Be Careful What You Ask for: NIH's Request for Comments on Conflicts of Interest in Research

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When a patient agrees to participate in a clinical trial to find a cure for cancer or to treat a mental illness, as a human subject, the patient relies and trusts that those conducting the study are doing so with the highest integrity in the pursuit of scientific knowledge. Yet, when the patient reads in *The New York Times* or *The Wall Street Journal* that the director of the department of psychiatry received millions of dollars for speaking engagements from the life sciences organization sponsoring research at the university or that the life sciences organization may have endowed a professor's chair at the university,[1] the patient begins to wonder if the results of the research are biased. One analysis found researchers were five times more likely to find favorable results in research when they had a financial tie to the drug company sponsoring the research.[2] However, the best policy to protect the integrity of research may not be to prohibit life sciences organizations from sponsoring clinical research. The synergy and innovation that result from the partnership of life sciences organizations and academic medical centers (AMCs) create remarkable cures for illnesses that society once may not have believed were possible.[3] AMCs should continue to promote their efforts to uphold the promise of integrity in science by creating environments in which they do not tolerate the appearance of conflict in research.

On May 8, 2009, the National Institutes of Health (NIH) published a request for comments on several areas of the regulation of conflicts of interest (RFC).[4] The request, titled "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors," garnered a lot of attention from AMCs and other individuals and entities in the research community. This article examines the regulation of conflicts of interest in research and the healthcare industry's response to rising public concern about perceived conflicts of interest in research. First, this article places the NIH's request for comments in context against the background of efforts by other government agencies and the healthcare industry to regulate conflicts of interest. Second, the article reviews two important substantive areas where NIH has requested comments: (a) treatment of certain types of income and (b) institutional conflicts of interest. Finally, the article suggests that if the NIH (or another government entity) decides to further regulate conflicts of interest in research, it follows a balanced approach as proposed by the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC) and the Council on Government Relations (COGR). Under this approach, NIH should allow consideration for the particular facts and circumstances of an individual AMC's arrangements with life sciences organizations as they partner to further medical research. While some government regulation may be both appropriate and necessary, the activities of AMCs themselves are central to promoting integrity in clinical research.

Context for NIH's Concerns

NIH is far from the only government agency concerned about issues involving conflicts of interest. Within the Department of Health and Human Services (HHS), the Office of Inspector General (OIG), followed closely by the Centers for Medicare and Medicaid Services, have been actively evaluating concerns involving many sectors of the healthcare industry. Outside HHS, the Senate Special Committee on Aging, chaired by U.S. Senator Herbert Kohl (D-WI), as well as U.S. Senator Charles Grassley (R-IA), has actively promoted legislation and conducted oversight hearings on conflicts of interest topics.[5] Various state legislatures, with Massachusetts taking the most activist role, have passed legislation to regulate conflicts of interest.[6] The Department of Justice, and particularly the U.S. Attorney's Office in the District of New Jersey, has investigated and settled a number of conflict of interest matters.[7] NIH thus has a significant background of activities by other government agencies to consider as it reviews comments in response to the RFC and determines its next steps.

Over a two-year period, Senator Kohl conducted four oversight hearings exploring relationships between physicians and the pharmaceutical and medical device manufacturing industries.[8] The most recent hearing, held in July 2009, focused on industry funding of continuing medical education. Prior hearings focused on drug reviews, payments by the medical device industry to consultants, and relationships between physicians and pharmaceutical manufacturers. These hearings brought attention to the issues that led Senator Kohl to introduce, and Senator Grassley to co-sponsor, the Physician Payments Sunshine Act (Act)[9] whereby manufacturers of drugs, devices and biologics would be required to disclose publicly a wide range of payments and gifts to physicians. In testimony before the Committee, OIG Chief Counsel Lewis Morris acknowledged that "[a] productive collaboration between medicine and commercial interests can expand knowledge, drive innovation, and improve quality of care."[10] Another OIG official, Gregory Demske, Assistant Inspector General for Legal Affairs, had earlier conceded that relationships between physicians and

pharmaceutical and device manufacturers and suppliers can "advance medical science and benefit patients." In his testimony, Mr. Demske advocated a coordinated effort by the healthcare industry, the medical community, and the government to address and mitigate risks involved in these relationships, noting that it would be "inappropriate and impractical to rely solely on Government enforcement to address an issue of this complexity."[11]

With respect to industry self-regulation, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed), two industry associations for pharmaceutical and medical device manufacturers, have taken the lead in publishing two of the most detailed, voluntary codes of conduct that address relationships with healthcare providers.[12] The AdvaMed Code contains a detailed section (added effective July 1, 2009) that addresses royalty payments by requiring that royalty arrangements meet certain contractual standards, setting forth criteria for when royalty arrangements might be appropriate (for novel, significant or innovative contributions) and providing standards for calculating royalties (to preserve objectivity of medical decision making and avoid improper influence).[13] Both codes specifically address arrangements with nonprofit organizations, including research grants.[14] These codes provide a significant backdrop for evaluating the industry's own efforts at promoting self-regulation.

These enforcement activities, statutory and regulatory pronouncements and voluntary industry codes described above, provide a context for evaluating the questions and responses to NIH's RFC. The clear message from these efforts is that self-regulation and development of internal mechanisms for recognizing, addressing and managing conflicts of interest by the industry members affected must be a part of any overall government regulatory framework. The NIH should consider making any proposed amendments to the existing regulations consistent with existing government agencies' actions and balancing such proposals with the AMCs' and life sciences organizations' own efforts.

Financial Interests

One key issue raised in NIH's RFC involves the definition of "significant financial interest" under the current regulations. Institutions are responsible for ensuring that investigators submit a list of significant financial interests to a designated official before the institution applies to participate in Public Health Service (PHS)-funded research.[15] NIH posed a couple of overarching questions in the RFC, including whether it should maintain the current exemptions from the definition of significant financial interest, whether the current de minimis thresholds of $10,000 and 5% ownership interest are reasonable (and should be consistent for all types of research) and whether it should automatically consider certain types of significant financial interests to constitute a financial conflict of interest. The following issues in defining significant financial interest generated numerous comments: (a) de minimis or threshold amounts, (b) the treatment of royalty income earned from the institution and (c) income from seminars, lectures or teaching

engagements sponsored by public or nonprofit entities and income from service on advisory committees or review panels for public or nonprofit entities.

It is possible to strike a balance in the outlined areas by dropping the de minimis thresholds for reporting, while maintaining them for purposes of disclosure to PHS. However, instituting automatic financial conflicts of interest would seem to go too far because AMCs and life sciences organizations can themselves manage potential conflicts arising from many unique relationships between the parties. Creating a bright line rule sounds appealing, but is likely to harm research without significantly benefitting research integrity. There is general consensus that royalty income, regardless of source, should no longer be exempted from the definition of significant financial interest. The exemptions for the aforementioned types of income from nonprofit entities should be maintained. Examining the comments explains the rationale for some of these positions.

Reporting versus disclosure

The AAMC and the AAU submitted joint comments in response to the RFC through their respective presidents, Dr. Darrell Kirch and Dr. Robert Berdahl. The AAMC/AAU were careful to distinguish between requiring an investigator to report significant financial interests to his or her institution and requiring disclosure to PHS of this same information.[16] The AAMC/AAU position respects the need for institutions to regulate themselves and we agree that institutions should have this leeway.

De Minimis Thresholds

Some organizations advocated lowering the current de minimis thresholds for disclosing financial interests. For example, the AAMC/AAU joint comments recommended that the current $10,000 threshold be lowered to $5,000.[17] On the other hand, Eva J. Pell, who is Senior Vice President for Research at Pennsylvania State University, supported removing the de minimis threshold entirely, but also suggested that this is an area that could be left to the individual institutions to regulate.[18] The de minimis threshold is already quite low—we recommend retaining it for purposes of disclosure at its present levels, but dropping it entirely for internal reporting purposes. Changing the dollar value from $10,000 to $5,000 is only likely to create confusion, draws too fine a line and is a compromise without real empirical evidence to justify making the change.

Royalty income

With respect to the issue of royalty income, Roberto Peccei, the Vice Chancellor for Research at the University of California, Los Angeles, and Lynette M. Schenkel, Assistant Vice President, Responsible Conduct of Research at the University of Oregon, illustrate divergent viewpoints. Mr. Peccei believes that there is merit in requiring investigators to report royalties received through their institutions,[19] while Ms. Schenkel supports maintaining the current exemption.[20] The AAMC/AAU commenters supported reporting of royalties received through the applicant institution. A number of other AMC representatives, including Ms. Pell from Pennsylvania State, also supported the AAU/AAMC position to remove the exemption for royalties received from the institution.[21] Royalty income, regardless of source, does benefit individuals and consequently could create bias. We agree that the government should remove the current exemption.

AMCs should continue to promote their efforts to uphold the promise of integrity in science by creating environments in which they do not tolerate the appearance of conflict in research.

Seminars, lectures, teaching engagements and advisory committees

The AAU and the AAMC support retaining the exemption for income from seminars, service on advisory committees, etc. for nonprofit entities.[22] The justification for this distinction is that these are professional activities that benefit the institution and should not be subject to "scrutiny" under the proposed NIH regulations.[23] (Ostensibly, it would be fair to conclude that the commenters saw the benefit of royalty payments as principally inuring to the individual.) Nonprofit leaders had similar viewpoints. Robert J. Beall, President and Chief Executive Officer for the Cystic Fibrosis Foundation, urged NIH to continue to exempt income from nonprofit sources, such as seminars, lectures, teaching engagements and service on advisory committees or review panels. His concern is that "[n]onprofits need input from researchers from academia and industry to help develop new therapies and improve delivery of care." In his view, barring participation in these activities would have adverse clinical consequences for the people with cystic fibrosis. However, he acknowledged that disclosure of this type of nonprofit work might be appropriate, so long as the disclosures are not used to create bars for investigators.[24]

Automatic financial conflicts of interest

AAMC and AAU do not favor setting bright line rules for "automatic" financial conflicts of interest.[25] Like many of her colleagues, Ms. Pell from Pennsylvania State urged NIH not to create automatic financial conflicts of interest, but instead

to allow institutions to consider the facts and circumstances of each particular case.[26] Bright line rules are appealing when grappling with complicated scenarios. They do not, however, make a complicated issue less complicated; they just ignore important factual distinctions. From this perspective, we agree with the AAMC/AAU position rejecting automatic financial conflicts of interest.

Other viewpoints

One commenter urged NIH to consider taking an entirely new approach. Dr. Jane Robbins, Senior Lecturer, Organizational Leadership, Department of Leadership, Policy and Organizations of Vanderbilt University, argued any strengthening of the regulations should only be viewed as a "stop-gap" measure while the entire conflict of interest system is overhauled.[27] Thus, in her view, the current exemption from the definition of "significant financial interest" of royalty income from institutional sources should not be maintained.[28] Her approach to investigators' work with nonprofit organizations is nuanced: consulting income, honoraria, or equity interests that are unrelated to marketing of commercial products, current or previously funded research or personal intellectual property (i.e. royalties) would not represent a conflict of interest.[29] She also recommended removing the de minimis thresholds.[30] Finally, she proposed treating all significant financial interests as automatically creating conflicts of interest.[31]

The AAMC, AAU and various AMC representatives submitted thoughtful comments in response to the RFC. Overall, these commenters advocate a balanced approach to regulating significant financial interests that includes dropping the de minimis thresholds for internal reporting, dropping the exemption for royalty income from the institution and maintaining the exemption for income from seminars, lectures, teaching engagements and advisory committees involving nonprofit or public entities. Automatic conflicts of interest rules do not have a role in such a balanced approach.

Institutional Conflicts of Interest

In 1995, PHS mandated that institutions receiving PHS funding implement conflict of interest policies focusing on individuals conducting the research,[32] but PHS did not require regulation of institutional conflicts of interest. NIH and the Office for Human Subject Protection (OHRP) have published some limited guidance on institutional conflicts of interest.[33] With the focus on institutional conflict of interest from the AAU/AAMC reports[34] and Senator Grassley's very public investigations of this issue,[35] NIH has included institutional conflict of interests in its RFC.[36]

Specifically, the NIH posed the following questions: (1) how would institutional conflicts be defined and (2) what would a policy address in order to assure PHS of objectivity in research?[37] Most commenters, including but not limited to the AAMC/AAU and the COGR, stated that institutional conflict of interest is too complicated for regulation at this time and that the AAMC/AAU had comprehensively addressed the issue in their reports.[38] Yet, citing their findings at several prominent universities, Senators Grassley and Kohl urged NIH to increase transparency in this area, pointing to the lack of NIH oversight, the almost $24 billion in extramural funds distributed annually to the NIH and the additional $10 billion in American Reinvestment and Recovery Act funding to the NIH as support for their position. In their July 7, 2009 letter to Dr. Raynard Kington, the Acting Director of NIH, the lawmakers recommended that researchers with NIH grants report their outside income, universities complete plans to manage potential conflicts and NIH publish such information on its website.

Definition of Institutional Conflict

The AAMC/AAU offer a balanced definition of institutional conflict that sets the stage for transparency and objectivity in policy:

> An institution may have a conflict of interest in human subjects research whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the conduct, review, or oversight of human subjects research.[39]

In effect, when a high-level official at an institution has a financial conflict of interest, the institution has a financial conflict of interest. The official's activities are deemed to be that of the institution.

Most commenters to the NIH RFC accepted the AAMC/AAU definition as one that encompasses the issue of institutional conflict of interest.[40] However, Dr. Robbins may have best emphasized the importance of institutional conflicts of interest in her response:

> Institutional conflict of interest is inseparable from individual conflict of interest. In the final analysis, institutional integrity is all that matters; the institution creates and oversees the structure within which the individuals work, thereby setting the constraints and freedoms that determine levels of individual conflict. Institutional conflict of interest thus may be defined as follows:

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> Institutional Conflict of Interest is a choice-driven condition that implicates the entire institution in a financial conflict with the potential to undermine the reputation of or trust in the institution, but that may arise at either an individual or institutional level.[41]

Whether or not institutions utilize the AAMC/AAU definition, the principle that the acts of individuals, whether deans or researchers, affect the institution's reputation as a whole should be the crux of the definition. In addition, the definition needs to recognize that institutional investments whether contributions to its foundation, technology transfer rights, master agreements with sponsors, speaker/consultant/advisory committee fees, procurement of goods and services or other interests in life sciences organizations appear to create a bias in the outcome of research.

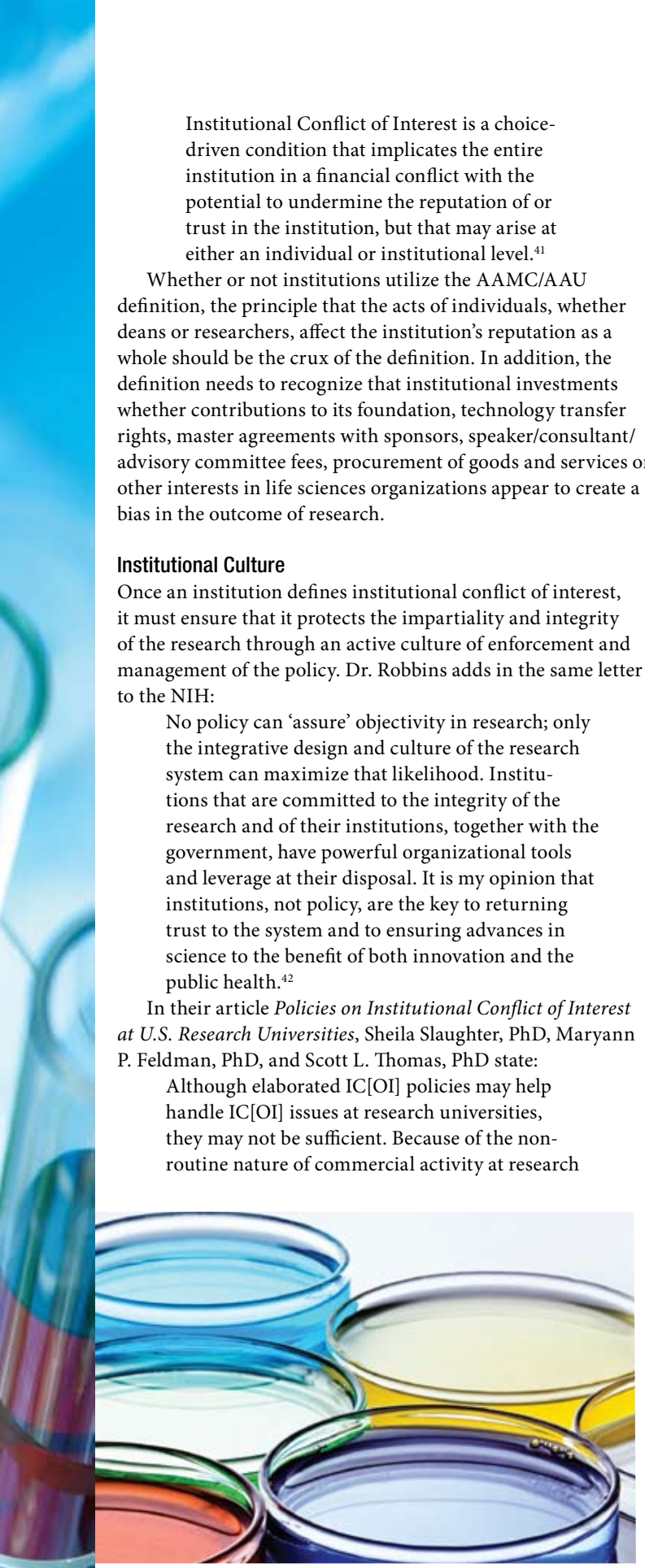
Institutional Culture

Once an institution defines institutional conflict of interest, it must ensure that it protects the impartiality and integrity of the research through an active culture of enforcement and management of the policy. Dr. Robbins adds in the same letter to the NIH:

> No policy can 'assure' objectivity in research; only the integrative design and culture of the research system can maximize that likelihood. Institutions that are committed to the integrity of the research and of their institutions, together with the government, have powerful organizational tools and leverage at their disposal. It is my opinion that institutions, not policy, are the key to returning trust to the system and to ensuring advances in science to the benefit of both innovation and the public health.[42]

In their article *Policies on Institutional Conflict of Interest at U.S. Research Universities*, Sheila Slaughter, PhD, Maryann P. Feldman, PhD, and Scott L. Thomas, PhD state:

> Although elaborated IC[OI] policies may help handle IC[OI] issues at research universities, they may not be sufficient. Because of the non-routine nature of commercial activity at research universities all ICOI is managed on a case-by-case basis. That means the institutional policy is only as strong as the various committees or senior officers responsible for developing and monitoring management plans to handle conflicts.[43]



Drs. Robbins, Slaughter, Feldman, and Thomas most likely have identified the essence of the issue in managing institutional conflicts of interest. Having a conflict of interest policy does not uphold the integrity of research if researchers and AMC officials do not disclose their financial interests. According to an article in *The New York Times*, Dean Alpern of the Yale School of Medicine stated "[i]t's really been an honor system thing, [i]f somebody tells us that a pharmaceutical company pays them $80,000 a year, I don't even know how to check on that."[44] This comment shows the potential flaws in relying solely on individuals to disclose and the lack of systems to identify conflicts of interest. The proposed Physician Payments Sunshine Act (mentioned above) may help create transparency to enable AMCs to know if their researchers and officials have financial interests in life sciences organizations.[45] However, such knowledge is only valuable in a university culture where its highest officials ensure the monitoring and managing of conflicts.

Considerations for Policy Development

Once the institution establishes its culture of management and enforcement, creating a policy is the next step to address such a complex issue by setting forth the processes to identify and manage effectively conflicts throughout the institution. While several universities have policies in place, few of these are sufficiently robust to identify and manage effectively institutional conflicts of interest such as through external audits.[46] Given the complex nature of funding at universities and AMCs, it can be hard to identify potential institutional conflicts of interest. Often, funding is provided to different departments, schools and divisions throughout the AMC, as well as through technology transfer offices and institutional foundations, making it difficult for institutional review boards (IRBs) to know that the institution received funding that might appear to conflict with the interests of the research.

COGR has created a toolkit, *Approaches to Developing an Institutional Conflict of Interest Policy*, which is available on its website.[47] The toolkit walks institutions through considerations in defining institutional conflicts of interest, building consensus by having a committee comprised of representatives throughout the institution, charging the committee on the approach to drafting the policy, weighing issues in areas to cover in the written policy and procedure and implementing the policy. It serves as a thoughtful guide as AMCs look to create or strengthen their institutional conflict of interest policies.

While a specific, government-mandated institutional policy probably would not be effective, the government could mandate aspects that are important to having an effective policy. The AAMC and the AAU suggest a sample institutional conflict of interest policy in their February 2008 report that includes three guiding principles. First, the AAMC and

the AAU recommend segregation of individuals involved in research policy from all decisions regarding institutional investments. AMCs may create firewalls or have other mechanisms to lessen the risk of influence on the research. Second, the AAMC and the AAU recommend that institutions have a rebuttable presumption against conducting research if there is a conflict of interest. In the event of a compelling circumstance and after approval of an effective management plan, research may proceed even though there is a conflict of interest. Considerations of the circumstances of the conflict may include, but are not limited to, the nature of the science, how closely the interest is related to the research and the degree of risk of the research to the human subjects. An AMC may determine it is uniquely situated to conduct the research due to the expertise of its researchers or its population of human subjects. In such a case, the AMC must put an effective management plan in place such as external monitoring to ensure the integrity of the research and it must document such management of the conflict. Third, the AAMC and the AAU stress that an institution consistently must apply its conflict of interest policy throughout the institution. This factor is critical as the consistent application of policies guards against bias. All of these principles from the AAMC/AAU would be helpful guidance in any government regulation on institutional conflict of interest.

Key provisions for institutional conflict of interest policy include, but are not limited to: (1) creating an institutional conflict of interest committee with members who are not affiliated with the AMC, (2) ensuring a process to identify when an institutional official has a financial relationship and (3) identifying when the institution develops a relationship with a life sciences organization sponsoring research at the institution.[48] One central issue with conflict of interest at AMCs is that IRBs and COI Committees may not coordinate information. Accordingly, each institution needs to create a central repository of all records related to institutional conflicts of interests including, but not limited to, technology transfer agreements and intellectual property interests of institutional officials such as deans and directors. An IRB should not be permitted to approve any research without asking the institutional conflict of interest committee about any financial interests that may conflict with the research. The institution must be diligent to ensure timely disclosure of conflicts so that the IRB acts on current information when approving research.

Moreover, AMCs need effective policies to manage conflicts through, for example: disclosure; divestiture; reduction of interests; deferral or waiver of royalty payment; prohibition of serving as an officer, as a member of the board of directors, on an advisory board, on a speakers bureau or as a consultant; erecting a firewall around an individual with a conflict; and using external auditors. Given the case-by-case nature of institutional conflicts of interest, a policy could not require a particular means of managing the conflict. As the AAMC and the AAU state,

> [t]here is no formula that dictates which strategies 'fit' which conflicts. The final determination is dependent on individualized assessment at the local institutional level of totality of the circumstances that need to be taken into account. Each institution is best positioned to make this assessment on its own behalf, consistent with the framework for federal regulation of conflicts of interest and with the institution's responsibility for the quality and integrity of the research conducts under its auspices.[49]

While some government regulation may be both appropriate and necessary, the activities of AMCs themselves are central to promoting integrity in clinical research.

Accordingly, government regulations could not dictate that all equity interests in intellectual property be managed in a particular fashion without overlooking the complexity of the relationship among the life sciences organization, institution, researchers and human subjects. Critical medical research could be stifled by overarching regulation of conflicts of interest management. Each institution needs to ensure its policy on institutional conflict of interest incorporates effective tools to manage any conflicts that arise. In addition, institutions must foster a vigilant culture that follows through in actually managing, and documenting the management of, any perceived conflict of interest.

Conclusion

In summary, COGR, AAU and AAMC offer balanced approaches to addressing conflict of interest in medical research. A balanced approach to defining what constitutes significant financial interests would involve (1) dropping de minimis thresholds for internal reporting purposes, while maintaining them for disclosures outside the institution; (2) dropping the exemption for royalty income paid through the institution (because it principally benefits the individual); (3) maintaining the exemption for income from seminars and advisory committees (because of the benefit to the institution from these professional activities); and (4) not creating any automatic financial conflict of interest rules.

It is critical for AMCs to recognize that institutional conflicts of interest exist, to establish an environment of vigilance against the appearance of institutional conflicts of interest, to identify such conflicts in a timely manner and to manage such conflicts to ensure the impartiality of the research. The guidance from AAMC, AAU and COGR

provides an excellent framework for AMCs to restructure and create their institutional conflict of interest policies and as a foundation for broad regulation by the federal government of institutional conflicts of interest. The research produced by AMCs and life sciences organizations changes American lives through medical findings. Government regulators should respect the need for this partnership. If NIH determines that further regulation of conflicts of interest is necessary, it should do so in the context of the activity from other government entities as well as the ongoing efforts of life sciences organizations and AMCs. C

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Endnotes

1 Gardiner Harris, *Top Psychiatrist Didn't Report Drug Makers' Pay*, N.Y. Times online, Oct. 4, 2008; Gardiner Harris and Benedict Carey, *Researchers Fail to Reveal Full Drug Pay*, N.Y. Times online, June 8, 2008; David Armstrong *US Probes Emory Doctor's Glaxo Ties*, Wall St. J. online, Feb. 26, 2009; Sarah Rubenstein, *What Did Emory Tell NIH About Nemeroff's Pharma Pay*, Wall St. J. online, Feb. 26, 2009.

2 Roy H. Perlis, MD, Clifford S. Perlis, MD, MBe, Yelena Wu, BA, Cindy Hwang, BA, Megan Joseph, BA, and Andrew A. Nierenberg, MD, *Industry Sponsorship and Financial Conflict of Interest in the Reporting of Clinical Trial in Psychiatry*, 162 Am. J. of Psychiatry 1957-1960 (Oct. 2005).

3 Committee on Conflict of Interest in Medical Research, Education and Practice, Board on Health Sciences Policy, Institute of Medicine, *Conflict of Interest in Medical Research, Education and Practice*, at 8-1 (Bernard Lo and Marilyn J. Field, eds., Apr. 2009).

4 74 Fed. Reg. 21610.

5 *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry: Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (Feb. 27, 2008) (testimony of Gregory E. Demske). *Medical Research and Education: Higher Learning or Higher Earning: Hearing Before the S. Spec. Comm. On Aging* (July 29, 2009) (statement of Lewis Morris), *available at* http://aging.senate.gov/hearings.cfm.

6 *See, e.g.*, Mass. Gen. Laws ch. 111N §§ 1-7; Cal. Health & Safety Code §§ 119400 – 119402; D.C. Code Ann. §§ 48-833.01 – 48-833.09; Maine Rev. Stat. Ann. tit. 22, § 2698-A; Minn. Stat. §§ 151.461, 151.47; Nev. Rev. Stat. § 639.570; Vt. Stat. Ann. tit. 22 § 4632; W. Va. Code § 5A-3C-13.

7 *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry: Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (Feb. 27, 2008) (testimony of Gregory E. Demske at 4-7).

8 *Paid to Prescribe?: Exploring the Relationships Between Doctors and the Drug Industry: Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (June 27, 2007); *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry: Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (Feb. 27, 2008); *Under the Influence: Can We Provide Doctors An Alternative To Biased Drug Reviews? Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (Mar. 12, 2008); *Medical Research and Education: Higher Learning or Higher Earning: Hearing Before the S.*

Spec. Comm. On Aging (July 29, 2009) (Hearing records *available at* http://aging.senate.gov/hearings.cfm).

9 S. 301, 111th Cong. (2009). Senator Kohl previously introduced a version of this legislation in 2007.

10 *Medical Research and Education: Higher Learning or Higher Earning: Hearing Before the S. Spec. Comm. On Aging* (July 29, 2009) (statement of Lewis Morris), *available at* http://aging.senate.gov/hearings.cfm.

11 *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry: Hearing Before the S. Spec. Comm. On Aging*, 110th Cong. (Feb. 27, 2008) (testimony of Gregory E. Demske at 4-7).

12 AdvaMed Code of Ethics, *available at* www.advamed.org; PhRMA Code on Interactions with Healthcare Professionals, *available at* www.phrma.org. In addition, the AAMC has published guidelines on Industry Funding of Medical Education, *available at* www.aamc.org.

13 AdvaMed Code of Ethics, at 6-7.

14 *Id.* at 10 – 11; 21 – 23; PhRMA Code, at 6, 13.

15 42 C.F.R. § 50.604(c) (1995).

16 Letter from Association of American Universities/Association of Academic Medical Colleges to Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (June 10, 2009) (AAU/AAMC Letter).

17 *Id.*

18 Letter from Eva J. Pell, Senior Vice President for Research, Dean of the Graduate School, Pennsylvania State to Jerry Moore, NIH Regulations Officer (July 7, 2009), at 3 (Pell Letter)

19 Letter from Roberto Peccei, Vice Chancellor for Research, University of California, Los Angeles to Jerry Moore, NIH Regulations Officer (July 7, 2009), at 2 (Peccei Letter)

20 Letter from Lynette Schenkel, Assistant Vice President, Responsible Conduct of Research, University of Oregon to Jerry Moore, NIH Regulations Officer, National Institutes of Health (July 7, 2009), at 1.

21 Pell Letter, at 3.

22 AAU/AAMC Letter.

23 *Id.*

24 Letter from Robert J. Beall, PhD, President and CEO, Cystic Fibrosis Foundation, to Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (July 7, 2009).

25 AAU/AAMC Letter.

26 Pell Letter, at 3.

27 Letter from Dr. Jane E. Robbins to Jerry Moore, NIH Regulations Officer (June 26, 2009), at 2.

28 *Id.* at 4.

29 *Id.*

30 *Id.* at 5.

31 *Id.* at 2.

32 42 C.F.R. § 50 (2000); 45 C.F.R. § 94 (1995).

33 National Institutes of Health, *Financial Conflict of Interest – Objectivity in Research: Institutional Policy Review* (Feb. 2003); Office for Human Research Protection, *Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing with Issues of Financial Interests and Human Subject Protection* (June 2001).

34 Association of American Universities, *Report on Individual and Institutional Financial Conflict of Interest* (Oct. 2001); Association of American Medical Colleges, *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research* (Oct. 2002); Association of American Medical Colleges – Association of American Universities, *Protecting, Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research* (Feb. 2008).

35 Gardiner Harris, Gardiner and Benedict Carey, *Researcher Fail to Reveal Full Drug Pay*, N.Y. Times online, June 8, 2008.

36 74 Fed. Reg. 21610 (May 8, 2009).

37 *Id.* at 21612.

38 Letter from Association of American Universities/Association of Academic Medical Colleges to Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (June 10, 2009); Letter from Council on Governmental Relations to Jerry Moore, NIH Regulations Officer, National Institutes of Health (July 7, 2009); Letter from Sandra Oliver, Vice President Public Policy & State Government Affairs, Bayer HealthCare LLC to Jerry Moore, Office of Management Assessment, National Institutes of Health (July 2, 2009); Letter from Kenneth I. Shine, MD, Executive Vice Chancellor for Health Affairs, The University of Texas System to Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (June 15, 2009); Letter from Roberto Peccei, Vice Chancellor for Research, University of California, Los Angeles to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Eva J. Pell, Senior Vice President for Research, Dean of the Graduate School, Penn State to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Russell Moore, PhD, Office of the Vice Chancellor for Research Gradual School, University of Colorado at Boulder to Jerry Moore, NIH Regulations Officer (July 6, 2009); Letter from Barbara Bierer, MD, Senior Vice President, Research, Brigham and Women's Hospital to Jerry Moore, NIH Regulations Officer (July 6, 2009); Letter from Jeffrey M. Creek, PhD, Associate Vice Provost for Research Compliance and Operations, University of Washington to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Michael Middleton, JD, Deputy Chancellor, University of Missouri to Jerry Moore, NIH Regulations Officer (June 17, 2009); Letter from Tony G. Waldrop, Vice Chancellor for Research and Economic Development, The University of North Carolina at Chapel Hill to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from James V. Maher, Provost and Senior Vice Chancellor, University of Pittsburgh to Jerry Moore, NIH Regulations Officer (July 2, 2009); Beth H. Israel, Associate Vice President Research Administration, Arizona State University to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Jordan L. Cohen, Interim Vice President for Research and Economic Development and Derek Willard, Special Assistant to the President for Government Relations and Associate Vice President for Research, the University of Iowa to Jerry Moore, NIH Regulations Officer (July 7, 2009).

39 Association of American Medical Colleges – Association of American Universities, *Protecting, Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research* (Feb. 2008), at 14.

40 Letter from Association of American Universities/Association of Academic Medical Colleges to Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (June 10, 2009); Letter from Sandra Oliver, Vice President Public Policy & State Government Affairs, Bayer HealthCare LLC to Jerry Moore, Office of Management Assessment, National Institutes of Health (July 2, 2009); Letter from Russell Moore, PhD, Office of the Vice Chancellor for Research Graduate School, University of Colorado at Boulder to Jerry Moore, NIH Regulations Officer (July 6, 2009); Letter from Barbara Bierer, MD, Senior Vice President, Research, Brigham and Women's Hospital to Jerry Moore, NIH Regulations Officer (July 6, 2009); Letter from Jeffrey M. Creek, PhD, Associate Vice Provost for Research Compliance and Operations, University of Washington to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Michael Middleton, JD, Deputy Chancellor, University of Missouri to Jerry Moore, NIH Regulations Officer (June 17, 2009); Letter from Tony G. Waldrop, Vice Chancellor for Research and Economic Development, The University of North Carolina at Chapel Hill to Jerry Moore, NIH Regulations Officer (July 7, 2009); Letter from Jordan L. Cohen, Interim Vice President for Research and Economic Development and Derek Willard, Special Assistant to the President for Government Relations and Associate Vice President for Research, the University of Iowa to Jerry Moore, NIH Regulations Officer (July 7, 2009).

41 Letter response from Dr. Jane E. Robbins to Dr. Jerry Moore, NIH Regulations Officer, NIH Office of Management Assessment (June 26, 2009).

42 *Id.*

43 Sheila Slaughter, PhD, Maryann P. Feldman, PhD, Scott L. Thomas, PhD, *Policies on Institutional Conflict of Interest at U.S. Research Universities, The Alliance for Biomedical Advances*, at 6.

44 Gardiner Harris and Benedict Carey, *Researcher Fails to Reveal Full Drug Pay*, N.Y. Times online, June 8, 2008.

45 S. 301, 111 Cong. (2009).

46 Sheila Slaughter, PhD, Maryann P. Feldman, PhD, Scott L. Thomas, PhD, *Policies on Institutional Conflict of Interest at U.S. Research Universities, The Alliance for Biomedical Advances*, at 4.

47 www.cogr.edu/files/publications_Conflicts.cfm.

48 Association of American Medical Colleges – Association of American Universities, *Protecting, Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research* (Feb. 2008), at 14-15.

49 Association of American Medical Colleges – Association of American Universities, *Protecting, Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research* (Feb. 2008), at 25.