



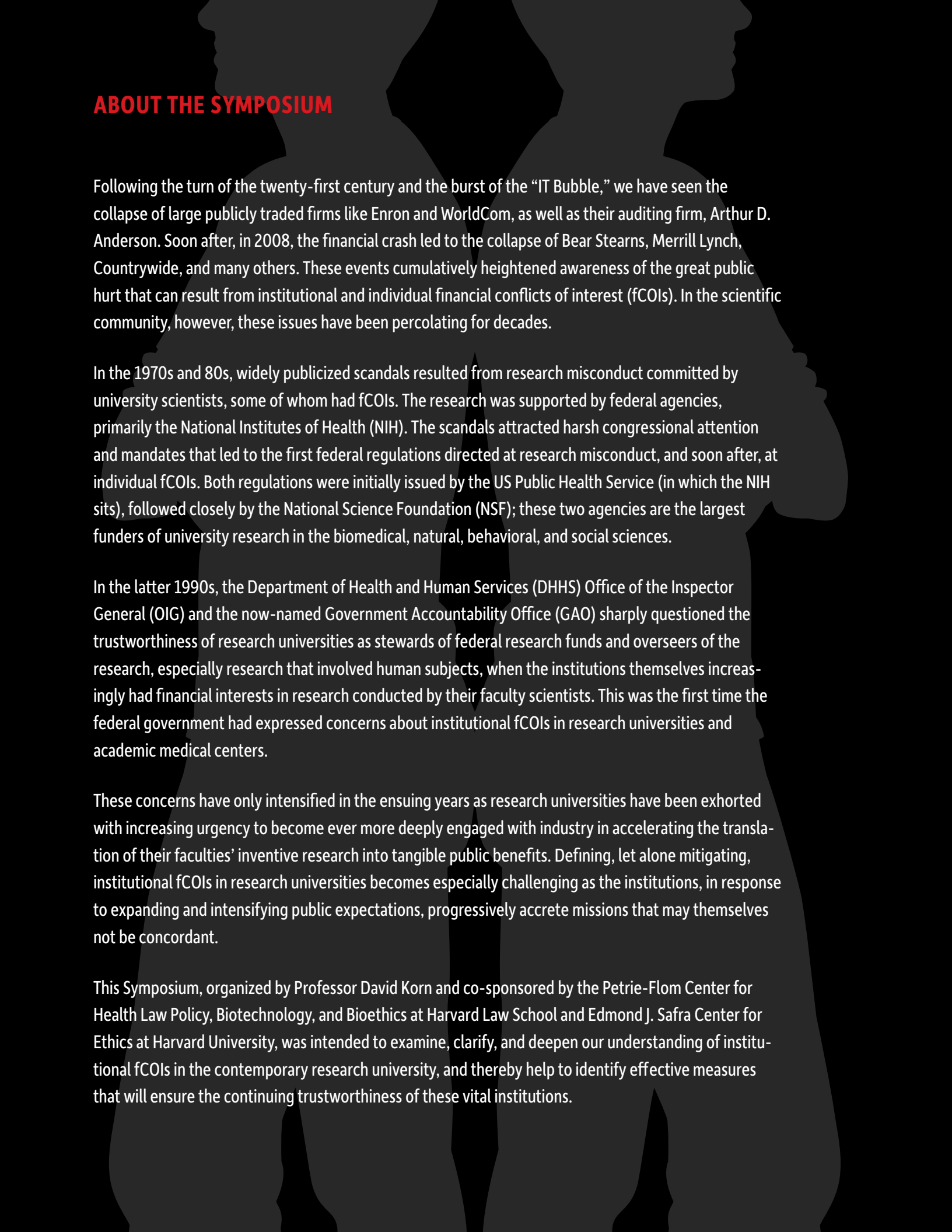
**INSTITUTIONAL FINANCIAL
CONFLICTS
OF INTEREST
IN RESEARCH UNIVERSITIES**

A symposium organized by Professor David Korn

Symposium Report

Harvard Law School, Cambridge, MA

November 2, 2012

The background of the page features a dark silhouette of three people in profile, facing each other as if in a conversation. The person on the left is slightly behind the other two. The person in the center is facing right, and the person on the right is facing left. The overall tone is professional and academic.

ABOUT THE SYMPOSIUM

Following the turn of the twenty-first century and the burst of the “IT Bubble,” we have seen the collapse of large publicly traded firms like Enron and WorldCom, as well as their auditing firm, Arthur D. Anderson. Soon after, in 2008, the financial crash led to the collapse of Bear Stearns, Merrill Lynch, Countrywide, and many others. These events cumulatively heightened awareness of the great public hurt that can result from institutional and individual financial conflicts of interest (fCOIs). In the scientific community, however, these issues have been percolating for decades.

In the 1970s and 80s, widely publicized scandals resulted from research misconduct committed by university scientists, some of whom had fCOIs. The research was supported by federal agencies, primarily the National Institutes of Health (NIH). The scandals attracted harsh congressional attention and mandates that led to the first federal regulations directed at research misconduct, and soon after, at individual fCOIs. Both regulations were initially issued by the US Public Health Service (in which the NIH sits), followed closely by the National Science Foundation (NSF); these two agencies are the largest funders of university research in the biomedical, natural, behavioral, and social sciences.

In the latter 1990s, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) and the now-named Government Accountability Office (GAO) sharply questioned the trustworthiness of research universities as stewards of federal research funds and overseers of the research, especially research that involved human subjects, when the institutions themselves increasingly had financial interests in research conducted by their faculty scientists. This was the first time the federal government had expressed concerns about institutional fCOIs in research universities and academic medical centers.

These concerns have only intensified in the ensuing years as research universities have been exhorted with increasing urgency to become ever more deeply engaged with industry in accelerating the translation of their faculties’ inventive research into tangible public benefits. Defining, let alone mitigating, institutional fCOIs in research universities becomes especially challenging as the institutions, in response to expanding and intensifying public expectations, progressively accrete missions that may themselves not be concordant.

This Symposium, organized by Professor David Korn and co-sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and Edmond J. Safra Center for Ethics at Harvard University, was intended to examine, clarify, and deepen our understanding of institutional fCOIs in the contemporary research university, and thereby help to identify effective measures that will ensure the continuing trustworthiness of these vital institutions.

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Co-Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics & Edmond J. Safra Center for Ethics, with support from the Oswald DeN. Cammann Fund



HARVARD UNIVERSITY
Edmond J. Safra Center for Ethics

¹ This meeting summary was edited by Holly Fernandez Lynch and David Korn, and except for "About the Symposium" and "Some Reflections on the Day," reports the views and statements of the presenters. We have not undertaken to verify any of the facts presented. Nothing in this summary should be cited as a representation of the views of either the Petrie-Flom Center or Edmond J. Safra Center for Ethics. We gratefully acknowledge the work of our writer, Ms. Kathi Hanna, in preparing the first draft of this document.

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I. WELCOME

**Glenn Cohen, J.D., Assistant Professor and Faculty
Co-Director, The Petrie-Flom Center for Health Law Policy,
Biotechnology, and Bioethics, Harvard Law School**

**Lawrence Lessig, J.D., M.A., Roy L. Furman Professor of Law
and Leadership, Harvard Law School; Director, Edmond J.
Safra Center for Ethics at Harvard University**

The directors of the programs co-sponsoring the symposium welcomed participants and underscored the importance of addressing the issue of institutional conflicts of interest in maintaining the integrity of the research university.

II. INTRODUCTION AND OVERVIEW

**David Korn, M.D., Consultant in Pathology,
Massachusetts General Hospital; Professor of Pathology,
Harvard Medical School**

Dr. Korn provided an overview of the evolution of the term “conflicts of interest” within the context of university-based research and cited several major reports on the topic over the past two decades. He noted the tension between expectations placed on universities with regard to their changing public and social responsibilities and the desire that they remain free of conflicts that could undermine their credibility and authenticity.

Korn joined the Stanford University faculty as Professor of Pathology in 1967. At the time, the Faculty Handbook’s treatment of “conflict of interest” was terse and pointed:

“Most major universities, including Stanford, have taken the position that consulting relationships are on balance overwhelmingly beneficial, and there is no disposition to change that view. At the same time, it would be foolish to ignore the fact that some of the complications arising from this state of affairs can cause damage to the university and to the individual, as well. Chief among these complications is that tangled and thorny set of problems embraced by the general title of ‘conflict of interest.’

“The issues subsumed under that heading are principally ethical and as such they are not readily codified to rules of behavior. In any event, this university has never found it necessary to spell out the rules or codes of ethics for its faculty and staff. The relationship between the university and its staff assumes that full-time staff members owe their primary professional allegiance to the University and that they will be alert to the possibility that outside obligations, financial interests, or employment can affect the objectivity of their decisions as members of the University community. If those assumptions are valid, as we believe them to be, then no codes or monitoring devices are needed; if they are not valid, then none will suffice.”

Although academia and academic research, especially in the natural and applied sciences, have changed profoundly since 1967, the descriptors “tangled and thorny” remain apt to this day.

Korn asked what do we mean by institutional financial conflict of interest, and why must we be concerned about it? A 2001 report

issued by an Association of American Universities (AAU) Task Force, on which Korn sat, contains the following definition:

“An institutional financial conflict of interest may occur when the institution, any of its senior management, or trustees, or a department, school, or other sub-unit...has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of... organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university.”

A report issued by an Association of American Medical Colleges (AAMC) Task Force convened by Korn and chaired by William Danforth, long-time Chancellor and later Chairman of the Board of Washington University of St. Louis, offered the following, terser definition:

“An institution may have a conflict of interest in...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. ...research.”

Most recently, a 2009 report of the Institute of Medicine (IOM) offers the following definition (generalized by Korn beyond the boundaries of the medical profession and its vendor industries):

“Institutional conflicts of interest arise when an institution’s own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution’s primary interests. For academic institutions, such risks often involve the conduct of research within the institution that could affect the value of the institution’s patents or its equity positions or options.... Conflicts of interest may also arise when institutions seek and receive gifts or grants from companies....”

The IOM report defines conflict of interest as “a set of circumstances that creates a risk that professional judgments or actions

II. INTRODUCTION AND OVERVIEW *cont'd*

regarding a primary interest will be unduly influenced by a secondary interest.” This formulation, based on work by Harvard Professor Dennis Thompson in the early 1990s, is equally applicable to individuals and institutions; it makes clear that conflicts arise from sets of circumstances and not from moral failings; and it effectively does away with the tortured distinction between “potential” and “actual” conflicts of interest.

One assumes that all universities require annual disclosure of outside interests by their senior leadership, including department chairs and directors of centers and large interdisciplinary laboratories. The General Counsel typically reviews these disclosures, and findings of concern may be discussed with the Audit Committee of the governing board. Boards tend to require their own annual disclosures from members. Imperfect though these efforts may be, these are the processes in place.

But, Korn asked, what about the financial interests of the institutions themselves and the influences they have in shaping the very culture and ethos of an institution? All definitions of conflicts of interest are rooted in a hierarchical ordering of interests, or in the case of research universities, of missions, not only distinguishing primary from secondary, but also rank ordering within a set of interests that may arguably all be primary. And adding to the challenge, the missions of the contemporary research university are not constant but tend to accrete over time as public expectations change, and these accreting missions may not always be concordant. What is a primary, secondary, or tertiary mission may become ambiguous and inconstant over time.

In a meeting in the 1980s in the office of then Congressman Al Gore, Chairman of the House Oversight and Investigations Committee, Congressman Gore asserted that the “public depends on its universities to serve as independent arbiters of knowledge.” Yet universities are expected to do more than produce and arbitrate knowledge.

The Morrill Act of 1862, which established the land-grant universities to advance agriculture and the mechanical arts (ergo, the A&M universities), created a different set of missions for the university. Since then, universities increasingly are recognized as founts of ingenuity and innovation that produce tangible benefits to society. After World War II, the creation of Massachusetts’s Route 128 corridor and the Silicon Valley became fabled and captured the imagination of political leaders at all levels of govern-

ment. Later, the surging biotechnology and information technology industries, founded by university graduates building on university inventions, intensified the identification of research universities as engines of socioeconomic development.

When President Barack Obama signed the “Patent Reform Act” in 2011, he asserted that research universities are pivotal to job creation and the nation’s economic recovery. And last spring, a congressionally mandated report from a National Research Council committee charged with identifying “Ten Breakthrough Actions Vital to Our Nation’s Prosperity and Security” entitled its third recommendation “Strengthening Partnerships with Industry” and asserted that our nation’s prosperity and security demand that we: “Strengthen the business role in the research partnership...and accelerate ‘time-to-innovation’ in order to achieve our national goals.”

In closing, Korn said there is nothing inherently inappropriate about these expanding roles and responsibilities. However, meeting expanding public expectations that are not necessarily concordant, while maintaining the public’s confidence in the authenticity, integrity, and trustworthiness of the research university, becomes increasingly challenging. This symposium aimed to help those who are committed to surmounting these challenges.

III. EVOLVING ROLES, ENDURING VALUES, AND CONFLICTING PUBLIC EXPECTATIONS OF AMERICAN RESEARCH UNIVERSITIES²

A Quest for Utopia: The Great American University Yesterday, Today, and Tomorrow

Jonathan Cole, Ph.D., John Mitchell Mason Professor of the University and Provost and Dean of Faculties, Emeritus, Columbia University

Dr. Cole focused on the historical significance and values of American research universities and outlined the core values that have influenced and characterized their growth and stature. Over time, shifting expectations and external forces have challenged these values, which can create conflicts if not identified, managed, and resolved.

Cole began by recognizing that many of the technologies, conveniences, and inventions in use today had their origins at great universities. Although most members of the public think of universities in terms of undergraduate education, teaching, and the transmission of knowledge, they often do not recognize their critical role in creating new knowledge.

The publication of *The Endless Frontier* in 1945 by Vannevar Bush, Director of the U.S. Office of Scientific Research and Development during WWII, gave impetus to the growing distinction and preeminence of great U.S. universities on the generation of new knowledge and discoveries. Since World War II, 60 percent of all Nobel Prizes in science have been awarded to Americans or to foreign nationals working in American universities. The most cited literature and discoveries result from the work of American scientists and scholars.

Several core values have contributed to this success. Cole described six of the core values discussed in his book, *The Great American University*. The first value is universalism, or meritocracy, where individuals are judged on the quality of their work rather than on characteristics such as gender, race, nationality, or social origin. The second value, organized skepticism, involves incessant questioning of claims to fact and truth. Third, free and open communication of ideas involves eliminating secrecy and prior restraint on publication, as well as censorship. The fourth value is free inquiry and academic freedom, which lies at the heart of the way universities are organized to create their own

criteria of excellence independent of government or external political ideology. The fifth value is the peer review system that ensures scholars of equal standing will judge the merits of works proposed by others. The final core value, disinterestedness and collectivism, is relevant for the financial conflict of interest discussion, as it enjoins scientists not to profit from their discoveries, but rather to allow them to be part of the public domain. The theory is that new ideas are always built on ideas that preceded the scientist. During the past 50 to 60 years, the values of disinterestedness and collectivism have changed the most of all the core values.

In addition to these core values, other factors have shaped the modern university. Talented people have been recruited from around the world to U.S. universities. University administrators value a high level of autonomy from the state, and seek to ensure that government does not excessively intrude into university operations. Of course, this is a tall order since huge amounts of government financing coming from the NIH, the NSF, the Departments of Defense and Energy, among other agencies, fund a great deal of the fundamental and applied research carried out at these universities. The end result is that government provides resources and some autonomy from government control, and universities provide a skilled and well-trained labor force, better educated citizens to participate in the democratic process, and life-changing discoveries. Finally, competition among universities has been a hallmark of the growth of American universities to their current position of preeminence.

Today, universities make a significant impact on the U.S. economy. As a result, Cole believes the U.S. university now faces significant challenges and demands. First, he believes it would be good for the growth of knowledge for U.S. universities to have more international competition; they should not fear such competition, even if it means that they no longer dominate the top 20 or 50 world universities. Second, federal and state government influence — including the negative impact of antiterrorist legislation, increased surveillance of faculty and students, restrictive visa policies, regulations that restrict research and publication, and decreased funding — have affected the research process at U.S. universities. Third, universities can create an internal threat to themselves with their intellectual property policies. Cole

² Audience discussion points were integrated into Cole's and Fisher's summaries, rather than provided in a separate summary section, because they helped to clarify the presentations.

III. EVOLVING ROLES, ENDURING VALUES, AND CONFLICTING PUBLIC EXPECTATIONS OF AMERICAN RESEARCH UNIVERSITIES *cont'd*

favors universities' licensing and patenting intellectual property, but noted that often high-profile faculty members make substantial discoveries and then expect high-equity shares, restrictive IP rights, and exceptions to the financial conflicts of interest policies of their institutions. Another internal threat involves the commercialization of university sports, which can create conflicts of interest. Finally, Cole believes the role of the humanities is becoming increasingly important in the world of science and technology. Yet the humanities are taking a back seat at most universities to the sciences and engineering – suggesting that a liberal arts education is being devalued at these great universities. He believes that the humanities disciplines need a manifesto of the kind produced for science by Vannevar Bush after WWII.

Cole expressed concern about whether the current economic model of universities will withstand the structural changes and growth taking place. The creation of MOOCs (Massive Open Online Courses) and their spinoff into private companies, like Coursera and EdX, created by faculty in leading universities can have enormous democratizing consequences for the education of people worldwide who do not have access to these great universities. It is surely premature to assess the impact of these online efforts. Every decade we seem to search for and find the next silver bullet that will revolutionize primary and higher education. Few ever live up to their promise or advertising, and there are good reasons to be skeptical about the ability of MOOCs to transform higher education. Yet, some observers are again concerned about the consequences of online education for the physical nature of the campus and how teaching and learning occur alongside this phenomenon. And, despite the fact that a focus on depth of knowledge in a given field is essential, Cole believes universities should not be organized in silos.

In sum, Cole supports strengthening and articulating more clearly what constitutes financial conflict of interest at both the institutional and individual levels. It will be important to consider the effect of overregulating the research enterprise and the consequences for knowledge growth that might outweigh the benefits of what is provided by restrictive policies and education. It will be important to outline how to maintain the university's values while working more closely and collaboratively with industry. Cole fears that some of the norms and values that existed previously no longer exist—the culture has changed. This is evidenced by the fact that when the media cover a case of conflict of inter-

est, it becomes obvious that people within the institution did not see any wrongdoing, indicating a strong cultural shift in values and morals regarding financial conflicts of interest.

The University's Capacity for Attestation

William (Terry) Fisher, Ph.D., J.D., WilmerHale Professor of Intellectual Property Law; Faculty Director, Berkman Center for Internet and Society, Harvard Law School

Professor Fisher described institutional approaches to managing conflicts of interest, which can arise when faculty engage in income-generating outside activities. In many of these activities, there is the hazard of corrosion of the university's capacity for attestation, its reputation for objectivity, and its ability to protect the credibility of individual faculty members. To avoid this corrosion, it is important to be transparent, and to reveal any conflict before one is obligated to do so. In some instances, however, transparency is not enough, so additional provisions must be in place to prevent undermining the university's reputation.

Fisher began by noting that most major universities permit faculty to engage in outside, income-generating activities, which is an important practice to continue. Universities consistently maximize the combination of reputation and credibility of faculty members to preserve the capacity of members to influence good public debate. However, when intentionally concealed financial conflicts of interest of individual faculty members come to light, this undermines the overall reputation of universities. Fisher believes universities should prevent faculty members from behaving in ways that corrode the reputation for objectivity of the university as a whole. Although individual faculty members do not bear the full reputational costs of concealed financial conflicts of interest, individual financial conflicts of interest policies can provide a foundation for creating institutional financial conflicts of interest guidelines.

Fisher described Harvard University's standards for its faculty members participating in outside activities. First, outside activities are prohibited if they threaten the faculty members' core responsibility to provide high-quality instruction to Harvard students. Second, outside activities are encouraged if they advance the university's mission of promoting the public good through dissemination of knowledge and engagement in matters of pub-

III. EVOLVING ROLES, ENDURING VALUES, AND CONFLICTING PUBLIC EXPECTATIONS OF AMERICAN RESEARCH UNIVERSITIES *cont'd*

lic importance. Third, outside activities are encouraged if they strengthen the faculty members' teaching and scholarship. Examples include encouraging business school professors to serve on company boards, and encouraging law school professors to represent clients or to appear as expert witnesses. The common thought is that by participating in the professional practice about which they teach, faculty members will be better teachers when they return to the classroom. Fourth, in order to respect faculty members' freedom, income-generating outside activities are tolerated as long as they do not interfere with faculty members' ability to perform university responsibilities.

Fisher noted that Harvard has a set of "imperfect" rules to implement these standards. First, there is a 20-percent cap on outside activities, which means a faculty member cannot spend more than one day per week on outside activities. Second, the various deans serve to guide faculty members in the right direction regarding monetary incentives and non-monetary rewards. Third, the university's culture plays a large role in identifying what activities are considered respectable work and what are philistine behaviors.

Although some faculty members have sufficiently powerful reputations and carry clout individually, for most faculty members, their reputation for objectivity is derived from the institutions of which they are part. Fisher notes that membership in the Harvard community gives added credence to the voices of most of its faculty; association with the university gives the appearance of greater independence and impartiality. However, this reputational benefit is fragile and subject to corrosion when concealed financial conflicts of interest are exposed. Thus, Fisher believes that university administrators must organize to preserve the university's power of attestation, that is, its unique position to affirm the truth, and he described several strategies to achieve this.

First, transparency is a general and widely accepted principle. It compels faculty members to reveal a conflict if it is related to a publicly expressed opinion and a reasonable member of the intended audience would consider it important in determining how much weight to accord the opinion. However, transparency can have the ironic effect of revealing an academic culture riddled with financial interests, and if the public exaggerates the force of those interests, the university's reputation for objectivity could be compromised. At some point, protecting the univer-

sity's public service mission and the power of attestation upon which it depends may require curbing the scope of outside activities. Thus, Fisher described a rough model for managing fCOIs. If interests are slight, then there is no need for regulation. If interests are medium or greater, there is an obligation of transparency. When interests pass a predetermined threshold, the outside activity should be prohibited.

Fisher confronts institutional financial conflicts of interest regularly in his role as Chair of the Berkman Center for Internet and Society at Harvard Law School. Most of the Center's \$7 million budget comes from organizations that have a potential interest in the issues the Center addresses. The following funding policy appears on the Berkman Center website to address financial conflicts of interest challenges:

"We do not accept grants that limit our ability to carry out research in the way we see fit — free of outside influence and consistent with our organizational mission and values. We do not undertake research or accept funds at the request of outside organizations unless it is consistent with our existing research agenda, mission, and overall philosophy. We are transparent about our funding sources, announcing the receipt of funds through our normal communication channels.

"All corporate donors agree to give their funds as unrestricted gifts, for which there is no contractual agreement and no promised products, results, or deliverables. We have experimented with different arrangements at times in the past and have come to believe that this is the most productive approach for both the center and our donors."

With respect to *institutional* financial conflicts of interest, Fisher follows a similar strategy as that followed for *individual* financial conflicts of interest. However, for two reasons, he advocates and abides by a more stringent application of this general approach at the institutional level than at the individual level. First, the hazard to the university's reputation for objectivity is greater when the interested party is a part of the university itself, rather than an individual employee. Second, the administrative burdens associated with transparency are more easily borne by institutions. Consistent with these principles, the Berkman Center

III. EVOLVING ROLES, ENDURING VALUES, AND CONFLICTING PUBLIC EXPECTATIONS OF AMERICAN RESEARCH UNIVERSITIES *cont'd*

maintains transparency and reveals all donations (no matter how small) to individual projects and to the Center as a whole. Since transparency is insufficient to protect the reputation of the Center and the affiliated Harvard faculty in all circumstances, Fisher explained that the Center completely renounces certain types of risky associations, such as sponsored research by corporations.

Finally, although the Center generally does not accept a sponsored research request that would be seen to taint the work it produces, it is also possible to accept the funds but to diversify the sources supporting specific programs, thus neutralizing the influence of any single donor.

Fisher concluded by saying that creating a culture reinforced with periodic consultation among the members of the university may be a better strategy than establishing imperfect rules. In addition, he noted that even if a university shares a common mission within all of its schools, it is appropriate for the rules to vary across individual schools. An ideal approach would be to anticipate particular controversies that may arise, and then rely on a gold standard set of guidelines developed by a group similar to the one at this meeting to adjudicate and resolve conflicts.

IV. INSTITUTIONAL CONFLICTS OF INTEREST IN PRACTICE, PART 1

Investing in Faculty Start-Ups and Other Adventures

Derek Bok, J.D., A.M., University Research Professor and former faculty chair of the Hauser Center for Nonprofit Organizations, and President emeritus, Harvard University

Professor Bok described several cases of institutional conflict of interest he encountered as President of Harvard University and discussed their evolution, increased occurrence, and growing complexity.

Bok began by describing an institutional conflict of interest situation he faced in 1980 regarding a tenured professor who wanted to give the university a block of stock in his start-up company. The company was formed based on the research of Harvard faculty, and he was not asking the university for any financial investment. This was an unusual proposal at that time, and Bok believes it was one of the first times this type of situation had arisen at an institution of higher education. In considering how to respond, Bok spoke to various people within the university; most had questions and concerns about risks with accepting the offer. For example, would the professor spend more than the 20 percent of his time allotted for outside activities on this company? Would graduate students be exploited to do company business rather than their own research training? Would there be excessive secrecy to ensure financial gain? These risks, however, would exist regardless of whether Harvard had a stake in the company, and rules were in place to help minimize them.

After further consideration, a more worrisome risk emerged, unique to the sort of ownership proposal at hand: a potential bias in considering promotions, salary, and office space of professors. Bok noted that even if the administration could avoid actual bias, there would be a perception that any time a professor in whom the university had a financial interest was promoted, people might believe it was because the university was making money from that professor's company. In addition, there was the possibility of perceived bias with regard to enforcement of rules about secrecy and the amount of time spent on outside activities. There might also be divisiveness and internal friction within the faculty if the university chose to invest in some professors' outside interests but not others'. Finally, Harvard's acquiring stock might be

viewed as a university endorsement of professors starting companies. In the end, Bok turned down the 1980 proposal, but in hindsight, he realizes that he was behind the times.

Bok said his judgment had little influence beyond Harvard University, because today many universities have stock ownership in companies founded by their faculty members. In fact, he said encouraging start-ups is often a mark of distinction that leads to public approval. Although there have been negative incidents involving human subjects research (e.g., the Gelsinger case at the University of Pennsylvania), Bok believes that in most cases, having financial interest in the work of university faculty has not been proven to have a deleterious effect on the quality or quantity of their academic work. In fact, studies have found that many professors involved in start-ups have continued to be productive in publishing papers and being cited frequently. Moreover, there has been little evidence of favoritism or exploitation of graduate students.

Bok provided two examples to indicate when investing in a faculty start-up might or might not be appropriate. First, a venture capital firm was set up in the Harvard Medical School to invest in faculty discoveries. The administration of the firm was completely separate from the university administration, the funds involved were contributed by outside investors, and top Harvard officials were not even aware of the investments or the professors involved. These funds have been instrumental in bridging the gap between a useful discovery and the point at which an outside investor might become interested. Arrangements of this kind do not appear to create any significant risk of adverse consequences. In another case at a different university, approximately 30 percent of the university endowment was invested in one particular company. Bok believes that this latter case created an institutional fCOI because the university could well feel strongly tempted to go to great lengths to help the faculty members involved succeed commercially, even if doing so involved compromising normal academic standards and norms.

Bok noted that he now sees a much bigger problem with regard to institutional financial conflicts of interest than investing in a professor's start-up company. Universities have numerous opportunities to get involved in enterprises that could see a profit, which may be used to finance other departments or areas. For example, medical schools' establishing drug testing divisions

IV. INSTITUTIONAL CONFLICTS OF INTEREST IN PRACTICE, PART 1 *cont'd*

to test products for pharmaceutical companies is very similar to individual faculty members receiving money to test products for companies in which they have a financial interest. In both instances, there is a financial incentive to achieve results that are favorable to the drug companies, which conflicts with the duty to be objective.

Financial conflicts of interest also spread beyond research into areas where universities make a profit to help the bottom line, creating potential conflicts of interest that could undermine academic values. Bok named eight such potential conflicts: executive education programs, intercollegiate athletics, alumni cruises, patent licensing, campuses abroad, extension schools, online education, and internal subsidies. History shows that in some of these cases, universities have actually sacrificed academic standards and values for commercial reasons.

In the 1920s, many universities offered correspondence courses, which involved nonrefundable enrollment fees. However, because the major expense for these courses was paying graduate students to grade exams and papers, and because many people dropped out too late to receive a tuition refund but long before completing the course and prior to expenses being incurred, the universities made a profit on the human frailty of people who did not persevere. A current example occurs with intercollegiate athletics, where universities with winning teams have higher gate receipts and television revenues. In order to succeed both financially and on the playing field, universities admit athletes who otherwise would not be accepted and allow them to take easier courses so that they can remain academically eligible to remain on their teams.

Despite these examples, Bok does not believe that all profit-making activities by a university are inappropriate, or that potential institutional conflicts are all wrong. In fact, the profit motive can play a useful role in sparking ingenuity, lowering costs, and improving quality. The risk of exploitation is probably low with executive education, alumni cruises, and overseas campuses because those who engage the university's services are usually in a position to assess the value of what they are receiving and turn to another provider if they are not satisfied. However, in certain instances where customers are vulnerable, there is a possibility of exploitation similar to what has occurred in athletics and

earlier in correspondence courses. Bok is concerned with online education being run for profit because there will be a temptation to attract large numbers of students by offering great lectures and wonderful visuals, but little incentive to have students drive up incremental costs and lower profits by participating in active discussion groups or receiving personal attention from the instructor, which are essential components of learning.

Bok closed by saying that institutional financial conflicts of interest are a much more pervasive problem than he imagined when he first faced the issue in 1980. Universities have not been willing to discuss regulation of such conflicts because of the uncertainty of the outcome and the fear of losing revenue. Eventually, however, universities will have to consider the issues involved and develop appropriate rules and safeguards to avoid embarrassment and inappropriate compromise of academic values. In going forward in developing policies, university administrators would be wise to involve faculty members in the discussion because of their genuine concerns for protecting and maintaining high academic values.

The Olivieri Case: Institutional Financial Conflicts Perspectives

Jonathan H. Marks, B.C.L., M.A., Associate Professor of Bioethics, Humanities and Law, and Director, Bioethics Program, Pennsylvania State University

*Professor Marks discussed the details of the Nancy Olivieri case, which provides a glaring example of how institutional conflicts of interest can not only put the public's health at risk, but also bind university scientists in protracted litigation over research results.*³

Marks explained that Nancy Olivieri was a Toronto-based hematologist affiliated with the University of Toronto and the Hospital for Sick Children. In the 1980s and 1990s, she was studying thalassemia major, a genetic disorder found more often in certain populations that impedes proper uptake and processing of oxygen. Patients must have frequent blood transfusions, which results in accumulations of iron in the heart, liver, and other organs. At the time, the standard therapy for this build-up involved an all-night infusion, which was uncomfortable and

³ Marks disclosed that he was counsel for Nancy Olivieri in *Olivieri v. Commission in the European Court of Justice* between 1999 and 2003.

IV. INSTITUTIONAL CONFLICTS OF INTEREST IN PRACTICE, PART 1 *cont'd*

intrusive especially for children; thus, an oral chelator would have been far preferable. Olivieri identified a potential oral therapeutic in 1989, called deferiprone, and requested funding from the Medical Research Council of Canada to conduct a randomized clinical trial. The Council told her to find an industry partner, which she did in Apotex.

In 1993, Apotex asked Olivieri to sign a research contract that contained a confidentiality clause. There was no university review process for the contract, and the university ethics review board did not examine such agreements.

In 1995, Olivieri signed another contract with Apotex for continuation of the pilot study as a long-term efficacy and safety trial. In contrast to the 1993 contract, this agreement had no confidentiality clause. During the course of this trial, Olivieri became concerned about evidence that pointed to the toxicity of the study drug and its declining efficacy over time. Olivieri informed Apotex and the Ethics Board that was monitoring the study that she wished to re-consent the study subjects with this new risk/benefit information. The Ethics Board agreed that Olivieri should inform participants about her concerns. However, Apotex began efforts to hold Olivieri to the confidentiality clause of the first contract, claiming that it prohibited her from sharing information, even with subjects. The company threatened to pursue all legal remedies against Olivieri if she disclosed her findings to subjects, which she did nevertheless.

Marks said what is striking about this case is the response of the University of Toronto and the Hospital for Sick Children. A report by an independent inquiry commissioned by the Canadian Association of University Teachers (CAUT) found that these institutions failed to protect Olivieri, her study subjects, the integrity of the science, and the public health. Throughout these events, Olivieri had to rely on the Canadian Medical Protective Association as well as her own funds for her legal defense. The CAUT Report held that the University of Toronto and the Hospital for Sick Children should have come to her defense. Eventually, Apotex removed Olivieri from the study and discounted her unfavorable data by alleging protocol violations (allegations that an expert's report subsequently disproved). Apotex then submitted data to the European Medicines Agency for a marketing authorization and attempted to discredit Olivieri to the regulators.

The CAUT inquiry sought the opinion of a leading legal expert regarding the confidentiality clause in the first contract. The expert concluded: "To the extent that it prohibits a physician from disclosing to a patient information that the physician has acquired pursuant to her research (or otherwise), this clause is illegal and void if there is a material or significant risk to the patient." The legal opinion added: "In these circumstances, the researcher does not have to establish the complete accuracy of her concern—a risk is a risk, not a certainty—but only that it was not an unreasonable concern."⁴

The CAUT investigation concluded that Olivieri's plan to inform subjects, regulators, and the scientific community of the risks of the experimental drug was appropriate and that Apotex's actions to block her from doing so were not. Further, the Hospital for Sick Children and the University of Toronto could have and should have supported Olivieri in the exercise of her rights and obligations, as this was a matter of academic freedom as well as protection of the public interest. CAUT also concluded that such conflicts are widespread and demand concerted efforts to identify and address them.

CAUT further concluded that the failure of the University of Toronto and the Hospital for Sick Children to defend Olivieri was, in part, related to discussions that the university had been having with Apotex for many years regarding what would have been a \$92 million donation⁵ to build a new biomedical research center to benefit the university and its affiliated health care institutions. In 1998, after the Olivieri case became public, the University agreed to suspend discussions about the donation until the dispute was resolved and Apotex was cleared of wrongdoing.

In 1998, Apotex asked University President Pritchard if he would lobby the Government of Canada against proposed changes to drug patent regulations that would adversely affect Apotex's revenues. Pritchard wrote to the Prime Minister, stating that the proposed rules could jeopardize the planned donation, and thus, the building of the new research center. The lobbying efforts failed. In 1999 Apotex withdrew its offer of \$92 million, making a much smaller donation. Marks reported that Pritchard later said the request by Apotex to lobby the government was inappropriate, and he regretted his actions. In 1999, Olivieri was relieved from her position at the Hospital for Sick Children.

⁴ The legal expert's opinion can be found in Appendix F of the CAUT report. This figure includes matching gifts.

⁵ This figure includes matching gifts.

IV. INSTITUTIONAL CONFLICTS OF INTEREST IN PRACTICE, PART 1 *cont'd*

Marks concluded that the lesson to be learned from this case is that because of institutional financial conflicts of interest, neither Olivieri, her research subjects, scientific freedom, nor academic research independence were protected. Although the University of Toronto desired the Apotex donation in order to conduct good work, the offer skewed its ability to do the right thing in the Olivieri case. Integrity requires institutions to examine the alignment of their mission with their practices. Although the mission may evolve over time, some apparent opportunities can undermine adherence to the mission. Institutions must ask whether potential funding streams will undermine their commitments to their mission, and whether the sources of funds can distort or corrupt their research priorities and agenda. Marks also warned of the potential for distortion of “organizational skepticism” in which projects that don’t promote the commercial interests of large corporate sponsors receive increased skepticism, while those that fit the priorities of sponsors do not.

In sum, the Olivieri case was an egregious example of institutional corruption and conflicts of interest. We know about this case because, according to Marks, Olivieri dedicated her life and career to making it known. More troubling is what happens when the researcher does not stand up to such pressures, or is not prepared to take the personal risks required to do so.

Audience Discussion

Panelists were asked whether they felt there are inherent conflicts of interest when university professors are paid to produce on-line courses for for-profit entities. If a university helps a faculty member through the reputational value of affiliation and other means of support, does it have a right to demand exclusivity in terms of that faculty member’s time, access, and commitment? Bok responded that there is tension in the desire to disseminate knowledge to as many people as possible while maintaining the value of in-person education and protecting the rights of students to exclusive access gained through admissions and tuition. It was suggested that there are likely to be greater concerns when a university as an institution tries to profit from on-line education than when an individual does, because it could

be acting in a way that conflicts with the best interests of matriculated students on campus. Most institutions do have policies regarding conflicts of commitment, but they tend to focus on the individual, not the institution.

Another question focused on the best approach to oversight. Distortions of the university’s research agenda can occur in the absence of adequate peer review, which is often lacking in industry-sponsored research. Panelists pointed out that Institutional Review Boards, which review the ethics of human subjects research, are not typically charged with reviewing conflicts of interest, nor are they currently constituted to do so.

Other discussants focused on the insidious nature of institutional conflicts of interest when all parties believe that the primary and secondary interests of the university are being served by the relationship. Universities are always seeking funds; thus, any activity that brings in funds can obscure potential pitfalls, especially if the relationship or activity also purports to serve public health or social needs. Panelists agreed that oversight by Boards of Trustees is not necessarily an optimal solution, as Boards and Board members can themselves be conflicted.

The panelists did not reach a consensus on the optimal approach to resolving conflicts, but agreed that broad ongoing discussions in the academic community are needed.

V. INSTITUTIONAL CONFLICTS OF INTEREST IN PRACTICE, PART 2

Afternoon Welcome

**Martha L. Minow, J.D., M.A., Dean and Jeremiah Smith, Jr.
Professor of Law, Harvard Law School**

Dean Minow welcomed the conferees to the Law School and stressed the importance of the symposium. She said that one of the greatest risks we face is not knowing our biases, which can affect the pursuit of truth and justice. Or, we might underestimate the degree to which biases affect our judgments. This is complex because we are inherently conflicted. The phenomenon of conflicts of interest is really just the tip of the iceberg, reflecting what we claim to be the line at which our objectivity is influenced. Thus, despite our practices, rituals, and codes to guard against such conflicts, we are not always aware of how influences, in particular money, can affect our views.

One possible response would be to throw ourselves into total doubt, so afraid of our biases that we become paralyzed and afraid to say anything. However, it is especially important for the research university to remain the place for real science to counter the “industry of doubt”—that is, the efforts to plant doubt about the scientific validity of, for example evolution, the dangers of tobacco use, or climate change—which fosters pseudoscience. It is also important to constantly discuss these issues to raise consciousness, elevate critique, and open new lines of inquiry.

Minow concluded by thanking the speakers for their contributions to these important discussions.

Walking the Tightrope: Protecting Trustworthiness While Engaging with Industry at MIT

Claude Canizares, Ph.D., M.A., Vice President for Research, Associate Provost, and Bruno Rossi Professor of Physics, Massachusetts Institute of Technology (MIT)

Dr. Canizares discussed the long and successful history of MIT's focus on applied research and its transfer into uses that serve the public. MIT's relationships with industry have played a crucial role in these successes, which has focused attention on the institution's approaches to resolving conflicts of interest.

Canizares said that MIT was originally founded as a land-grant institution to promote the industrial arts, and thus has been home to earnest cooperation throughout its history—but this cooperation has changed significantly in the past few decades. MIT's engagement with industry is an important component of the institution's success. As part of MIT's mission, Canizares believes industry relationships should be treated with the same respect as transmission of new knowledge and independent scholarship. To date, he believes MIT has been successful in maintaining balance. However, if trustworthiness is lost, it will be difficult to regain.

Current economic and social conditions have exacerbated pressure from elected officials, taxpayers, and industry leaders for universities to engage with industry, often in well-intentioned hope that these engagements will create jobs. Universities face pressure to increase return on investment as states' education budgets are slashed. Another source of pressure on institutions comes from public frustration about what is widely perceived as uncontrolled growth in tuition costs. As a result, university leaders are looking at commercial engagements as a way to assuage public frustration. Recently, MIT and over 140 other universities signed a joint letter in which they pledged to redouble efforts to encourage the transfer of research products into the commercial sector.

The challenge remains in learning to balance and reconcile the unavoidable tensions between preserving the sanctity of the academic enterprise and the desire to earnestly cooperate with industry to transfer the fruits of research to society. Despite strong emphasis on working with industry, Canizares said MIT first and foremost is a university devoted to sound, unbiased scholarship and grounded firmly in the same traditions that gave rise to Harvard. MIT's underlying principles include a firm commitment to open, unfettered education, exploration of new knowledge, open and unencumbered publication of results, and independence from biases — all of which are prerequisites for the trustworthiness that flows from the institution's impartiality.

One of the major components of industrial engagement is industry-sponsored research. Canizares faces issues stemming from financial conflicts on a daily basis at MIT. A recent faculty committee report examining fCOIs in research reiterated MIT's strong commitment to working closely with industry alongside the Institute's responsibility to ensure that financial relationships

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do not compromise its research, teaching, outreach, or other activities. Currently, industry funds account for approximately 16 percent of MIT's \$700 million of research sponsorship, and that figure increases to 20 percent when including direct sub-awards from industry that involve the pass through of federal funds.

A second component, which has developed over the past 30 years, is MIT's involvement in fostering start-up companies through licensing of new technology, much of which emerges from federal research. Each year, MIT is awarded 150 to 200 patents and issues approximately 100 licenses, which account for about 25 new start-up companies each year. Annual gross revenue from licensing and royalties is between \$80 million and \$150 million. Canizares believes that the Bayh-Dole Act giving universities ownership of intellectual property derived from federally sponsored research has greatly accelerated licensing activities at all institutions. A third component of MIT's earnest cooperation is that industry is an important source for philanthropy. In 2011, 700 companies provided research support or gave gifts to MIT; 175 funded more than \$100,000 and 40 funded more than \$1 million.

Earnest cooperation also includes a nonfinancial component where industry leaders serve as MIT trustees, members of visiting or advisory committees, or advisors to consortia. In addition, MIT faculty and senior officers serve as directors and advisors for companies, but are not allowed to hold line management positions unless they take leave from the Institute.

MIT researchers do not engage in direct conduct of clinical trials on safety or efficacy of drugs or devices because MIT has no medical school or affiliated hospital. The lack of a medical school could indicate that perhaps MIT is less exposed to the scrutiny placed on medical colleges. However, MIT has associations with numerous biotechnology and major pharmaceutical companies, and Canizares believes that some of MIT's environmental safety studies are as politically sensitive and subject to public scrutiny as are clinical trials.

MIT relies on a collection of policies and procedures to help preserve openness and independence regardless of the source of support in the design, conduct, and reporting of research, which ultimately impacts trustworthiness. Canizares noted that officers and trustees identify potential conflicts and are separated from decisions that might be perceived as conflicts. An investment company that is separate from the academic enterprise

manages the MIT endowment. Although MIT's technology licensing office takes equity and royalties from start-up companies, it is careful about future follow-on engagements and will divest itself of the equity to avoid potential financial conflicts of interest. Canizares believes the fact that MIT has many licenses with diverse companies means there is a low value to divesting any one. He notes that universities' dependence on the federal government raises a host of important issues that are poorly discussed or addressed, despite the fact that this sort of dependence is far more substantial than universities' dependence on industry.

In addition, MIT adheres to strict boundaries with regard to corporate sponsors, although Canizares believes they can be even more clearly defined. For example, MIT insists on retaining complete freedom to publish and categorically refuses any attempts made by companies or government agencies to require prior approval. MIT does allow prior review for patentable information or inadvertent inclusion of proprietary information, but insists that the institution owns or jointly owns intellectual property invented by its researchers. Canizares says that adhering to these and other principles has led to MIT's walking away from potentially lucrative sponsorships.

Subtle potential effects on decision-making, such as the desire to please sponsors or donors, are much harder to manage, and strong economic pressures on public universities are starting to cause erosion. Canizares noted examples of policies adopted by other universities that grant corporate sponsors greater rights over sponsored research, including ownership of the intellectual property coming out of the research. He is concerned that these responses to external pressures may be the beginning of erosion that may progress quickly.

Canizares closed by stating that the trustworthiness of research conducted in universities depends on the integrity of the researchers, the research, and the culture of the institutions, and the idea that people across disciplines are subject to criticism and critique. Finally, Canizares believes that the humanities should be involved in ensuring this integrity, as they are critical observers and analysts of science and R&D, and they provide an understanding of the context within which scientific and technical advances will reside. Recently, MIT received a \$100 million unrestricted gift, of which \$75 million was invested in the School

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of Humanities, Arts and Social Sciences to ensure the ongoing strength and vitality of those fields, which receive far less support from public and industrial funds. He also noted that increasingly, research activities include not only scientists and engineers, but also members of the School of Humanities, Arts and Social Sciences.

The Lion in the Path: Research Universities Confront Society's New Expectations

Hunter R. Rawlings III, Ph.D., President, Association of American Universities (AAU)

Dr. Rawlings, who served as President of University of Iowa and Cornell University before coming to AAU, described the evolution of the American research university and how societal pressures and expectations—from the state, industry, and the public—challenge the core mission of these institutions and diminish public trust. Research universities can protect institutional integrity through adherence to the principles of autonomy, neutrality, and authority.

Rawlings began by discussing a 2011 letter from the National Advisory Council on Innovation and Entrepreneurship, consisting of the presidents of 141 universities (including MIT), to the U.S. Secretary of Commerce declaring its intention to “expand efforts to encourage, recognize and reward faculty interest in research commercialization by providing incentives and encouraging engagements with industry, entrepreneurs and venture partners.” Why did AAU presidents believe it is worthwhile to promote student and faculty entrepreneurship and to incentivize relationships with industry?

As a professor of Classics, Rawlings prefers to view the university along the lines of its European model: a disinterested and open-minded community pursuing truth for truth's sake. That was Plato's vision when he founded his Academy outside the walls of Athens, untainted by the polis. The academy, ancient and modern, has long prided itself on maintaining its autonomy and neutrality. Thus, the 2011 letter reflects a pressing predicament of the modern research university. As an institution of higher learning, the university's fundamental mission lies in the academic realm, in the education of students and in the pursuit of knowledge. But it now seems to be going down a path of greater col-

laboration with the state, pushed by the state's desire for economic help, and drawn by its own thirst for research funding and prestige.

These pressures are not new. Some American universities have pursued a pragmatic public mission at least since the Morrill Land-Grant Act was signed into law 150 years ago. Land-grant universities owe their existence and initial endowments to the federal government, and their mission to their states, which saw them as engines of education and economic development when both were sorely needed. As President of Cornell University, New York State's first land-grant university, Rawlings saw the values of these universities first-hand.

Since World War II, the pragmatic mission of the university has expanded further and American universities have played a crucial role in driving the nation forward. Federal funding for university-based research has led to many of the advances that support our economic competitiveness and our lifestyle. The Bayh-Dole Act of 1980 vastly enhanced universities' ability to participate in the innovation process by giving them the intellectual property rights to the products of federally funded research. Thus, the 2011 letter is the latest manifestation of an historically accepted and valuable component of the American university's mission.

Nevertheless, embracing innovation and entrepreneurship may not sit well with all members of the academy, who might ask whether the university can maintain its integrity, academic freedom, and creative spirit of inquiry in the face of pressure to commercialize research results and drive regional economic growth. Although major research universities have established policies to manage individual conflicts of interest—intended to minimize bias in faculty research—as collaborations have expanded from the individual to the departmental, program, or school level, the need for management policies has also expanded.

One example of the conflicts that can arise occurred in 1998 when the pharmaceutical company Novartis agreed to fund \$25 million of basic research at the University of California, Berkeley. In exchange, Novartis received exclusive first rights to negotiate the licenses on roughly a third of the department's research, including projects funded by state and federal sources. Faculty and students reacted strongly to the agreement claiming that the department's objectivity had been compromised, while others insisted that the deal benefited the department and the pur-

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suit of cutting-edge science. This controversy underscored the need for robust methods of managing conflicts of interest, not only at the individual level, but also at the institutional level, particularly given the apparent permanence of cooperative ventures between industry and academia and the growing pressures on universities to assist in economic development.

While some universities have codified their policies regarding potential institutional conflicts of interest, these policies tend to be broad and general, offering little specific guidance to presidents and provosts confronted with potential relationships with the for-profit sector. Not all solutions to these conflicts are legal; they are often a matter of institutional culture. Moreover, perceived conflict of interest or commitment can damage a university all by itself.

Events during summer 2012 at the University of Virginia further demonstrate the need to address institutional conflicts of interest. In this case, the Board of Visitors announced that they were removing President Terry Sullivan because she was moving too slowly to take advantage of the potential profits to be made in online education as a means of solving the university's budget problems. Pressures on university presidents to perform according to corporate measures of success are widespread. The rise of for-profit universities, and the partnership between not-for-profit universities and for-profit companies offering platforms for online education exhibit the creeping conversion of education into a business, and the wholesale conversion of students into consumers. Is the university a neutral party pursuing truth or an economic engine pursuing someone else's interest? Rawlings said the problem is that intense focus on purposes other than academic opens the door to a slippery slope that can end in the corruption of the university and damage to its reputation.

Perhaps the most grievous transgression of academic values now perpetrated by universities, including major research universities, occurs not in the realm of technology transfer, but in the domain of big-time intercollegiate athletics. Institutional conflicts of interest arise in some universities that have chosen to engage and invest in what amounts to an entertainment industry. The pursuit of gridiron glory has overrun not only whatever educational values may have originally been associated with athletics programs, but also in some cases the moral values of those involved. Recent high-profile examples of the pitfalls of over

glorifying athletics remind us how difficult it is for universities to manage businesses in which the highest duty is conceived by some to be owed not to academic values or to students, but to other claims on institutional loyalty.

Having explicitly laid out their commitment to innovation and economic development in the 2011 letter to the Secretary of Commerce, Rawlings said these signatory universities must now make explicit their commitment to the protection of their core academic values. To meet this test, they must define the principles that will guide decisions when educational and economic missions diverge. Society trusts universities because universities do not serve private interests; they are trusted to pursue the truth. The university accomplishes this mission through the education of students, the pursuit and dissemination of knowledge, and through some economic engagement with society, which should always be in the public's interest. In all these activities, the university must uphold its side of the social contract; it must maintain its integrity so that it remains worthy of society's trust.

Rawlings said that autonomy, neutrality, and authority constitute institutional integrity. Although in none of these domains is the university "pure," it needs to hold these three values to the highest possible standard while acting in the world. Autonomy means that the university is maximally governed by itself, even if it is ultimately governed by the state. Neutrality means that the university does its utmost not to take sides on political or economic issues. Authority means that the university stands as a trustworthy source of knowledge. In a world overflowing with information and opinions, both individuals and society seek voices they can trust. When they are not beholden to special interests, and because they develop expertise based upon free inquiry, universities provide that authority. However, this authority can be undermined by the communications revolution in which a popularity-driven approach to truth seeking produces "knowledge" that cannot be trusted.

Trust in universities, as in all other institutions including government, private business, and churches, has diminished. In addition to the public outcry over tuition costs and student debt, the three pillars of institutional integrity – autonomy, neutrality, and authority – are under assault. Motivated by budget constraints and ideology, many governors and public governing boards are forcing university presidents out of office. This is a conspicuous

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attack upon institutional autonomy, and it is nationwide. At the same time, ironically, states are asking more from their universities than ever before in the pragmatic realm of economic development. This pressure compromises the neutrality of universities.

Given these assaults upon its integrity, the university's responsibility to preserve its neutrality becomes more urgent, as does the need to assert its autonomy and to uphold its authority. First, universities must be able and willing to say when the commercialization of research crosses a line. Universities must strongly assert that their greatest economic contribution comes from the education of students. Second, universities need to think hard about the seductions of massive open online courses (MOOCs). The eventual possibility of a new source of revenue has sent universities scrambling to jump on the MOOC bandwagon, creating a tension between educational and economic imperatives. Rawlings asked, can we use our three principles to guide sensible consideration of MOOCs? In terms of a responsibility to authority, universities must speak up regarding the contradictions inherent in the MOOC model, that is, content is not the same as education. Universities have a responsibility to assert their autonomy, to push back against outside pressures to adopt MOOCs simply because they are new and innovative. What matters is how and how much are students learning. The university's neutrality demands that the education of its students not become beholden to external financial interests. Maintaining institutional integrity in the rapidly evolving world of online education may be the most difficult challenge of all.

Such a pronouncement is not meant to discourage the pursuit of effective models for online education, said Rawlings. Rather, it is that universities must strive to uphold their neutrality, authority, and autonomy even as they extend their traditional mission into new realms of practice. The same warning applies to technology transfer and the entrepreneurial university. The university exists in the context of society, and to the extent that it can serve the public good through business ventures or through open online courses, it should pursue those activities. Unlike big-time intercollegiate athletics, where entertainment values have in some cases overwhelmed educational values, both technology transfer and online education can serve as useful extensions of the university's core mission.

Rawlings closed by stating that, since research universities ultimately serve the public, putting their knowledge and expertise to use in achieving public purposes makes perfectly good sense, as long as the university maintains its reputation for academic integrity and independence. The context in which universities now find themselves underscores the importance of this stricture.

Audience Discussion

One participant raised the issue of the "neutrality trap" in which journalists feel compelled to provide opposing points of view on a scientific issue to give the appearance of being objective, even when one side has all the facts and data, and the other does not. Panelists agreed that it is the research university's obligation to provide the expertise needed for the public to discern the validity and weight of evidence in matters where science is being disputed, for example, climate change or evolution.

Another participant raised concerns about the role of university technology transfer offices (created to accelerate the movement of academic discoveries into applications) and whether they should be as intent on producing revenue as they are, given that most fail to do so, especially given the investment in the research. Panelists agreed that an over emphasis on revenue generation can have distorting effects on what is important in the university research environment.

A third issue concerned the university's role in being an advocate or taking positions on political or social issues. While individual faculty members inevitably will be consulted for their opinions in their area of expertise, Rawlings urged caution against institutions taking such positions, as doing so might not serve the interests of the diverse community that makes up the university as a whole.

VI. INSTITUTIONAL CONFLICTS OF INTEREST IN Awardee INSTITUTIONS

Managing Financial Conflicts of Interest in an Expanding World of Industry-Academia Collaborations in Science and Medicine

Sally Rockey, Ph.D., Deputy Director for Extramural Research, National Institutes of Health

Dr. Rockey discussed recent efforts by the National Institutes of Health (NIH) to issue regulations on institutional financial conflicts of interest and the events that led up to this push for accountability.

Rockey began by noting that while researchers depend on NIH for funding, NIH depends on researchers to conduct viable, appropriate research. Universities have an interest in maintaining the integrity of the institution, and NIH has an interest in maintaining the objectivity of research. The relationship between NIH and grantee organizations should be considered a partnership, rather than a relationship between clients and stakeholders, said Rockey. NIH recently significantly revised and reissued a 1995 regulation on individual financial conflicts of interest. Although this regulation is focused on the individual investigator and the grants NIH funds, it also is about institutions because they play the major role in managing individual financial conflicts of interest.

NIH provides oversight of the entire grant making process, and some have questioned whether it should have a larger role in managing employees and individuals at the awardee institution. The current regulation requires all key personnel associated with NIH research grants to disclose to their institutions any significant financial interests (SFIs) related to their institutional responsibilities; SFIs associated with their clinical work and teaching, activities beyond research, as well as research itself are included. However, Rockey said that every disclosure of a significant financial interest is not necessarily a financial conflict of interest. The institutions are expected to evaluate the relationships of their faculty members and researchers to determine whether the financial interests constitute a conflict.

As part of the regulation, NIH receives relevant financial conflict of interest information, provides oversight, and conducts efforts to ensure compliance. NIH works to promote objectivity, but is not in the business of trying to hinder professional relationships of investigators. The idea behind the regulation is that institu-

tions will manage financial conflicts of interest that arise. Managing a conflict might mean, for example, that an investigator cannot participate at all in the funded research project, that the investigator is moved to an independent analytical position, or that the investigator is prohibited from recruiting patients. Institutions have numerous options for managing fCOIs short of making investigators step down from the project or totally divest their conflicting financial interests.

The process for updating the 1995 regulation began in 2007 when NIH asked the public two questions about institutional conflicts of interest: (1) how should the term be defined, and (2) what should institutional conflicts of interest policy address to ensure objectivity? It became clear from responses that the concept lends itself to no clear, agreed-upon definition, a problem that must be addressed before a policy may be developed. The definition varies depending on whether it is being defined by an investigator, research administration, or professional society. The Notice of Proposed Rulemaking for the regulation asked if institutions should be required to have an institutional conflicts of interest policy in place to receive an NIH or other DHHS award. Such questions were driven in part by the DHHS Office of the Inspector General (OIG), which at the time was doing a study of the policies for managing institutional conflicts in DHHS-supported institutions. Although the Notice was not describing a particular policy or even including a set definition of institutional conflicts of interest, the community responded that requiring a policy with no further guidance would create massive confusion. Rockey said it was obvious that additional information and more deliberation were needed, so NIH decided not to add institutional conflicts of interest policy to the regulation.

In 2011, the DHHS OIG issued its report on institutional fCOI policies. Most of the institutions reviewed by OIG held equity in non-publicly traded companies, and the institutional policies reviewed focused more on institutional integrity — such as ensuring open exchange of research results through publications and disclosing financial conflicts of interest on informed consent forms — than on institutional financial conflict of interest itself. Nonetheless, the OIG recommended that NIH promulgate rules on institutional fCOIs. Rockey said this directive raises questions about what it means for the federal government to take a regulatory stance on managing institutional financial conflicts of interest. Rockey believes it would be difficult for a federal agency to

VI. INSTITUTIONAL CONFLICTS OF INTEREST IN AWARDEE INSTITUTIONS *cont'd*

create such rules, since the definition of conflict is not clear and because institutional fCOIs go to the core of how institutions are constructed, how they manage employees, how they manage decisions, how they manage endowments, how they prescribe drugs at their hospitals, and what holdings their deans, chairmen, presidents, and provosts can have. In addition, these issues extend beyond the biomedical research community to the entire institutions in which they are housed. Thus, all parties should share a common goal of assuring that outside influences are not affecting the objectivity of research. Rockey thinks that NIH can help facilitate discussions with universities to develop guidance or regulations in this area.

An example of how individual and institutional financial conflicts of interest can be difficult to distinguish is evident in a recent case study involving Ronald DePinho, the current President of the MD Anderson Cancer Center. DePinho asked for waivers of the institution's financial conflicts of interest policy to permit continuation of his stock ownership and other relationships with certain companies. The University of Texas system reviewed his request and granted a waiver of the policy as applied to DePinho's relationship with three of the companies. Rockey said that DePinho requested the waivers to ensure researchers at the cancer center could conduct research for the companies and accept research funds from them in the future. DePinho was allowed to maintain his holdings, but they were to be put in a blind trust, which removed his ability to control the funds. By granting this waiver, researchers at the cancer center would be able to accept funds from these companies, work on NIH projects where one of the companies was cosponsor, or work on federally funded projects using drugs or therapeutics developed by the companies. This case demonstrates that it is important to look at financial conflicts of interest in different ways, and it also shows how complicated these issues can be. However, this example was not without controversy.

In closing, Rockey said there has been much discussion in the community about the role of NIH in the pipeline from basic sciences to translational sciences to products, and what it means for managing financial conflicts of interest if NIH is fostering relationships between universities and the private sector. For example, NIH recently developed the National Center for Advancing Translational Sciences. The goal of the Center is to catalyze new and effective ways to develop, test, and implement diagnostics

and therapeutics. One program at the Center involves the discovery of new therapeutics using existing molecules, which is a rescue and repurposing program. A therapeutic drug development program may start with 10,000 compounds, and 10 to 15 years later only one of these compounds actually gets Food and Drug Administration (FDA) approval and becomes commercially available to treat patients. However, many of the other compounds may have use for different conditions. The first partners for this program — Pfizer, AstraZeneca, and Eli Lilly — have agreed to open their libraries of compounds to universities for research. The Center is working to create agreements for handling the intellectual property rights as well as conflicts of interest. As the program progresses, it will be important for NIH to assure that the research is conducted in an unbiased way and that objectivity is preserved. The current focus is on individual as contrasted with institutional conflicts, that is, on ensuring the individuals participating in the grants do not have problematic holdings with the companies of interest.

The Perspective of the DHHS OIG

Julie Taitsman, M.D., J.D., Chief Medical Officer, DHHS OIG

Dr. Taitsman described the role of the DHHS OIG in providing oversight of DHHS agencies as well as the institutions they fund or interact with. One area of focus is financial conflicts of interest, both individual and institutional.

Taitsman explained that DHHS OIG provides internal oversight for the agencies within DHHS, including FDA, NIH, and the Indian Health Service, as well as external oversight for hospitals, drug companies, physicians, and medical device companies that receive Medicare and Medicaid funding. Approximately 80 percent of the oversight is directed toward recipients of Medicare/Medicaid funding. OIG's mission is to protect the integrity of DHHS programs and the health and welfare of program beneficiaries. Taitsman said the two important components of this mission are 1) protecting federal money to ensure it is used wisely and 2) protecting patients to ensure they receive high quality care. DHHS OIG does not directly regulate universities or academic medical centers.

DHHS OIG has approximately 1,700 employees throughout the United States, all involved in some type of oversight or analysis of

VI. INSTITUTIONAL CONFLICTS OF INTEREST IN Awardee INSTITUTIONS *cont'd*

policy. Auditors audit recipients of federal funds, specifically trying to recoup overpayments and review program violations. Investigators and attorneys work with law enforcement partners to enforce fraud and abuse laws, such as the Anti-Kickback Statute, the False Claims Act, the Stark law, and others. Evaluators serve as the think tank for the organization, creating reports on policy and making recommendations for improving business practices or requirements within various departments. Although OIG is the oversight agency for DHHS and its agencies, it does not directly fund medical research or education. NIH has a medical research budget greater than \$30 billion, and since much of that money is used for extramural research at universities and academic medical centers, the OIG has abiding interest in how NIH ensures that any financial conflicts of interest of recipients of research awards are detected, reduced, eliminated, or effectively managed by the researchers' institutions.

OIG has created a series of reports on fCOIs. The first examined how well NIH kept track of financial conflicts of interest of grantees, the second assessed how grantees managed such conflicts, and the third focused on institutional financial conflicts of interest. Although there is no federal requirement to report institutional fCOIs, the study examined whether grantee institutions had established policies in this area. Of the 156 institutions reviewed, 69 had written policies and procedures addressing institutional financial conflicts of interest; 18 institutions, including 3 without written policies, identified 38 conflicts that most commonly involved institutions holding equity in companies related to their NIH funded research. As a result of these analyses, OIG recommended that NIH promulgate regulations addressing institutional fCOIs.

OIG focuses on conflicts of interest because of their potential effects on data integrity, that is, the accurate and reliable reporting of research results, as well as the potential downstream misuse of federal funds.

OIG recently turned its attention to the clinical investigation of new medical treatments, focusing on the large subset of clinical research that is used to provide evidence in support of marketing applications to the FDA. Although OIG's role in overseeing financial conflicts of interest is indirect, ultimately it is responsible for conducting oversight to ensure FDA makes sound efficacy and safety determinations. This includes ensuring the quality of care of human subjects in clinical trials, ensuring consumers have

access to safe and effective products, and ensuring worthwhile products are not unfairly denied entry to the market. Once products are approved, federal programs through the Centers for Medicare and Medicaid Services (CMS) pay for them, so OIG also ensures that CMS makes sound coverage decisions. Assurance of financial integrity involves the money the federal government spends to support research and to purchase health care services. Annual federal health care spending on Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) is approximately \$770 billion, and OIG works to ensure that money is well spent.

Taitsman prefers the IOM definition of conflict of interest as "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." She defined primary institutional interests for research hospitals and universities as improving care, saving lives, developing new technologies, advancing knowledge, and discovering cures, and secondary interests as financial gain, investment interests, increased grant funding, academic standing, publications, and prestige.

Traditionally, universities, hospitals, and independent institutes conducting research programs have established internal Institutional Review Boards (IRBs), and Taitsman argues it is important that these IRBs have support from institutional leadership to be effective and respected. However, in the past 3 decades, many free-standing IRBs have been established, which are for-profit companies that make money by overseeing research. Taitsman defined the primary interests of all IRBs, academic and commercial, as ensuring the integrity of the research data, protecting human subjects by ensuring appropriate informed consent, and ensuring that risks to subjects are minimized and are reasonable in relation to potential research benefits. On the other hand, the secondary interests of commercial IRBs that are employed by pharmaceutical and medical device companies for a majority of their clinical trials include staying in business, being profitable, generating repeat and new business, and receiving fees from study design review and oversight. She sees a real risk for the free-standing IRBs to feel financial pressure to keep their customers (sponsors, researchers, and scientists) happy, to approve trials quickly, and to impose minimal oversight burdens. Taitsman believes that for commercial IRBs to be effective and respected, it is important that they, similarly to institutional IRBs as noted earlier, have support from leadership that promotes a culture of high quality and integrity.

VI. INSTITUTIONAL CONFLICTS OF INTEREST IN AWARDEE INSTITUTIONS *cont'd*

Just because someone has a conflict of interest does not necessarily mean that they will act in a way to advance that interest, but Taitsman's experience offers circumstantial evidence suggesting that it is likely. For example, financially interested sponsors have a motive to bury unfavorable results (e.g., results showing a product is unsafe or ineffective) by delaying or never publishing the findings, and Taitsman has seen data suggesting that published research funded by drug manufacturers is indeed more likely to show favorable than unfavorable results; studies with favorable results funded by interested sponsors are more likely to be published at all, and the publication is undertaken without delay. Maybe it is just coincidence that drug companies frequently delay publishing data that would hurt them financially, or perhaps it has to do with the biases of research journals, but it is striking that they achieve desired results at a higher rate than researchers without these interests. So just as it is in a manufacturer's interests to have studies come out a certain way, and they do tend to come out that way in research publications, so too might we expect that a for-profit IRB will make oversight decisions that are in the IRB's financial interest at a higher rate than an uninterested IRB would make those decisions.

OIG issued a series of reports in the 1990s about the increasing use of free-standing IRBs, and found that there was a potential for cursory reviews by the IRB, as well as for IRB shopping by investigators. As a result of the study, the Government Accountability Office created a highly problematic sham study protocol that was submitted to three of these IRBs. One of the three approved the protocol unanimously and eventually was closed as a result of the investigation.

[Editors note: To this point, it is of note that in the past decade, most of the major independent IRBs have won accreditation of their programs from the Association for the Accreditation of Human Research Protection Programs, an organization of increasingly international scope, which Dr. Korn played an instrumental role in creating in 1999-2000.]

OIG also has concerns about so-called "head count compensation," which occurs when drug companies pay physicians a pre-determined fee for every patient enrolled in a research study. A better compensation arrangement is based on reimbursement of costs for the amount of time and effort a physician spends enrolling subjects rather than per capita payments for successfully

convincing patients to become study subjects. OIG also looks for "seeding trials" and other marketing schemes masquerading as clinical research. Seeding trials occur when companies are close to securing marketing approval for a drug or device, but they nonetheless approach clinicians to participate in trials, the real goal of which are to familiarize the clinician with the product so he or she will prescribe it when it comes to market. Often companies' marketing departments run these trials, and the data collected are either not reviewed or destroyed.

Taitsman said many people believe it is safer to give money to an institution than to an individual, but she provided two examples that make one wonder if this is true. First, many institutions allow pharmaceutical companies and device companies to pay travel expenses directly to the institution for residents and fellows to attend conferences. Second, industry often sponsors endowed chairs at medical schools. In this case, not only does the physician-professor receive money, but also prestige from the endowed professorship. In both examples, there is a large kick-back risk to the institution, whose faculty clinicians may control formulary decisions for drugs and decide what medical devices are available in affiliated hospitals. In some cases, particularly at very prestigious institutions, these decisions could also influence practice guidelines or patterns at other facilities.

Another area that concerns OIG is industry funding for continuing medical education (CME). Taitsman noted that there is an emerging trend for medical schools and major teaching hospitals to move away from industry funding. A recent (2008) Senate Finance Committee report identified potential vulnerabilities when the pharmaceutical industry funds CME or clinical practice guideline development. Some stakeholders responded to that report by deciding that only medical schools, teaching hospitals, academic medical centers, and universities should be allowed to run CME programs sponsored by industry. OIG's Chief Counsel and Chief Medical Officer published a New England Journal of Medicine Sounding Board article highlighting the potential kick-back risk of this recommendation, pointing out potential financial conflicts of interest when institutions accept industry funding for education. There are trends in the private sector where CME sponsors are awarding multi-year institutional grants and distancing sponsors from CME programs. Taitsman said she would like to see limits on industry's educational control through creating pooled funding mechanisms similar to a model currently

VI. INSTITUTIONAL CONFLICTS OF INTEREST IN AWARDEE INSTITUTIONS *cont'd*

used in patient assistance programs, activity level accreditation so only useful programs are approved, and ultimately the elimination of industry funding.

OIG may review financial conflicts of interest in companies that publish the drug compendia that influence whether Medicare and Medicaid will pay for a drug.

In closing, Taitsman acknowledged that hospitals and research institutions fear OIG, and she hopes to improve communications and establish partnerships with them through education. Further, OIG has an advisory opinion process that allows some business arrangements that have a risk of presenting fCOIs to nonetheless be approved if that risk is outweighed by a real potential benefit.⁶

⁶ Audience discussion points following this presentation were integrated into the summaries above, as they clarified topics discussed by Rockey and Taitsman.

VII. CONCLUDING SESSION

**Lawrence Bacow, J.D., M.P.P., Ph.D., President emeritus,
Tufts University (Rapporteur)**

Dr. Bacow opened the discussion by revisiting the origins of the American research university and the early conversations about its mission. Deliberations about mission are at the heart of debates about conflicts of interest. At one end of the spectrum is the view that universities should support the paradigm of the detached scholar pursuing knowledge for its own sake. A more progressive view envisions an engaged university, one that is generating knowledge that can benefit the public. These two views are sometimes competing, but it is clear that we cannot return to the ideal of Plato's Academy. Rather, we have to learn how to manage conflicts going forward.

In some ways the research university is a victim of its own success—as it has produced innovation and invention, more is expected of it. Thus, the external boundaries are growing more porous. Ironically, the internal boundaries remain rigid, and so universities have had to create new structures to force the partnerships needed across disciplines to respond to external demands.

Bacow said that we now take for granted changes in mission that at one time were seen as revolutionary. Thus, we need to confront the responsibilities of faculty to their institutions. Traditionally, a certain portion of their time is theirs to use as they wish, within certain limitations set by the university. However, there are growing opportunities for faculty to capitalize on their time and expertise, which can raise questions about conflicts of commitment, jealousy among faculty, and ownership of materials and ideas produced during that personal time.

During his tenure as Tufts University President, Bacow said he spent a great deal of time puzzling over the opportunities posed by new resources in the form of grants, contracts, and gifts, and the complexities and contingencies that nearly always are attached. The job of university leadership is to manage these complexities. In addition, institutions must manage conflicts in their own ways, reflecting their unique missions and cultures. He suggested that these are not problems necessarily amenable to solutions but rather conditions that need to be managed, in perpetuity. Institutions will differ in how they do so.

Rawlings suggested there might be value in gathering university leadership to review these issues, and develop principles that are grounded in research. Identifying the complexities could help spotlight best practices. Participants added that it would be useful to review existing policies to identify themes and principles and to seek data from institutional research offices.

Marks encouraged review of the systemic influences that result from university-industry relationships. There will be times when the public interest is aligned with private interests. In those cases, incentives and interests can be aligned for the public good. However, when interests are not aligned, questions that should be answered in the public interest might not be taken up because there are no funding streams to support such inquiries. He encouraged ongoing efforts to identify such areas of research, as they might reveal where conflicts in the research agenda could be detrimental to the public good.

Marks said that one way for institutions to manage conflicts is to consider whether accepting funds from one source will create an imbalance in perspective, that is, is there another side of the question that is not being funded? This led to a discussion of whose responsibility it is to identify and fill those gaps. Bok suggested it was not the job of the university or individual researcher to fill those gaps—that is more a responsibility of funding agencies. In fact, many funders engage in exercises to identify research needs that call out for public funding because other sources are not available.

Cole said that there are times when searching for the truth and solving practical problems can be fully aligned, for example, the work of Pasteur. He also said that we need to better understand revealed preferences, that is, how well do we understand policy-makers' or the public's commitment to the research university? A further concern is the tendency to over regulate the university, which can abridge academic freedoms.

Rockey said that there are efforts underway to reform some of the regulations applicable to human subjects research. However, she added, government officials are being asked to reduce regulatory burden at the same time they are held to higher expectations regarding oversight. There is always a concern about creating new burdens without attendant benefits.

VII. CONCLUDING SESSION *cont'd*

Rawlings asked Fisher to outline how one might approach a study of these issues. Fisher said the first step would be to identify the common ground—that is, what types of conflicts exist, and how have individuals and institutions responded to them? The next step would be to survey and evaluate how institutions have dealt with these issues and convene a group to articulate default principles that might have potentially broad appeal. Finally, a process should be identified to seek consultations and guidance from a larger body. Fisher continued that the principles might include: 1) a default condition of transparency in revealing financial contributions, including the terms and conditions of contracts and gifts; 2) a general prohibition against limits on publication as a condition of an award or gift; and 3) a policy that donors or funders hold no control over the findings or results of the research venture. While exceptions can be found for each of these, these principles would be the default against which exceptions must be justified. A member of the audience noted that transparency alone might not be sufficient—it must be put in context, not just posted without explanation. Another audience member said that it can be difficult for the public to determine the sources of research funding at universities.

There was general support for such an approach as a first step to preserve the core of the research university against the backdrop of conflicts of interest.

Korn noted that while many universities take these issues seriously, some appear either not to have policies or not to enforce them, which leads to highly publicized scandals, often in industry-funded drug studies. In addition, universities with abundant resources might be more stringent in enforcing their rules than universities more “hungry” for funds. For these reasons, it would be useful to gather a community of diverse universities to identify, at the very least, best practices.

Rockey said that the system for overseeing individual fCOIs relies on self-reporting. Conflicts that are reported have to be posted. However, oversight bodies can only go so far. Bad actors will find ways around any set of rules, and it is not wise to regulate around the exception. She noted that we do not have a solid research base for understanding what influences or biases people. Thus, it is difficult to know exactly where to draw the lines. Cole added that institutional conflicts of interest are one subset of deviant behavior. The literature on individual deviant behavior points to

competition, monetary gain, and reputations as motivators. At the institutional level, a lack of a culture of integrity can create pressures to commit deviance, including the means by which to do so. He added that the vast majority of individuals and institutions follow the rules, a fact that the public might not appreciate.

Bacow closed the session by thanking the speakers and audience members for their participation, and Dr. Korn for his efforts in planning and coordinating the day.

VIII. SOME REFLECTIONS ON THE DAY

Professor David Korn

A series of public policies, starting with the Morrill Act of 1862, have created greater expectations of research universities beyond their historical missions of educating, conducting research in pursuit of truth, and serving the public as arbitrators of “truth” itself. Particularly since World War II, universities increasingly are recognized as founts of ingenuity and innovation that produce tangible benefits to society. Efforts to accelerate the transfer of science and technology were spurred by the Bayh–Dole Act and the Patent and Trademark Law Amendments Act dealing with intellectual property arising from federally-funded research. Most recently, in signing the Patent Reform Act of 2011, President Obama asserted that research universities are pivotal to job creation and the nation’s economic recovery. Collaborating with industry and receiving industry funds for research have been a critical aspect of meeting these expectations.

Current economic and social conditions have further exacerbated pressures on universities from elected officials, taxpayers, and industry leaders to engage with industry, often in well-intentioned hope that these engagements will create jobs. Universities face steadily intensifying pressure to increase efficiency and return on investment as state education budgets are cut, and public and political irritation grows from what is perceived as uncontrolled and unsustainable growth in tuition costs. Pressures increase on university presidents to perform according to corporate measures of success. These trends have the potential to convert education into a business and students into consumers.

As research universities have responded to these multiple demands by expanding their research programs and actively seeking collaborations with private sector partners, they have become victim to their own success. As they have produced more innovation and invention, more is expected of them.

Relationships with outside funders and collaborators, while often productive, can also create conflicts of interest for the individuals and institutions involved. Such conflicts can adversely affect the educational environment, the validity or credibility of research results, or the overall integrity and reputation of the institution. They can undercut the mission of the university to seek truths, question “facts,” freely and openly communicate ideas and knowledge, be open to the pursuit of all research ques-

tions, and retain neutrality. Yet, all the panelists at this symposium agreed that there is no going back; the expectations, pressures, and trends that create the potential for conflicts are here to stay and are likely to increase over time. As the then-Vice President of Research at MIT stated, “I deal with conflicts of interest every day,” and as the Tufts University President-emeritus stated, “these are not problems necessarily amenable to solutions but rather conditions that need to be managed, in perpetuity. Institutions will differ in how they do so.”

Several speakers noted that conflicts of interest are not limited to the research environment. They can arise, for example, from over-commercialization and over-valuation of university athletic programs, from executive education programs, alumni cruises, patent licensing policies, campuses abroad, extension schools, online education, internal subsidies, and fundraising. In each of these areas, history shows that university officials and faculty sometimes have sacrificed academic values in their relentless pursuit of revenues.

Participants agreed that society trusts universities to the extent that the institutions are trustworthy, that is, remain committed to core values of objectivity, integrity, credibility, authenticity, and to their vital service to the public as “independent arbiters of knowledge.” The university accomplishes its mission through the education of students, the pursuit and dissemination of knowledge, and varying degrees of economic engagement with industry. In all these activities the university must consistently uphold its side of the social contract; it must maintain its integrity and, as Professor William Fisher put it, “its capacity for attestation.”

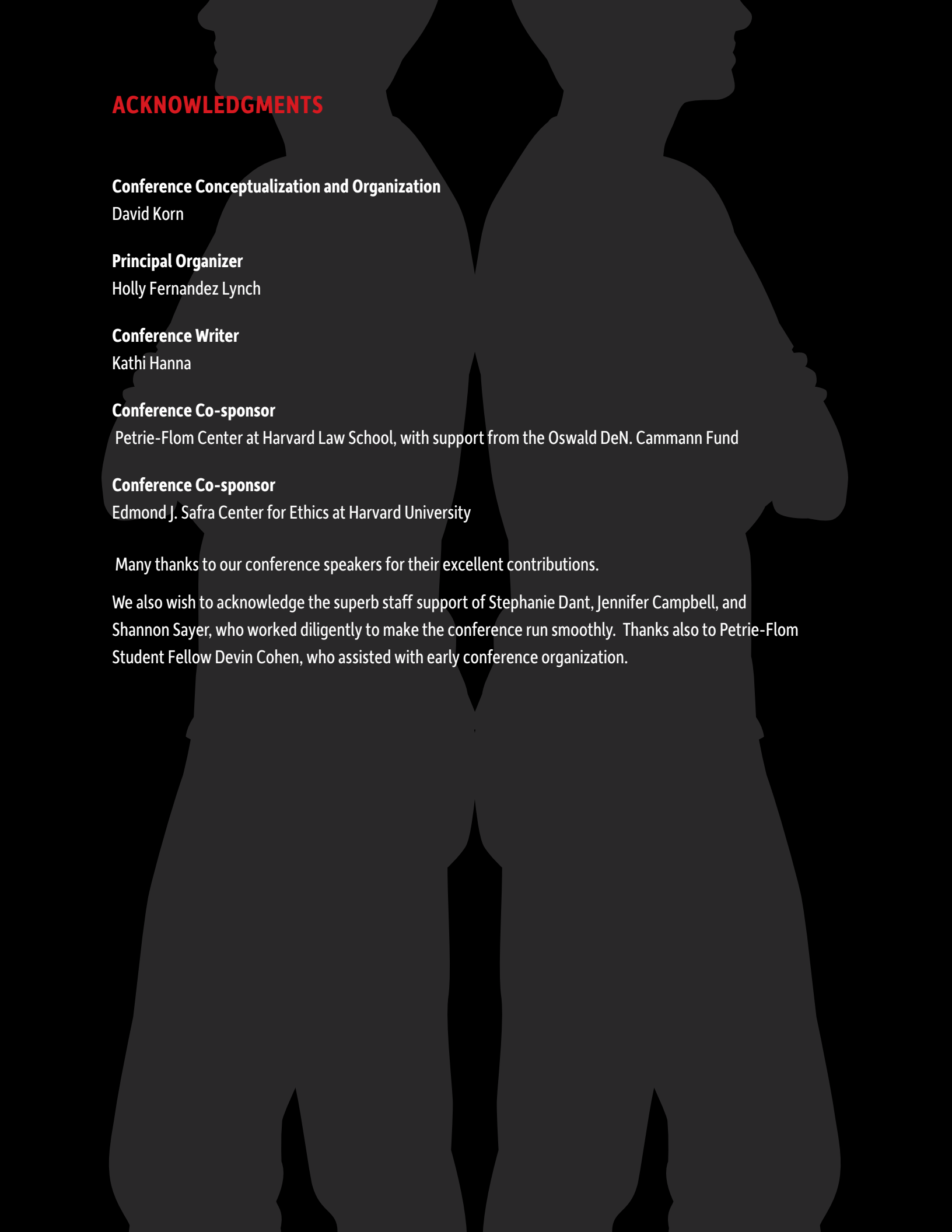
Participants agreed that laying the burden of oversight on Boards of Regents or Trustees is not an optimal solution, as Board members themselves are often conflicted. Neither are new state or federal regulations the answer.

There was broad agreement that the university exists in the context of society, and to the extent that it can serve the public good through business ventures or revenue-generating measures, it should pursue those activities. However, the job of university leadership is to manage these complexities in ways that best reflect and protect their institutions’ unique missions and cultures. Common guidance and basic principles would assist in achieving that goal.

VII. SOME REFLECTIONS ON THE DAY *cont'd*

At the end of the day, there appeared to be an implicit consensus among the speakers that what is necessary to protect research universities is not so much more policies but rather university leaders, officers, and faculty committed to creating, protecting, and promulgating to all members of the university community a culture of integrity centered on core values of autonomy, objectivity, what Professor Jonathan Cole describes as “organized skepticism,” and the resolute protection of academic freedoms. This must begin with a clear articulation of these values, and their relentless protection by the institutions’ leadership. The instantiation of a culture of integrity is abetted by developing a set of institutional basic principles that flow from its core missions and values, and from these principles policies can then be adopted and adapted as necessary to meet the needs of the different professional schools and major administrative functions.

Two final comments: First, in our rapidly changing culture, ever-expanding information technologies and the world wide web enable not only the discovery of information and data, but the dissemination of opinions and assertions on any and every topic imaginable without any assurance or certification of credibility or reliability – what some have referred to as “unjuried information.” This capability makes it more essential than ever that research universities protect their independence, objectivity, and credibility – their ability to continue to serve the public as “independent arbiters of knowledge.” Second, I would posit that many of the scandals involving research universities in recent years have resulted from the failure of institutional leadership, in their pursuit of revenues, prestige, improved academic and athletic rankings, and such, to protect the institutions’ integrity and their academic freedoms from infringement and corruption.

A background image showing the dark silhouettes of three people standing and facing each other in conversation. The person on the left is partially visible, the person in the center is more prominent, and the person on the right is also partially visible. They appear to be in a professional or academic setting.

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