

***Objectivity v. Commercialization—AMC Institutional Conflict of Interests in Research:
An Academic Discussion***
AHLA Public Interest Convener Session
January 27, 2011
Washington, DC

I. Introduction

A. AHLA Public Interest Convener Session

Through its Public Interest Committee, the American Health Lawyers Association (AHLA) promotes discussion among stakeholders on key health law and policy issues. On January 27, 2011, the Committee sponsored a convener session, *Objectivity v. Commercialization – AMC Institutional Conflict of Interests in Research: An Academic Discussion* (the “Convener Session”). This session was held at the AHLA’s conference on Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions in Washington, DC.

Medical research is often driven by two primary aims: (1) the development of knowledge and the scientific process and (2) the development and commercialization of new products and therapies to treat medical conditions. Both underscore a “greater” goal—to improve the health and wellbeing of individuals. Commercialization of new products can serve yet another goal—to generate financial gain for the organizations and individuals involved in that process.

Investments in and financial donations from commercial research sponsors can be important sources of funding for academic and nonprofit organizations.¹ But, when the institution has a financial interest in the research sponsor, or in the outcome of research itself, that interest could impact objectivity and research integrity. Financial interests may also impact the institution’s role in protecting the safety and welfare of human subjects.² Existing federal regulations address individual conflict of interests in medical research, but do not address *institutional* conflict of interests, or “ICOI.”

Over the last decade, industry thought leaders, such as the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Institute of

¹ Ass’n of Am. Med. Colleges, Task Force on Financial Conflicts of Interest in Clinical Research, *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution’s Financial Interests in Human Subjects Research*, Oct. 2002, p. 1 [hereinafter *Task Force Part II Report*].

² *Id.*

Medicine (IOM) and the Council on Governmental Relations (COGR), have issued a number of guidance documents on ICOI. Many of these documents have outlined general principles that should govern the identification and management of ICOIs at teaching hospitals and academic medical centers (AMCs); several have included sample policies for these purposes. However, few teaching hospitals and AMCs have focused on developing policies and procedures to address actual—or potential—ICOI.

On January 2011, the Office of the Inspector General of the Department of Health and Human Services (OIG) issued its report on *Institutional Conflicts Of Interest at NIH Grantees*.³ In this report, the OIG recommends that the Office of Extramural Research for the National Institutes of Health (NIH) propose amendments to existing regulations that will govern ICOI. While the Department of Health and Human Services (HHS) is in the process of amending regulations on individual conflict of interests in the conduct of research sponsored by the Public Health Service (PHS), these amendments will not address institutional conflict of interests.

In light of the current regulatory environment, the Public Interest Committee sponsored the January 2011 Convener Session as a forum for open dialogue among industry stakeholders, to discuss the impact of financial interests on the objectivity of research and the protection of human research subjects, and to explore ways to identify and manage ICOI while balancing these competing goals.

During the Convener Session, Dr. Sally Rockey, Deputy Director of Extramural Research at NIH, provided an overview of the existing and proposed federal regulations for conflict of interests in PHS-funded research. Panel participants then discussed a series of hypothetical scenarios involving ICOI and medical research. These scenarios were designed to highlight both the complexities and subtleties of this topic. The panelists included the President of the IOM, Chief Counsel to the Inspector General of the OIG, a law firm partner specializing in research issues, a consultant specializing in managing the responsible and ethical conduct of research and research operations, and in-house attorneys representing teaching hospitals and AMCs.

The purpose of this white paper is to provide a summary of the Convener Session and, based on the panelists' discussion, to identify key principles and best practices that teaching hospitals and AMCs may consider when identifying and managing ICOI in research.

³ Dept. of Health & Human Svcs., Office of Inspector General, *Institutional Conflicts of Interest at NIH Grantees*, Jan. 2011, available at <http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf> [hereinafter *OIG ICOI Report*].

B. Background

Clinical research is central to the mission of many teaching hospitals and academic medical centers.⁴ However, because of the financial realities of the health care industry, this mission cannot be fully accomplished without funding from government and industry sponsors. A conflict of interests—or the *appearance of* a conflict of interests—in clinical research can arise from the financial and professional relationships between institutions, individual researchers and research sponsors.

The Bayh-Dole Act⁵ requires the transfer of government-funded inventions to universities with federal contracts for the purpose of furthering development and commercialization. Streams of funding that result from the Bayh-Dole Act can be significant sources of support for the institution's mission to provide quality health care, educate health care providers, and advance science and knowledge through research. However, as noted above, financial interests based on the commercialization of new products and technologies may potentially create institutional bias which, in turn, may threaten the institution's ability to maintain objectivity and transparency in the conduct of research.

PHS currently regulates individual financial conflict of interests by requiring institutions receiving public funding for research to identify, manage and, to the extent possible, reduce or eliminate such conflicts. NIH promulgated the regulations in 1995⁶ and, to date, most research institutions have policies and procedures designed to identify and manage those financial interests. Existing regulations require the investigator to determine if a significant financial interest (SFI) exists and to report SFI to the institution. The institution must then determine if the significant financial interest constitutes a financial conflict of interests (FCOI) within the meaning of the regulations. The regulations then require the institution to manage, reduce, and, if necessary, eliminate the FCOI.

Significantly, the proposed amendments to the regulations would shift the burden of identifying SFI from the individual investigator to the institution. However,, neither the existing

⁴ Issues related to institutional conflict of interests may also apply to basic or “bench” research. However, because of the potential impact of ICOI on human research protections, the AHLA focused the Convener Session on the conduct of clinical research.

⁵ 35 U.S.C. §§ 200-212.

⁶ 42 C.F.R. Part 50 Subpart F.

nor the proposed regulations prescribe the specific means by which institutions must manage FCOI. As noted by Dr. Rockey during the Convener Session, this allows an institution flexibility to determine whether an FCOI appears to affect PHS-funded research and, if so, to manage the FCOI in a manner that best suits the institutional—and individual—circumstances.

In its January 2011 report, the OIG surveyed 250 grantee institutions (including universities, medical schools and private research organizations) and found that, although not required to do so, seventy of the 156 institutions responding to the survey have written policies and procedures addressing institutional interests. Some of these policies and procedures address only financial interests held by the institutions themselves, while others also consider the interests of both the institution and their employees or officials.⁷ Citing the Institute of Medicine’s 2009 report on conflict of interests, the OIG stated that “[a]n institutional conflict may arise when an institution’s own financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials pose a risk of undue influence on decisions involving the institution’s research.”⁸

Further, the OIG noted that because no existing Federal regulations require grantee institutions to identify and report institutional conflict of interests, the NIH lacks information on the number of conflicts that may exist and, perhaps more importantly, the impact these conflicts may have on federally-sponsored research.⁹ OIG recommended, therefore, that NIH “[p]romulgate regulations that address institutional financial conflicts of interest,” and, “[u]ntil regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures regarding institutional financial interests and conflicts.”¹⁰

Over the last decade, a number of industry leaders have provided guidance and sample policies designed to help institutions identify, analyze and manage institutional conflict of interests. For instance, in its October 2001 *Report on Individual and Institutional Financial Conflict of Interest*, the AAU suggests a definition of ICOI, provides a three point approach to

⁷ *OIG ICOI Report*, *supra* note 1.

⁸ *Id.* (citing Institute of Medicine of the National Academies, *Conflict of Interest in Medical Research, Education, and Practice*, ch. 8, Apr. 21, 2009).

⁹ *Id.*

¹⁰ *Id.*

addressing ICOI, and identifies a list of questions teaching hospitals and AMCs should ask when analyzing potential ICOI.¹¹

One year later, in October 2002, the AAMC published its report on ICOI, entitled *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects*. The AAMC refined the definition of institutional financial conflict of interests (a definition that many institutions currently follow)¹² and set forth the fundamental principle that technology transfer should be segregated from human subject administration. The AAMC also discussed how institutional financial conflict of interests can be based on the financial interests of institutional officials (individuals), and suggested *ipso facto* circumstances under which ICOI exist.

In February 2008, the AAMC and the AAU partnered to provide a model institutional financial conflict of interest policy designed to further assist teaching hospitals and AMCs in developing ICOI policies and procedures.¹³ And, in its 2009 publication entitled *Conflict of Interest in Medical Research, Education, and Practice*, the Institute of Medicine (IOM) recommended that AMC boards establish standing committees on institutional financial conflict of interests and that the NIH develop rules governing such conflicts.

As defined by the AAMC and the AAU, an institutional financial conflict of interest exists 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.”¹⁴ The scenarios presented during the Convener Session—and set forth below—demonstrate that an individual acting on behalf of an institution may create an institutional conflict due to that individual’s position and influence within the organization. These scenarios also illustrate that identifying ICOI can be a difficult task because of the complex relationships between researchers, institutions, and research sponsors.

¹¹ Ass’n of Am. Universities, Task Force on Research Accountability, *Report on Individual and Institutional Financial Conflict of Interest*, Oct. 2001.

¹² *Task Force Part II Report*, *supra* note 1 at 2-3.

¹³ Ass’n of Am. Med. Colleges – Ass’n of Am. Universities Advisory Committee, *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, Feb. 2008.

¹⁴ *Id.* at 14.

II. Executive Summary

Even though commercialization of new technologies and therapies may give rise to an appearance of ICOI, and industry thought leaders have provided significant guidance on ways to identify and manage these conflicts, many research institutions have not adopted policies and procedures governing ICOI. For instance, as noted in the OIG's January 2011 report, less than half of institutions responding to the OIG's survey have in place policies and procedures to address ICOI. There are a number of reasons that institutions have focused on individual conflict of interests, but have paid relatively little attention to those that exist at the institutional level. First, as the scenarios below illustrate, ICOI can be subtle, or complex, and not always easy to recognize. The relationship between an institution and a research sponsor can have one or several facets—for instance, it may be based on receipt of royalties or an investment interest, or it may exist by virtue of the sponsor's philanthropic activities. And, it is not always clear when the interest of an *individual*—such as an institutional official or a well-established researcher—rises to the level of an *institutional* conflict of interest.

Second, research institutions rarely receive research funding in a coordinated manner. Funds may flow from a variety of sources, including government and industry sponsors, and may be awarded to various departments, units or affiliated entities, such as a foundation or school of medicine. Similarly, not all departments, units, affiliated entities or individuals conducting research at an institution may be aware of the different sources of financial support for research. Third, institutional officials may not be concerned with ICOI to the same extent as individual conflicts of interests because, in contrast to the direct relationship with the individual researcher, the institution's relationship with the patient is indirect, or at least less tangible.

As noted previously, the AHLA Public Interest Committee sponsored the Convener Session to examine guiding principles and best practices for identifying and managing ICOI in research. The panelists' discussion highlighted the following principles and best practices:

- When individuals who are in a position to influence the conduct of research receive significant remuneration from industry sponsors, the public—and patients—may begin to question both motives and decision-making. Therefore, a research institution should consider public tolerance for the appearance of any conflict of interest before accepting royalties (based on commercialization of new products, therapies) or financial support

from an industry sponsor, or before engaging in research involving a technology that generates cash flow to the institution.

- On the other hand, if accepting financial support from a research sponsor poses little or no risk to the institution's ability to maintain objectivity, or its ability to ensure appropriate safeguards for human subjects are in place, then institutional risks associated with the real—or potential—ICOI *may* be minimal.
- Institutions that manage ICOI effectively have established—prospectively—institutional processes to do so. The first step an institution should take in creating these processes is to identify an overarching set of principles to guide the institution's decision-making.
- A key consideration in establishing ICOI policies and procedures is how the institution will support the investigator and scientific exploration, while separating the institution's financial interests from its academic interests, i.e., the promotion of scientific investigation and discovery.
- Public disclosure of financial (and other) interests is necessary, but may be considered a minimum expectation in managing ICOI.
- Effective management of ICOI also includes administrative mechanisms to isolate financial interests from clinical and research decision-making processes.
- When identifying, managing and isolating financial interests, the research institution should take into account its size and scale (i.e., the number and type of departments, units and affiliated organizations). Isolating an interest within one department or unit may, for example, be sufficient to manage the conflict from an institutional standpoint.

III. Guiding Principles and Best Practices for Identifying and Managing ICOI

By examining the subtleties of the fact patterns (below) the Convener Session panelists identified best practices and a range of responses and recommendations in managing ICOI. These fact patterns are hypothetical in nature and are not attributable to any particular research institution.

A. Use in the Best Interests of the Patient

Outstanding Academic Teaching Hospital (OATH) conducts extensive research in diseases of the gastrointestinal tract, and provides tertiary and quaternary level care for rare GI conditions to patients from around the US, including Medicare and Medicaid patients. OATH receives grants from the National Institutes of Health to support its GI research. As required by the Bayh-Dole Act, OATH has a royalty distribution formula that allocates one third of any patent royalties to the Principal Investigator who develops a patentable invention. Like almost all academic medical centers, OATH keeps a portion of patent royalties for its own institutional purposes as well, and distributes a portion to its affiliate, Affiliated Medical School; OATH and AMS each also receive one-third of royalties.

Dr. Susan B. Goot conducts research in OATH's GI research labs and is also a practicing clinical gastroenterologist. She investigates the use of a nasally inhaled antibiotic used to treat bacterial pneumonia, and discovers that it is surprisingly effective at suppressing and eliminating a certain category of precancerous intestinal polyps. After a great deal of work, Dr. Goot and her colleagues invent a novel method for delivering this old antibiotic into the GI tract, using a specially formulated high-fiber cereal developed in conjunction with Nature Mega-Products, Inc., a for-profit natural foods company. They plan to market the product as GastroPuffs. Patients suitable for GastroPuffs eat a bowl of cereal a week for the rest of their lives, assuring a strong market in the product.

Recognizing the potential value of the invention, OATH applies for a utility patent for the formulation of the drug used in the high-fiber cereal delivery method (which is different than the nasally inhaled formulation). Nature Mega-Products is listed as co-inventor. While the patent application is working its way through the Patent and Trademark Office (and through various international filings as well), Dr. Goot coordinates a multi-center trial, sponsored by Nature Mega-Products, to test the drug and delivery method for treatment of precancerous intestinal polyps. The results are spectacular: 75% of the targeted polyps in the subject population are entirely eliminated with no serious side effects. Based on the results of the trial, the FDA approves the drug formulation and delivery method for use in humans. At about the same time, the PTO issues a utility patent for the drug and delivery method.

OATH and Nature Mega-Products anticipate a world-wide market for GastroPuffs of hundreds of millions of dollars in sales annually. Preliminary projections show OATH and Nature Mega-Products each receiving in excess of \$3 Million per year from GastroPuffs sales. Royalty revenue will provide a much-needed source of funds for both OATH and its affiliated medical school. Dr. Goot will benefit as well, of course.

Dr. Goot plans to continue to see GI patients at OATH, and also intends to continue to conduct research in intestinal cancer, to treat other categories of polyps, and to treat the 25% of patients who do not benefit from GastroPuffs. She would like to accept funding from any source, including the NIH and Nature Mega-Products, but also other companies as well. In addition, GI services are a major clinical specialty at OATH, and attract patients from around the country and around the world. Clinical revenues from GI services cross-subsidize low-income outreach clinics, supplemental services for seniors not covered by Medicare, Medicaid or insurance, and OATH's award-winning "Community Wellness Plan" that is credited with substantially reducing the utilization rate for low-income patients in OATH's service area.

Guiding Principles and Best Practices:

1. Individuals are often relatively unaware of their own potential conflicts. Most researchers are convinced their judgment will not be affected by anything other than objective evidence, that, for them, money does not matter. The difficulty in addressing these issues begins with an academic "mind set" that tends to deny, be unaware of, or even be offended with respect to, increasing attention paid to conflict of interests.
2. Bias exists not just with respect to financial interest but also scientific advocacy. Though researchers are—legitimately and with good reason—biased "in favor" of their area of research or scientific hypotheses, the combination of scientific advocacy and financial interest can threaten objectivity and research integrity.
3. Effective management of ICOI also includes administrative mechanisms to isolate financial interests from clinical and research decision-making processes.

Panelist Discussion:

In this scenario, while the researcher is receiving royalties for her invention, she is also potentially prescribing that same product—GastroPuffs—to her patients. This raises the issue of how an individual’s research activities and relationship with industry can give rise to an *institutional* conflict of interest.

The critical issue in addressing conflict of interest in medical research—both at the individual and the institutional level—is that many researchers are relatively unaware of their own potential conflicts. Researchers and scientists may deny the existence or risks of conflicts, convinced that financial matters do not, or will not, affect their scientific judgment. As a result, many researchers may neither understand how to identify a potential conflict of interest, nor be aware of the legal and compliance risks associated with conflicts. Moreover, panelists noted that individuals participating in the research enterprise may not appreciate the distinction between bias resulting from scientific advocacy—that is, a researcher’s belief in, or support of, his or her own scientific hypotheses and research designs—versus bias resulting from financial or other external influences. When financial interest is combined with scientific advocacy, the combination may be more than simply additive—it may result in risk to research integrity.

The panelists also identified several means of managing ICOI, such as those described in the above scenario. Most panelists agreed that the starting point is disclosure of the interest to both the institution and patients. By disclosing to patients the physician’s and the institution’s financial interests, the physician—and the institution—provide the patient the opportunity to ask questions and, if desired, to seek a second opinion or an alternative course of care.

Panelists nevertheless recognized that disclosure of a conflict of interests most likely will *not* resolve the conflict, or the appearance thereof. Several panelists suggested that isolating the financial interest from certain research activities and clinical decision-making is a viable option for managing ICOI. For instance, the institution could forego any royalties based on prescriptions for the commercialized product, or, alternatively, it could apply controls to redirect the flow of royalties to minimize the impact, or appearance, of a financial conflict of interest. Another option may be to consult independent third parties to help the institution determine whether, in light of the conflict, the research should occur, or whether an alternative means of managing the ICOI is appropriate.

Panelists also considered the notion that receipt of royalties (pursuant to Bayh-Doyle) may *not* pose a significant risk where entities affiliated with the AMC are separate. For instance, if the hospital is a legal entity separate from the university, prescriptions for hospital patients for certain products invented or discovered at the university may raise fewer concerns. On the other hand, one panelist suggested that when an institution analyzes its ICOI, it should look at the entire academic enterprise—and affiliated organizations—rather than individual components of that enterprise, particularly if the public does not perceive a difference between the affiliated entities. The panelist noted that, in some instances, the size and complexity of an organization may impact its ability to identify and isolate a conflict of interests. In larger institutions, it may be difficult to identify the conflicts, due to the sheer number of individuals—and sponsors—involved in clinical research. Institutional officials may therefore need to implement “firewalls”—that is, administrative, financial or operational barriers—between the AMC and the industry sponsor or donor *and* between the AMC and the component receiving financial support from the sponsor or donor, so the institution can minimize the potential impact of that support on the objectivity of research personnel.

B. Educating the Medical Community

Dr. Goot becomes internationally famous for her GastroPuffs breakthrough. Hospitals and medical schools from around the country invite her to speak on nutrition-based cancer prevention therapies and the promise of future nutritionally-based therapeutic developments. Nutraceutical companies, including Nature Mega-Products but also other companies sponsoring research at OATH and in her labs, feature her as a speaker at all-expense paid seminars in Tucson and Miami Beach targeted at community-based internists, GI doctors and oncologists. Initially, Dr. Goot accepts only her travel expenses and a modest honorarium of \$500 per speech, but Nature Mega-Products asks her to join its speaker bureau in exchange for \$2,500 per speech plus expenses. According to NMP, she can speak as often as she wants, up to twice a week if desired. The seminar sponsors offer \$20,000 plus expenses for two days’ participation in their programs in Tucson and Miami Beach.

Nature Mega-Products is grateful to OATH for the institutional research that led to development of GastroPuffs. It offers to sponsor Grand Rounds presentations at OATH once a

month, with speakers provided at the sole expense of NMP, on topics related to nutrition, diet and health. In addition, Nature Mega-Products decides to endow the GastroPuffs Chair of Gastroenterology at OATH, which will provide much-needed salary support for an OATH gastroenterology clinical researcher. The Chair is funded with an assignment of 10% of NMP's GastroPuffs royalties.

Guiding Principles and Best Practices:

1. Institutional policies can provide *prospective*—rather than “ad hoc”—guidance to institutional officials to avoid an institutional conflict of interests.
2. The institution should establish administrative “firewalls” to prevent donors from influencing—directly or indirectly—the institution’s research, clinical and educational missions.

Panelist Discussion:

This scenario highlights the importance of an ICOI policy in providing guidance to key employees whose actions or interest may give rise to an institutional conflict. This scenario also highlights the need for complete information about a potential conflict before it exists, as well as the need for fair and consistent application of an ICOI policy as it applies to both the institution and those individuals who act on the institution’s behalf.

A research institution may only become aware of a potential conflict if the individual discloses that information prior to or at the time of receipt of compensation. While the institution may become aware of an employee’s receipt of funds for participation in a speakers’ bureau, for example, this will likely occur only after the fact, when the potential—or actual—conflict of interest already exists. Theoretically, databases maintained by industry sponsors to report and track financial relationships with clinical investigators can provide important information regarding potential conflict of interests. However, searching this information—on a case-by-case basis—to determine the scope of an individual’s potential conflict of interests can be administratively burdensome and impracticable. An effective ICOI policy—in concert with

educating the medical community about the importance of the policy—may therefore help prevent an actual conflict, or the appearance thereof.

With respect to the amounts of compensation offered to Dr. Goot, panelists noted there is no “bright line,” between acceptable versus unacceptable amounts. And, panelists noted, depending on the nature of the activity and the underlying relationship with the sponsor or donor, there may be a “sliding scale” of acceptability. For instance, while a modest payment of \$500 plus actual expenses may be within the range of fair market value for a single speech by Dr. Goot, panelists noted that a payment of \$2500 from the manufacturer may be perceived as payment in exchange for (indirect) marketing of the manufacturer’s product. Similarly, accepting payments upwards of \$2500—with no limit on the number of speeches given—may create a relationship whereby Dr. Goot essentially functions as a marketing “spokesperson” for the company. Even if she speaks generally about nutrition-based cancer prevention therapies, Dr. Goot’s more frequent—and arguably more extravagant—speaking engagements benefit both Dr. Goot and the manufacturer.

Some panelists recommended a zero tolerance for participation in speakers’ bureaus (an increasingly common policy of AMCs) while others felt fair market payments for speaking, coupled with disclosure of the speakers’ interests, would alleviate concerns. In any event, for any speaking engagements by a researcher, the manufacturer should have no editorial rights pertaining to the content of the speech.

Similarly with respect to support for grand rounds, panelists stated that the manufacturer should neither be permitted to select speakers or determine topics for, or have editorials rights with respect to the content of, the grand rounds, nor should the manufacturer have any representatives present. Panelists recognized that the institution would have to “negotiate” with the manufacturer, because the manufacturer would be less willing to support the grand rounds if there are too many “strings attached,” and too little benefit to the manufacturer. Yet, the panelists felt that institutions must have some barrier between sponsors or donors and the content of their educational activities. As one panelist commented, there may be ways to manage ICOI concerns without simply saying “no” to financial support. For instance, the institution could accept the financial support for the grand rounds, but require that topics discussed during these sessions not bear directly on any products developed for or manufactured by the sponsor.

Similarly, with respect to the endowed chair, one panelist suggested that the institution could accept the funds, but not give the donor any naming rights. In other words, while the institution could accept the funds to support the chair, it would not give the manufacturer the ability to essentially market itself by attaching its name to the chair position. Other panelists raised concerns regarding the level of control the manufacturer may have with respect to the research and academic activity of the individual selected for the chair position. One panelist suggested that this concern could be alleviated by requiring the chair to be filled by someone who does not conduct any research related to the manufacturer's products or interests or related to the research of the colleague—in this case, Dr. Goot—who obtains royalties from products developed for or manufactured by the sponsor.

One panelist summarized these issues in the following manner: When there are large amounts of money going to those with influence in research, decision-making is perhaps skewed and one begins to question motives. The panelist analogized the issue of financial conflict of interest to False Claim Act (FCA)¹⁵ exposure and the financial incentives for *qui tam* relators. However, as the panelist noted, a sponsor or donor is almost always going to expect something in return for its financial support. If the sponsor or donor is a public corporation, it has a duty to its shareholders to increase revenue and profits and to act in the shareholders' interests. One would not give away the assets of the corporation without expecting something in return for its shareholders.

Another panelist took a different view, noting that if the financial relationship does not result in harm, or risk of harm, to patients, then perhaps it is not a problem for the institution to accept financial support from an industry sponsor or donor. A key consideration for this panelist however, is the institution's ability to separate the financial support from any decisions that might affect patients or research participants.

C. Transparency and Objectivity

¹⁵ 42 U.S.C.1320a-7(b)(7).

OATH implements a conflict of interest policy requiring all basic and clinical researchers to disclose certain defined financial interests, including stock ownership and participation in speakers' bureaus. Dr. Goot duly discloses her activities on the Nature Mega-Products speakers' bureau, but she neglects to mention that she also owns 10,000 shares of NMP stock, obtained by converting a portion of her OATH-allotted royalty interest into NMP equity. She reasons that since OATH already knows about – indeed gave her – the royalty interest, what she does with it doesn't create additional issues.

Nature Mega-Products decides to enter into a "Phase 4" study of GastroPuffs and engages Dr. Goot to oversee and conduct research into the long-term effects of GastroPuff consumption. NMP proposes to pay Dr. Goot \$15,000 for each new principal investigator recruited at another institution, a scientific advisor fee of \$25,000 per year, and \$50 per year for each patient she personally enrolls in the study. Most of her patients are covered by Medicare, which has approved GastroPuffs as a covered drug if prescribed by a physician. Because this Phase 4 work will not involve any bench lab work, and data required by Nature Mega-Products are available through the normal medical record, Dr. Goot does not seek IRB approval of the study, nor does she mention it to OATH, or disclose it on the conflict of interest annual disclosure document.

Guiding Principles and Best Practices:

1. The institution must determine whether the compensation is more than what is being provided in return, and whether the compensation may—in any way—be tied to referrals.
2. The institution should follow established principles and consider the applications of those principles in light of existing regulatory and industry guidance.

Panelist Discussion:

In examining this scenario, one panelist noted that the intent of the parties—which is not made clear in the hypothetical described above—is integral to determining whether an ICOI exists. Generally, the institution would need to determine whether any financial support is within the range of fair market value for the items or services being performed by the researcher. This panelist noted that the institution would also need to determine whether the financial support is given in exchange for—or to influence the making of—referrals or other business for the sponsor and, importantly, whether there is also the potential for FCA liability.

The panelists generally agreed that it is critical to establish key principles for identifying and managing ICOI, and to follow those principles when addressing specific conflicts and scenarios as they arise. One panelist pointed out that institutions who manage ICOI effectively are those with well-established institutional processes to manage the conflicts. For example, the institution’s disclosure form would be designed to ask researchers key questions designed to elicit as much information as possible related to the researchers’ potential conflicts. In addition, the institution would have in place a strong audit and compliance program to ensure the processes are effective. Another panelist added that it is equally important to communicate the institution’s principles and expectations with respect to ICOI to those involved in research and, to the extent possible, to consistently apply the policy to individual conflict situations.

One panelist pointed out that the databases required by the Physician Payment Sunshine Act in Section 6002 of the Affordable Care Act may further assist institutions in identifying conflicts and consistently applying their policies. Yet, as the panelist also pointed out, it is still unlikely that the institution will—without significant effort—be able to reconcile information maintained on a sponsor-by-sponsor basis, in the absence of uniform file formats. Another panelist also raised the point that the cost of compliance—i.e., to monitor payments made to researchers by industry sponsors—uses institutional resources that would otherwise be devoted to patient care and the conduct of clinical research. Therefore, panelists noted, the institution must strike a balance between meeting the goals of objectivity and transparency in research, while also generating financial support for research activities.

D. Owning a Bet on the Future of Health Care

OATH has another physician-scientist working in the area of respiration in premature neonates and adults with highly compromised lung function. Dr. I. Burreit Eezere is investigating better methods for ventilating these patients; he is particularly concerned about the high cost of current ventilators, now running \$40,000 or more each, and the difficulty that small hospitals have in procuring and maintaining them. As a result, Dr. Eezere believes that hundreds of patients die each year in the U.S. who could benefit from access to a ventilator; the toll world-wide is likely in the tens or hundreds of thousands, including fragile neonates.

Working in the OATH labs, Dr. Eezere invents a very low-cost method of providing reliable high-frequency ventilation support for adults and neonates. It uses parts found in most bioengineering workshops and can be put together quickly and cheaply. Without the sophisticated controls that current ventilators have, his invention costs less than \$100 in parts to make. He tests it on rabbits and has remarkable success.

In the U.S., and in the first world generally, ventilators are a mature market. A few established companies supply hospitals that operate intensive care units (ICUs), where these bedside ventilators are used. Despite months of effort working with an experienced technology transfer consultant, OATH and Dr. Eezere are not able to find any company interested in taking his device under a license for further development and testing preparatory to production and distribution. OATH and Dr. Eezere estimate that the costs of producing prototype devices for testing in humans, and of conducting clinical trials in a suitable location (China? India? Africa?) are likely in the \$500,000 to \$1.5 Million range. No company expresses interest in funding that work. Dr. Eezere suspects that existing market players have no desire to upset the current highly profitable market for ventilators in the first world, and no interest in developing a device for the third world because doing so would affect their overall profits.

Despite the success of GastroPuffs, OATH doesn't have that kind of money to invest in developing a product that may never be able to compete in the American marketplace. It politely declines to invest further in the device.

Dr. Eezere is not a quitter. He forms a start-up company to develop and test prototypes of his device; the government of Viet Nam expresses a willingness to provide funding for clinical trials in that country. Dr. Eezere talks to Dr. Goot, who agrees to liquidate some of her Nature Mega- Products stock and invest the proceeds in development of the device, and between them they secure commitments from other venture philanthropists committed to advances in global

health. With the venture capital and the Vietnamese government support, Dr. Eezere believes he can just manage to get the device tested and data submitted to the FDA for approval so that his device can be marketed throughout the third world.

Because the device was invented at OATH, OATH owns the rights to it. It is now negotiating a license agreement with Dr. Eezere's start-up company.

Guiding Principles and Best Practices:

1. When considering its options for commercializing an invention, the institution should consider whether it—or its researchers—currently or in the future may conduct additional research with respect to the same clinical condition or area. Commercialization may affect the institution's ability to conduct additional research and development activities without the appearance of bias.
2. The institution may want to consider relying on external advisors to assess the research data and the options for further research, development and commercialization of resulting inventions.
3. Before accepting royalties, or initiating a research project that may impact its financial interests, a research institution should consider public tolerance for (the appearance of) ICOI.
4. Research institutions making decisions related to research, development and commercialization may also need to consider a number of other complex legal and regulatory issues, including those related to intellectual property rights and tax-exempt organization requirements.

Panelist Discussion:

This scenario illustrates the institution’s desire to support scientific exploration while protecting its organizational assets. In analyzing this scenario, one panelist noted that an institution involved in commercialization of one new product needs to consider whether it may conduct further research in this area. The outcome of that research—for financial and legal reasons—could affect the institution’s ability to further commercialize its inventions. Panelists suggested that an independent, external advisor may be consulted to provide an independent assessment of the research and commercialization activities and possibilities. This could help alleviate any institutional “bias” in making these decisions, i.e., based on financial issues and “return on investment” concerns.

Panelists pointed out that, even if the external advisor or the institution itself finds a means to manage the ICOI, the institution may still need to address tax exempt issues—i.e., is the institution inappropriately using its assets by conducting the research and development for both products? And, as illustrated by this scenario, the institution would also need to consider other complex areas of law and regulation; for instance, the institution would need to conduct an export control analysis to determine whether it must obtain appropriate licenses and certifications, etc.

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