisfaction with autonomy was significantly lower for all physicians in 1997 than in the earlier iteration.

- A more recent study (4) examined how physicians respond to theoretical clinical scenarios that compare capitation and fee for service payment. A random sample of family physicians was surveyed. The authors discovered that physicians were less likely to perform or order discretionary services when presented with capitated payment, although this did not apply in life-saving situations. Physicians also reported more discomfort when reaching decisions in capitated systems.

Managed Care

A wide body of literature has explored the impact on physicians of managed care mechanisms, particularly capitated payment, prior authorization, and referral management. This literature is based almost entirely on survey-based studies, usually targeted to primary care physicians in internal medicine, family medicine and pediatrics. Three main themes emerge:

- Physicians almost universally reported dissatisfaction with managed care approaches to payment and utilization management. Productivity-related incentives, bonuses tied to resource use, prior authorization requirements, and referral systems were all cited as mechanisms that cause discontent. Physicians frequently framed their dissatisfaction in terms of a loss of professional autonomy and felt less able to provide maximally effective care. (5-10)

- Physicians sometimes expressed the belief that acute conflicts of interest result from managed care compensation. Common concerns included incentives to avoid services or referrals they believed to be beneficial, and pressure to spend insufficient time caring for patients during the office visit. (8, 11,12)

- The only countertrends detected were physician satisfaction with managed care plans that tie incentives to patient satisfaction and quality outcomes, rather than utilization; and satisfaction with plans that provide significant physician and patient support services for chronic disease management. (8, 10)

Quality Incentives

The growing trend of linking payment to quality metrics has quickly generated its own literature. Some studies have examined the impact of such programs on process and outcome measures, while others explored physician perspectives on these efforts. Although most studies focused on programs that target physicians, a few studies have assessed the CMS Premier Hospital Quality Incentive Demonstration Project. Four key themes are evident in this literature:

- Most programs were too new at the time of study to fully assess their impact. However, preliminary data have revealed that incentive programs may often be too small in scope to significantly affect physician behavior. (13-15)

- Physicians frequently reported that they were not well informed about the details of quality incentive programs. It is unclear if the rapid expansion of such programs over the past few years has changed this dynamic. (16-18)

- Despite their limited knowledge of program specifics, physicians often expressed concern about the implementation of quality incentives. They anticipated being penalized because of inaccurate performance measurement, and felt they lacked the training and resources to satisfy new quality-driven programs. Some also believed that incentivizing quality might ultimately undermine medical professionalism. (19-22)

- The Premier Hospital program has not yet shown substantial improvement in patient outcomes, and nothing has been published addressing physician attitudes or perceptions of the program. (23,24)

Physician Ownership

The conflicts potentially generated by physician ownership of specialty hospitals, ambulatory surgery centers, and imaging technologies are significant, and have received increasing attention from researchers, regulatory agencies, and payers in recent years. Self-referral may represent a far more direct conflict of interest than externally constructed payment mechanisms such as managed care or paying for quality, and most forms of self-referral are legally prohibited. However, several legal and regulatory exceptions have enabled business arrangements that raise concerns about conflicts of interest. Despite these concerns, the volume of physician ownership in some types of ventures has increased dramatically in recent years, accelerating concerns about conflicts of interest and the resulting impact on physician behavior.

Several studies have examined the referral patterns, quality, cost, and utilization of these services, and the Medicare Payment Advisory Commission (MedPAC) has also explored these issues extensively. Most of the literature does not, however, explicitly address conflicts of interest or related threats to professionalism as a focal point. Instead, studies tend to discuss the impact of these arrangements on the competitive environment for community hospitals, or the cost implications for payers. MedPAC, for example, as the lead agency advising Congress on Medicare payment policies, must focus its reports on how to adjust payment levels to improve efficiency and reduce overuse of services. Physician conflicts form a key contextual component of their discussion, but the Commission must ultimately produce specific financial and policy recommendations. The literature on physician ownership implies the presence of significant conflicts and major threats to professionalism, but provides only limited evidence and few conclusions. The following themes, however, have begun to emerge.

- The number of physician-owned specialty hospitals has more than doubled during the current decade, and the number of ambulatory surgery centers has grown by more than a third. (25) The use of physician-owned imaging technologies such as CT and MRI has also expanded dramatically. (26)

- Physician ownership is usually associated with higher rates of self-referrals. Moreover, physician-owned care sites treat patients who are, on average, better insured and less ill than those seen in community hospitals or academic medical centers. (25, 27-29). However, these facilities may provide better care and greater patient satisfaction, possibly contributing to their growth. (28)

- Geographic regions with a higher prevalence of physician-owned hospitals or technology experience higher utilization of expensive services. (25, 26, 29-31)

- Many observers have provided commentary highlighting the potentially severe conflicts inherent in these arrangements, but the research literature, to date, has not adequately explored these concerns. (32-35)

SUMMARY

Physician compensation arrangements inherently create incentives and disincentives that can influence clinical decision making and behavior. Some effects are by design and reflect the interests or needs of major stakeholders, while other consequences may be unintentional or even undesirable. Physicians must often respond to the expectations and requirements of external payers and purchasers, while simultaneously ensuring the financial viability of their own practice and providing high quality patient care. Conflicts of interest are inevitable in these circumstances, and physicians may routinely face ethical dilemmas arising from these pressures.

Research has shown associations between compensation mechanisms and resource utilization that may imply some erosion of medical professionalism. Physicians treating patients insured by capitated systems appear more likely than those in fee-for-service models to restrict the volume of diagnostic services, referrals, and office visits. Unfortunately, the evidence does not clarify whether physician responses to these different systems are motivated significantly by personal financial considerations. Physicians have long expressed concerns about the impact managed care has on patient care, clinical autonomy, and practice income. The evidence, though, does not support clear conclusions.

The research on recently emerging quality incentive programs is even less decisive. While these programs grow in number and scope, they remain too new to generate strong evidence of their impact. Physicians remain skeptical of the effects pay-for-performance efforts will have on medical care, concerns which mirror those voiced about managed care. The evidence, though, is limited and inconclusive.

Finally, physician ownership of medical infrastructure presents very direct and substantial opportunities for financial and ethical conflicts to emerge. Significant regulation has sought to minimize potential threats, but concerns persist. Research has shown that ownership is associated with higher rates of self-referral and overall utilization, but it remains unclear how much these patterns are driven by income-seeking behavior. Alternative explanations that highlight quality, satisfaction, and convenience may also help account for these findings.

While public concern about financial threats to medical professionalism usually focuses on physician relationships with the pharmaceutical and device industries, it remains important to recognize the fundamental impact payment mechanisms have on clinical decision processes. Although the evidence is not very conclusive, it is clearly suggestive of ethical challenges. Efforts to address physician conflicts of interest should acknowledge this broader context in the search for solutions.

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Appendix B

Suggested Public Disclosure Website Template for Academic Medical Centers

Guy Chisolm and Maya Wolpert

Representatives from device and pharmaceutical industries, public and private AMCs and one state government met in March, 2009 in Cleveland to discuss organizing principles and disclosure categories for public disclosure websites.[1] While consensus was neither sought nor achieved, the discussions influenced the authors' thinking. The opinions expressed here are not necessarily those of the attendees; however, based on these discussions and subsequent data from one AMC's efforts to determine what information their patients want about their physicians' financial ties with industry,[2] a template is suggested for uniform disclosure categories that could be adopted by AMCs. This template would ideally accompany other professional information about physicians and scientists whose financial interests are disclosed. The templates proposed for AMCs in Table 1 include what the authors believe to be key relationships between physicians/scientists and industry in an understandable format.

The categories in this template permit some flexibility. For example, if an AMC decided to disclose the reimbursement of expenses for consulting, it could add this category and it would still be clear to the reader that the consulting payment disclosed was solely the consulting fee and not the fee plus reimbursement. If an institution has stipulated that royalties cannot be accepted by an individual or the institution for the use of the product in question at that institution as Mayo Clinic has,** then this institutional decision could be made clear by altering the category or adding a footnote.

Inclusion of research funding with an accompanying statement such as "research grants are given to institutions, not individuals; however, funds have been designated to support the research and a portion of the salary by the listed company of this physician/scientist and his/her co-investigators" can help to educate patients and the public that these payments are not going personally and directly into the pockets of the researchers. For institutions that do not wish to confuse payments going to individuals and those going to institutions, these listings for research, education grants, and equipment donations for use by an investigator can be omitted from the individual's disclosure and a statement can be provided on the website that indicates to the reader that research, education, and equipment grants and contracts cannot go to individuals directly, but rather go to the institution.

Many physicians in settings other than AMCs have strong and varied relationships with industry. Independently practicing physicians and group practices should consider adopting analogous disclosure mechanisms with provisions consistent with those presented here. In such cases, if there are exceptions to the categories we suggest for AMCs, this should be made explicit, with an additional or substituted category, clearly defined and readable by the lay public.

We have not included in this commentary relationships that an AMC as an *institution* might have with industry, such as philanthropy, grants, contracts for research or education, or donations of equipment or supplies that are not specified for use by named individuals. We acknowledge that these relationships could represent the appearance of conflict of interest, and we recommend the creation of analogous disclosures for revealing academic institution-industry relationships.

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[1] Cleveland Clinic invited these representatives, all of whom were at that time discussing constructing public disclosure webpages. The intent was to share ideas for uniform disclosure. Consensus was neither sought nor reached; however, the various perspectives voiced at that meeting informed this appendix. We make no representations about the views of any attendee other than the co-authors.

[2] In late 2008, Cleveland Clinic went live with webpages disclosing in specific categories (consulting, rights to royalties, equity or inventor share for discoveries, ownership interests, and fiduciary roles) the financial ties that its physicians and scientists have with industry. Disclosed were names of companies within those categories, not amounts of money received. The website was structured to provide information believed to be of interest to patients. Cleveland Clinic has since surveyed its patients and learned that over 80% of the more than 1,300 responding patients were likely to review physician-industry relationship information if it were available online. However, respondents wanted information beyond what was provided; they wanted not only the types of relationships their physicians have with industry, but the duration and commitment of time and money. Over 90% also wanted to know Cleveland Clinic's *institutional* ties to industry.

**https://secure.ethicspoint.com/domain/media/en/gui/23071/mcConflict_of_Interest_Policy.pdf

Table 1: Financial relationships of individual physician or scientist in an Academic Medical Center (prior calendar year)

Physician/Scientist Name (and brief bio or click through to bio)				
Financial relationships for healthcare-related industry for calendar year, XXXX		Companies related to healthcare industry with which this physician/scientist has a relationship		
Fees for Services+		**Company A** (Indicate private or public)	**Company B** (Indicate private or public)	…
Consulting	Fees (Excluding expense reimbursement)	$ range[1]		
Speaking (using audiovisuals or printed materials under the control of the company sponsoring the talk)	Fees (Excluding expense reimbursement)	$ range		
Speaking (using no audiovisuals or printed materials under the control of the company sponsoring the talk)	Fees (Excluding expense reimbursement)	$ range		
Board of Directors/Board of Trustees/ Officer	Fees (Excluding expense reimbursement)	$ range		
Royalties	Royalties currently being paid for past inventions (dollar amount)	$		
	Royalties or rights to royalties for products being developed	☐ Yes ☐ No		
Stock or stock options acquired for role as inventor, discoverer, founder (Close of year value for stock, options, inventor's share or any other indication of ownership)		$ range		
Stock or stock options as personal holdings, *not* acquired for role as inventor, discoverer, founder (Close of year value for stock or options)		$ range		

+ Reimbursement includes travel, lodging, food, and other travel expenses

[1] Example of ranges $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000)

Funding of Research Note: research grants are given to institutions, not individuals; however, funds from the listed company have been designated to support the research and/or a portion of salary of this physician/scientist and his/her co-investigators.	Investigator names Title of grant Duration Total $ amount to institution for this research			
Funding of Research by HHS or other government agency that creates a potential conflict of interest with the listed company. Note: In such cases the potential CoI is evaluated and managed by the academic medical centers	Investigator names Title of grant Duration Total $ amount to institution for this research			
Donation of Equipment/Supplies for research Note: such donations are given to institutions, not individuals; however, they may be designated to support the research of this principal investigator and his/her co-investigators.	Retail value ($) of items given to institution for use by this physician/scientist	$ range		
Funding of Education Note: education grants are given to institutions, not individuals; however, they may be designated to support the research of this physician/scientist	Total $ amount to institution for use by this physician/scientist	$ range		
Charitable Donations Made by the listed company to a charity instead of the physician/scientist at the request of this physician/scientist	Total $ amount given, and to what charity	$ range		
Gifts to this physician/scientist	Market value	$ range		

Appendix C

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