

AAUP Recommended Principles & Practices to Guide Academy-Industry Relationships

Purpose: To sustain and protect academic freedom, academic professionalism, research integrity and public trust

**Dedicated to the memory of Victor J. Stone (AAUP President 1982-1984),
University of Illinois College of Law**

“To impart the results of their own and their fellow specialists’ investigations and reflection, both to students and to the general public, without fear or favor . . . requires (among other things) that the university teacher shall be exempt from any pecuniary motive or inducement to hold, or to express, any conclusion which is not the genuine and uncolored product of his own study or that of fellow specialists. Indeed, the proper fulfillment of the work of the professoriate requires that our universities shall be so free that no fair-minded person shall find any excuse for even a suspicion that the utterances of university teachers are shaped or restricted by the judgment, not of professional scholars, but of inexpert and possibly not wholly disinterested persons outside of their own ranks. . . . To the degree that professional scholars, in the formation and promulgation of their opinions, are, or by the character of their tenure appear to be, subject to any motive other than their own scientific conscience and a desire for the respect of their fellow experts, to that degree the university teaching profession is corrupted; its proper influence upon public opinion is diminished, and vitiated; and society at large fails to get from its scholars, in an unadulterated form, the peculiar and necessary service which it is the office of the professional scholar to furnish.” “1915 Declaration of Principles on Academic Freedom and Academic Tenure,” *AAUP Policy Documents and Reports*, Tenth Edition (Washington, DC: AAUP, 2006), pp. 294-95.

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Preface

The American Association of University Professors (AAUP) hereby issues this comprehensive report, “Recommended Principles and Practices to Guide Academy-Industry Relationships,” for public comment. Responses may be directed to Greg Scholtz, director of the AAUP’s Department of Academic Freedom, Tenure, and Governance (gscholtz@aaup.org). After a review of the comments received, the report will be revised as appropriate and published in a paperbound edition.

Work on this project has been funded by a bequest from the estate of Victor J. Stone, a professor in the College of Law at the University of Illinois at Urbana–Champaign who served as AAUP general counsel and from 1982 until 1984 as AAUP president, and by grants from the Open Society Foundations, the AAUP’s Academic Freedom Fund, and the Canadian Association of University Teachers (CAUT). Publication of the report is being supported by grants from a number of AAUP chapters and state conferences, a complete list of which will be published with the book.

This is one of the longest reports the AAUP has ever produced. It deals with issues that make the news weekly and that critically impact higher education in the United States and across the world. The days when industry-funded research was concentrated in a limited number of universities have passed. Every type and size of institution now faces both the opportunities and the responsibilities associated with businesses-sponsored research relationships.

The report opens with a summary of recommendations for principles that colleges and universities should adopt, as appropriate, in their governing and advisory documents and in their contracts with outside funders. The main body of the report follows, beginning with an overview of the history and current state of engagement between industry and the academy. The balance of the report details each of fifty-six recommendations and guidelines, offering not only rationales for them, but also documentation and qualifications. Those involved in reviewing, adopting, and implementing the recommendations should benefit from this more detailed information contained in the main report. Appendix A summarizes the sources for each of these 56 recommended principles, and notes which are closely drawn from previous recommendations issued by the AAUP and other professional associations, and which are new or adapted from other sources.

The report urges giving faculty governing bodies greater authority over the principles and standards regulating outside funding, and over the disposition of inventions derived from faculty research, but the report is by no means exclusively an assertion of faculty rights. It specifies—and emphasizes—the responsibilities that must come with outside funding, including public disclosure of all financial conflicts of interest. Not all will readily embrace these responsibilities, but the time has surely come when every institution needs to debate and consider them.

This report began with a 2010 decision by Committee A on Academic Freedom and Tenure to examine the issue. A small group met early in 2011 to draft a set of sample recommendations. The resulting discussion helped reveal the scope and challenges of the project. Jennifer Washburn, an investigative journalist familiar with the relevant literature, was invited to help prepare a full report in collaboration with the AAUP president. Valuable advice came from Ernst Benjamin, former AAUP General Secretary, and from AAUP’s Department of Academic Freedom, Tenure, and Shared Governance. A draft was then sent for review and comment to three AAUP standing committees (Academic Freedom and Tenure, College and University

Governance, and Professional Ethics—chaired, respectively, by David Rabban, Larry Gerber, and Debra Nails) and to numerous knowledgeable faculty members, administrators, and professionals. A substantial packet of responses included comments from Marcia Angell (Medicine, Harvard University), Gerald Barnett (Research Technologies Enterprise Initiative), Eric Campbell (Medicine, Harvard University), Michael Davis (Philosophy, Illinois Institute of Technology), John R. Fuisz (The Fuisz-Kundu Group LLP), Larry Gerber (History, Auburn University), Gregory Girolami (Chemistry, University of Illinois at Urbana-Champaign), Stanton A. Glantz (Medicine, University of California at San Francisco), Claire Katz (Philosophy, Texas A&M University), Jonathan Knight (former head of the AAUP Department of Academic Freedom, Tenure, and Shared Governance), Sheldon Krinsky (Urban and Environmental Policy, Tufts University), Russ Lea (Vice President for Research, University of South Alabama), Risa Lieberwitz (Labor and Employment Law, Cornell University), Gerald Markowitz (Public Health and American Social History, John Jay College of Justice), Debra Nails (Philosophy, Michigan State University), Richard Nelson (International Political Economy, Columbia University), Christopher Newfield (English, UC-Santa Barbara), David Rosner (History and Public Health, Columbia University), Donald Stein (Medicine, Emory University), and Stephen Wing (Epidemiology, North Carolina State University). Washburn and Nelson incorporated the responses as appropriate into a revised draft for the standing committees to review. The consultant readers are not, of course, responsible for the final recommendations, and providing their names here does not imply their endorsement of all of them, but thanks go to them for their serious, detailed, and immensely helpful engagement with the text.

Jim Turk, the Executive Director of the Canadian Association of University Teachers, participates in meetings of the AAUP's Committee A on Academic Freedom and Tenure. CAUT is issuing a much condensed (and adapted) version of our recommendations at about the same time as we place our full report online for comment. Faculty in other countries may find them useful as well.

Finally, with a project of this scope, we welcome the opportunity to recognize the critical help we have had from the AAUP's national staff. Greg Scholtz helped us manage the approval process and our requests from the Academic Freedom Fund. Bob Kreiser's wide knowledge of AAUP history gave us timely access to key documents. Mike Ferguson found copy editors and managed their work, while also providing cost estimates for the project. Ezra Deutsch-Feldman shepherded us through the complexities of handling such a long document. And we could never have managed this massive enterprise without Martin Snyder's flawless political and practical wisdom at every stage of the process.

Cary Nelson
AAUP President, 2006-2012

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APPENDIX A. The Origins of the AAUP Recommendations: A Summary of Which Recommendations Are New or Adapted or Closely Derived From Other Professional Academic Groups’ Recommendations

Glossary of Acronyms and Abbreviations

AAMC—Association of Academic Medical Centers
AAMC—Association of American Medical Colleges
AAU—American Association of Universities
AAUP—American Association of University Professors
ABIM—American Board of Internal Medicine
ABL—Advanced Biological Laboratory
ACE—American Council on Education
ACCME—Accreditation Council for Continuing Medical Education
ACP—American College of Physicians
ADAMHA—Alcohol, Drug Abuse, and Mental Health Administration
AGB—Association of Governing Boards
AIDS—Acquired Immune Deficiency Syndrome
AIR—Academy-Industry Relationship
AMSA—American Medical Student Association
APA—American Psychiatric Association
ASIM—American Society of Internal Medicine
ATS—American Thoracic Society
AUTM—Association of University Technology Managers
BB&T—Branch Banking and Trust
BBC—British Broadcasting Corporation
BD—Bayh-Dole Act
BIP—Background Intellectual Property
BMJ—(British Medical Journal)
CAUT—Canadian Association of University Professors
CDC—Centers for Disease Control
CFR—Code of Federal Regulations
CHE—Chronicle of Higher Education
CME—Continuing Medical Education
CML---chronic myelogenous leukemia
COGR—Council on Government Relations
COI—Conflict of Interest
CRADA—Cooperative Research and Development Agreement
DHHS—Department of Health and Human Services
DOD—Department of Defense
DOE—Department of Energy
DOJ—Department of Justice
DSM—Diagnostic and Statistical Manual of Mental Disorders
DSMB—Data Safety Monitoring Board
EBI—Energy Biosciences Institute
EPA—Environmental Protection Agency
EPRI—Electric Power Research Institute
ERTA—Economic Recovery Tax Act

ETS—Environmental Tobacco Smoke
FASEB—Federation of American Societies for Experimental Biology
FCOI—Financial Conflict of Interest
FDA—Food and Drug Administration
FFEL—Federal Family Education Loan
FRP—Request for Proposals
FSU—Florida State University
FTE—Full-time Faculty Equivalent
GAO—General Accounting Office
GAO—Government Accountability Office
GM—genetically modified
GSK--GlaxoSmithKline
HIV—Human Immunodeficiency Virus
IBM—International Business Machine
ICMJE—International Committee of Medical Journal Editors
IMAP—Institute of Medicine as a Profession
IND—Investigational New Drug
IOM—Institute of Medicine
IP—Intellectual Property
IRB—Institutional Review Board
IT—Information Technology
JAMA—Journal of the American Medical Association
MCV—Medical College of Virginia
MIT—Massachusetts Institute of Technology
MOU—Memorandum of Understanding
MTA—Material Transfer Agreement
NACDA—National Advisory Council on Drug Abuse
NADI—Novartis Agricultural Discovery Institute
NAS—National Academy of Sciences
NEJM—New England Journal of Medicine
NIDA—National Institute on Drug Abuse
NIH—National Institutes of Health
NRC—National Research Council
NRDA—Natural Resource Damage Assessment
NSAID—Nonsteroidal Anti-Inflammatory Drug
NSB—National Science Board
NSF—National Science Foundation
NYT—New York Times
NYU—New York University
OIG—Office of the Inspector General
OTT—Office of Technology Transfer
P&G—Proctor and Gamble
PEAC—President’s Engineering Advisory Council
PHS—Public Health Service
R&D—Research and Development
RFP—Faculty Research Proposal

RICO—Racketeer Influenced and Corrupt Organizations Act
RIN—Research Information Network
RIRs—Recommended Institutional Regulations
SCR—Semiconductor Research Corporation
SBU—Sensitive But Unclassified
SCA—Strategic Corporate Alliance
SPLC—Student Press Law Center
SSRI—Selective Serotonin Reuptake Inhibitor
TIRC—Tobacco Industry Research Committee
UCB—University of California at Berkeley
UCB-N—University of California at Berkeley-Novartis
UCLA—University of California at Los Angeles
UCSF—University of California at San Francisco
UIDP—University-Industry Demonstration Partnership
UIRC—University-Industry Research Center
UN—United Nations
US—United States
VCU—Virginia Commonwealth University
WAME—World Association of Medical Editors
WHO—World Health Organization

SUMMARY OF RECOMMENDATIONS

AAUP Principles & Practices to Guide Academic-Industry Relationships

The AAUP has drafted these principles and standards to encourage universities and faculties to adopt stronger, more comprehensive standards to guide sponsored research on campus and to more effectively manage individual and institutional financial conflicts of interest. In issuing these recommendations, the AAUP seeks to ensure the standards and practices are more consistently applied across the university as a whole. In total, the report contains 56 recommended principles. A majority (35) of these 56 Principles are closely drawn from previous statements issued by the American Association of University Professors (AAUP) and/or by other prominent academic societies and associations; the remainder are adapted from other sources, or are new recommendations. Appendix A identifies which recommendations fall into each category, along with sources.

The AAUP seeks to promote deeper awareness of how these commercial relationships—though often highly beneficial—may have far-reaching impacts on the university, its mission, its constituents (students, colleagues, patients, the public), and on the academic profession (in areas ranging from research integrity and research reliability to knowledge sharing, public health, and public trust). Although the report focuses primarily on academic-industry relationships, it addresses government- and nonprofit-sponsored research when related and appropriate. We recognize, for example, that some nonprofits receive substantial industry funding and can mask industry's role in selecting and even managing individual academic projects.

To be effective, academic senates or comparable faculty governing bodies will need to review and adapt these principles and standards, as appropriate, and will have to recommend their adoption in faculty handbooks, university policy statements, faculty guidelines, or collective bargaining contracts. Because students, graduate assistants, postdoctoral fellows, and academic professionals often work on sponsored research, the report addresses their working conditions in addition to faculty's. Faculty governing bodies will benefit from working closely with knowledgeable administrators, many of whom will be equally interested in adopting clear campus guidelines.

Contents: The 56 AAUP Principles, summarized below, include: GENERAL PRINCIPLES (these are principles that may be applied university-wide; they cover core academic norms and standards, such as authenticity of authorship, publication rights, and academic autonomy; they also address broad areas of academic-industry engagement, such as student education and training, financial conflicts of interest, and intellectual property management), and TARGETED PRINCIPLES (these are principles that address specific types of academic-industry engagement, including strategic corporate alliances (SCAs), industry-sponsored clinical trials, and academic-industry interactions at academic medical centers). For a more in-depth discussion of each of these 56 Principles, along with a discussion of related background issues and documentation, please see the main report.

Many of the Principles that the AAUP recommends in this report apply to the university generally, not just to corporate-sponsored research. Thus every faculty handbook should incorporate Principles 1, 2, 10, and 11-13. Principles 9 and 10, dealing, respectively, with impartial academic evaluation and with the necessity for fair grievance procedures, should guide all academic conduct. At many institutions, adoption of Principles 11-13—which should cover all IP, not just IP generated by industry sponsored research—would represent a significant change in recent campus culture. As campus administrations become increasingly interested in claiming the rights to faculty IP, the benefit of installing these principles in faculty handbooks and collective bargaining contracts is clear. Given that sponsored research and paid consultancies increasingly occur at all types of academic institutions, reviewing each institution’s existing conflict of interest (COI) policy statement—or establishing one, if none exists—should be a high priority. Principles 4, 7, and 22-31 identify concepts we believe every campus COI policy should include. Principles 3 and 11-21 relate to the management of campus-generated intellectual property (IP) and should be included in all university contracts for funded research. Principles 37-47 are salient for institutions that already have, or contemplate establishing, large-scale, multi-year research partnerships known as strategic corporate alliances (SCAs). Similarly, Principles 32-35 and 49-56 are of primary interest to institutions with faculty members or academic units engaged in medical research.

In putting forth the 56 Principles that follow, the AAUP encountered inevitable tensions between the ideal conditions we would like to promote and the realities of contemporary academic-industry relations. The AAUP sometimes states a principle first in more ideal terms and then offers qualifications, recognizing the partial compromises that may be necessary. Some faculty, academic senates, administrators, and universities will inevitably want to strengthen certain of these Principles, while others may wish to weaken them or make other adaptations. The AAUP seeks to strike a realistic balance in proposing these 56 Principles to guide academy-industry relationships, one that can stand the test of changing conditions. The primary value of these principles is to reaffirm the universities’ core academic and public missions, uphold professional academic and research standards, and influence contract relationships yet to be written or up for renewal.

Explanatory notes corresponding to the symbols ①-④ appearing in the text below may be found at the end of this Summary of Recommendations.

PART I—GENERAL PRINCIPLES & STANDARDS TO GUIDE ACADEMY-INDUSTRY ENGAGEMENT

PRINCIPLE 1—Faculty Governance: The university must preserve the primacy of shared academic governance in the planning, development, implementation, monitoring, and post-hoc assessment of all donor agreements and collaborations, including those with private industry, government, and nonprofit groups.

PRINCIPLE 2—Academic Freedom, Autonomy, and Control: The university must preserve its academic autonomy—including the academic freedom rights of faculty, students, postdoctoral fellows, and academic professionals—in all its relationships with industry and other funding sources by maintaining majority academic control over joint academy-industry committees and exclusive academic control over core academic functions (such as faculty research evaluations,

faculty hiring and promotion decisions, classroom teaching, curriculum development, and course content).

PRINCIPLE 3—Academic Publication Rights: Academic publication rights must be fully protected, with only limited delays (a maximum of 30-60 days[Ⓐ]) to remove corporate proprietary information, confidential information, and/or to file for patents prior to publication. Sponsor efforts to obstruct, and/or sponsored research agreements that do not permit, the free, timely, and open dissemination of research data, codes, reagents, methods, and results are unacceptable. Sponsor attempts to compel a faculty member, student, postdoctoral fellow, or academic professional to edit, revise, withhold, or delete contents in an academic publication (including a master’s thesis or PhD dissertation) or presentation (beyond these legally justified claims to protect explicit trade secrets) must be clearly prohibited in all written sponsored research contracts and in written university policies. A funder is of course free to make editorial suggestions, but the researcher must be free at all times to accept or reject them.

PRINCIPLE 4—The Authenticity of Academic Authorship: To protect the authenticity of academic publishing, universities and their affiliated academic medical centers should prohibit faculty, students, postdoctoral fellows, medical residents, and other academic professionals from engaging in practices variously described as industry-led “ghostwriting” or “ghost authorship.” Ghostwriting occurs when private firms or industry groups publish journal articles supporting commercial interests without publicly disclosing that the company initiated and often performed the initial drafting of the articles and recruited and/or paid university professors (sometimes referred to as “academic opinion leaders”) or others to sign on as nominal “authors.” Although ghostwriting has been especially widespread in academic medicine, prohibitions on ghostwriting should be applied university wide and should cover all faculty and researchers because the practice violates scholarly standards and is unacceptable in any academic setting.

PRINCIPLE 5—Access to Complete Study Data and Independent Academic Analysis: University codes of conduct should prohibit faculty and others from participating in sponsored research that restricts investigators’ ability to access the “complete study data”[Ⓑ] related to their sponsored research and/or that limits investigators’ ability to conduct unfettered, free, and independent analyses of complete data to verify the accuracy and validity of final reported results. All universities should also secure these basic academic freedom rights within the legal terms of all sponsored research contracts.

PRINCIPLE 6—Confidential and Classified Research: Classified research, as well as confidential corporate, government, or nonprofit research that may not be published, is inappropriate on a university campus and should not be permitted. Many institutions currently have written policies that ban “classified” government research on campus; the bans should be reviewed to ensure that they also clearly cover confidential corporate research. Universities employ a variety of mechanisms for moving confidential and classified research off campus, sometimes using governing structures less subject to academic oversight. Sorting through multiple categories of “national security,” “classified,” and “sensitive but unclassified” (SBU) information requires special monitoring by faculty governing bodies. These faculty bodies should presume that research results are always made freely available, absent a compelling case

to the contrary, to determine which research will be confidential and thus cannot be performed on campus. As historical precedent suggests, the special circumstances of a formal congressional declaration of war against specified nation-states may justify exceptions to the policies for the duration of the conflict.

PRINCIPLE 7—Academic Consulting: To address the potential for conflicts of commitment* and other financial conflicts of interest, all consulting contracts worth \$5,000 or more a year should be reported to and reviewed and managed by the university’s standing conflict of interest committee(s), charged with addressing both individual and institutional conflicts of interest (see Principle 24, below, for more discussion of these committees). Neither faculty nor administrators should sign a consulting contract that undercuts their professional ability to publicly express their own independent expert opinions, except when consulting with industry, government, or other parties on explicitly classified or proprietary matters. All such consulting agreements should be secured in writing.

A “conflict of commitment” arises whenever a faculty’s or administrator’s outside consulting and other activities have the potential to interfere with their primary duties, including teaching, research, time with students, or other service and administrative obligations to the university.

PART II—GENERAL PRINCIPLES TO GUIDE STUDENT EDUCATION AND TRAINING

PRINCIPLE 8—Recruiting and Advising Graduate Students, Medical Residents, and Faculty: The admission of graduate students to degree programs and the appointment of medical residents and faculty should not be based on their potential to work under a particular donor agreement or a particular collaborative research alliance, whether commercial, governmental, or nonprofit. A PhD student’s main advisor should not have any significant© financial interests, including equity, in a company that is funding or stands to profit from the research. Exceptions should evaluate both conflicts of interest and potential conflicts of commitment, all of which should be disclosed orally and in writing to all affected parties and periodically reviewed by an appropriate faculty body.

PRINCIPLE 9—Impartial Academic Evaluation: Students, postdoctoral fellows, academic professionals, and junior colleagues should always be entitled to impartial and fair evaluations of their academic performance. Because of the risk of both real and perceived bias, faculty members with a significant© personal financial interest in the outcome of their students’ research should not have sole responsibility for evaluating student progress toward a degree.

PRINCIPLE 10—Grievance Procedures: Universities should establish effective, well-publicized grievance procedures for all students, postdoctoral fellows, academic professionals, and faculty, tenured and untenured, so they may freely and safely report obstacles encountered while pursuing their educational objectives. Obstacles may include, but are not limited to, inappropriate commercial or other sponsor influence over the conduct of research and/or research analysis, unwarranted delays to degree completion, financial conflicts of interest, conflicts of

commitment, and conflicts over ownership of intellectual property. Faculty with financial conflicts related to a grievance filing should recuse themselves from its adjudication in formal proceedings. Informal resolution of grievances, when possible, is often preferable.

PART III—GENERAL PRINCIPLES TO GUIDE MANAGEMENT OF INTELLECTUAL PROPERTY (IP)

PRINCIPLE 11—Faculty Inventor Rights and IP Management: Faculty members’ fundamental rights to direct and control their own research do not terminate when they make a new invention or other research discovery; these rights properly extend to decisions involving invention management, intellectual property (IP), licensing, commercialization, dissemination, and public use. As such, faculty inventor “assignment” of an invention to a management agent,* including the university that hosted the underlying research, should be voluntary and negotiated, rather than mandatory, unless federal statutes or previous sponsored research agreements dictate otherwise. Faculty inventors and investigators retain a vital interest in the disposition of their research inventions and discoveries and should, therefore, retain rights to negotiate the terms of their disposition. The university, or its management agents, should not undertake intellectual property or legal actions directly or indirectly affecting a faculty member’s research, inventions, instruction, or public service without the faculty member’s and/or the inventor’s express consent.

**The term “invention management agent” covers all persons tasked with handling university generated inventions and related intellectual property, including, for example, university technology transfer offices, affiliated research foundations, contract invention management agents, and legal consultants.*

PRINCIPLE 12—Adjudicating Disputes Involving Faculty Inventor Rights: Just as the right to control research and instruction is integral to academic freedom, so too are faculty members’ rights to control the disposition of their research inventions. Inventions made in the context of university work are the results of scholarship. University policies should direct all invention management agents to represent and protect the expressed interests of faculty inventors, along with the interests of the institution and the broader public. Where the interests diverge insurmountably, the faculty senate, or an equivalent governing body, should adjudicate the dispute with the aim of selecting a course of action to promote the greatest benefit for the research in question, the broader academic community, and the public good.

PRINCIPLE 13—Shared Governance and the Management of University Inventions: Faculty have a collective interest in how university inventions derived from academic research are managed. Through shared governance, they also have a responsibility to participate in the design of university protocols that set the norms, standards, and expectations under which faculty discoveries and inventions will be distributed, licensed, and commercialized. The faculty senate, or an equivalent governing body, should play a primary role in defining the policies and public-interest commitments that will guide university-wide management of inventions and other knowledge assets stemming from campus-based research. These management protocols should devote special attention to the academic and public interest obligations covered in the AAUP Principles recommended here. They should also require the formation of a specially assigned

faculty committee to regularly review the university's invention management practices, ensure compliance with these Principles, represent the interests of faculty investigators and inventors to the campus as a whole, and make recommendations for reform when necessary.

PRINCIPLE 14—IP Management and Sponsored Research Agreements: In negotiating outside sponsored research agreements, university administrators should make every effort to inform potentially affected faculty researchers and to involve them meaningfully in early-stage negotiations concerning invention management and intellectual property. In the case of large-scale corporate sponsored research agreements like SCAs, which can impact large numbers of faculty, not all of whom may be identifiable in advance, a special faculty governance committee should be convened to participate in early-stage negotiations, represent collective faculty interests, and insure compliance with related university protocols. Faculty participation in all sponsored research agreements should always be voluntary.

PRINCIPLE 15—Humanitarian Licensing, Access to Medicines: In matters of IP and invention management, the university and its contracted agents should prohibit pursuit of institutional profits at the expense of the university's academic, research, and public interest missions. When lifesaving drugs and other critical public health technologies are developed in academic laboratories with public funding support, universities have a special obligation to license such inventions in a manner that will ensure broad public access in the developing as well as the industrialized world. Exclusive university licenses to companies for promising drugs or other critical agricultural, health, or environmental safety inventions should include provisions to enable distribution of drugs and other inventions in developing countries at affordable prices.

PRINCIPLE 16—Securing Broad Research Use and Distribution Rights: All contracts and agreements relating to university-generated inventions should include an express reservation of rights—often known as a “research exemption”—to allow for academic, nonprofit, and government use of academic inventions and associated intellectual property. Research exemptions should be reserved and well publicized prior to assignment or licensing so faculty and other academic researchers can share protected inventions and/or research results from sponsored projects (including related data, reagents, and research tools) with scientists located throughout the host university or at any other nonprofit or government institution. The freedom to share and practice academic discoveries, for educational and research purposes, whether patented or not, is vitally important for the advancement of research and scientific inquiry. It also enables investigators to replicate and verify published results, a practice essential to the academic enterprise and to the integrity of science.

PRINCIPLE 17—Exclusive and Nonexclusive Licensing: Universities, their contracted management agents, and faculty should avoid exclusive licensing of patentable inventions, unless such licenses are absolutely necessary to foster follow-on use of an invention or to spur investment in the development of an invention that would otherwise be incapable of realizing its public benefit. Exclusive or monopolistic control of academic knowledge should be used sparingly, rather than as a presumptive default. When exclusive licenses are granted, they should have limited terms (preferably less than eight years), include requirements that the inventions be developed, and prohibit “assert licensing,” sometimes referred to as “trolling.” Exclusive licenses made with the intention of permitting broad access through reasonable and nondiscriminatory

sublicensing, cross-licensing, and dedication of patents to an open standard may be expected to meet public access expectations. However, the preferred methods for disseminating university research are nonexclusive licensing and open dissemination, to protect universities' public interest mission, open research culture, and commitment to the advancement of research and inquiry through broad knowledge sharing. To enhance compliance and public accountability, universities should require all invention management agents to publicly and promptly report any exclusive licenses issued together with written statements detailing the necessity for the exclusive license and why a nonexclusive license would not suffice. The faculty senate, or a comparable governing body, should have the authority to periodically review exclusive licenses and corresponding statements for consistency with the principle.

PRINCIPLE 18—Upfront Exclusive Licensing Rights for Research Sponsors: Universities should refrain from signing sponsored research agreements, especially multi-year, large-scale strategic corporate alliance (SCA) agreements, granting sponsors broad title, or exclusive commercial rights, to future sponsored research inventions and discoveries unless such arrangements are narrowly defined and agreed to by all faculty participating in, or foreseeably affected by, the alliance. If this is infeasible, as in the case of larger SCAs, the faculty senate (or a comparable governing body) should review and approve the agreement and confirm its consistency with academic freedom, faculty independence, and the university's public interest missions. Special consideration should be given to the impact exclusive licenses could have on future, as-yet unimagined uses of technologies. When granted, exclusive rights should be defined as narrowly as possible, restricted to targeted "fields of use" only, and every effort should be made to safeguard against abuse of the exclusive position.

PRINCIPLE 19—Research Tools and Upstream Platform Research: Universities and their contracted invention management agents should make available and disseminate research tools and other upstream platform inventions (in which they have acquired an ownership interest) as broadly as possible. They should avoid assessing fees, beyond those necessary to cover the costs of maintaining the tools and disseminating them, and other constraints that could hamper downstream research and development. Relatedly, no sponsored research agreement should make contractual obligations that prevent outside investigators from accessing data, tools, inventions, and reports relating to scholarly review of published research, matters of public health and safety, environmental safety, and urgent public policy decisions.

PRINCIPLE 20—Diverse Licensing Models for Diverse University Inventions: Universities and their invention management agents should develop multiple licensing models for diverse categories of academic inventions, reflecting differing objectives and commitments made by faculty investigators and inventors, varying practices in the wider community and in different industries, and models appropriate for the conditions that present at different stages of the development of those specific technologies. Licensing models commonly used to address opportunities in biotechnology, for example, should not be established as defaults in institutional policies or used indiscriminately across other areas of innovation. Faculty investigators/inventors and their management agents should work cooperatively to identify effective licensing and/or distribution models for each invention with the goal of enhancing public availability and use. This may involve more established models (exclusive or nonexclusive licensing), or more emergent ones (patent pools, open sourcing, and public licensing, offered by institutions like

Creative Commons for copyright-based work).

PRINCIPLE 21—Rights to “Background Intellectual Property” (BIP): University administrators and their agents should not act unilaterally when granting sponsors rights to university managed background intellectual property (BIP) related to a sponsor’s proposed research area but developed without the sponsor’s funding support. Universities should be especially mindful of how BIP rights will affect faculty inventors and other investigators who are not party to the sponsored research agreement. University administrators and managers should not obligate the BIP work of one set of investigators to another’s sponsored-research project, unless that BIP is already being made available under nonexclusive licensing terms, or the affected faculty inventors and investigators have consented. To do otherwise would have a chilling effect on professorial collegiality and on the willingness of faculty to work with university licensing agents.

PART IV—GENERAL PRINCIPLES TO GUIDE MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST (COI)

A conflict of interest is broadly defined as a situation in which an individual or a corporate interest has a tendency to interfere with the proper exercise of judgment on another’s behalf. Those who prefer to distinguish between individual and institutional COI often define the former as a set of circumstances creating a risk that a secondary interest, such as financial gain, may unduly influence professional judgment or actions regarding a primary interest, such as research conduct, teaching, or patient welfare. Correspondingly, an institutional COI occurs when the financial interests of an institution or institutional officials, acting within their authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other governing activities of the institution. A growing body of empirical research has shown that financial conflicts of interest are associated with decision-making, as well as research, bias. (See the main report for details.) COI may also introduce unreliability into the research process, undermine public trust, and erode respect for institutions of higher education. Disclosure of a COI, even full disclosure with informed consent, fails to resolve or eliminate such biases and other problems.

PRINCIPLE 22—Comprehensive COI Policies: Every university should have a comprehensive, written COI policy, covering both individual and institutional COI (the terms are defined under Part IV above and discussed in greater detail in the main report). Universities should be explicit in their guidelines about how financial COI will be reported, reviewed, managed, and/or eliminated. The guidelines should also spell out how the university will enforce its COI policies. University policies should clearly delineate which financial conflicts of interest must be reported, which are prohibited, and what actions will be taken if faculty members do not comply with university COI disclosure and management policies. Actions may include: a faculty-led investigation leading to possible censure, federal-grant agency notification, a temporary hold on interactions with conflicted sponsors, or a temporary ban on receipt of outside research funding.

PRINCIPLE 23—Consistent COI Enforcement Across Campus: University COI policies must be adopted consistently across the whole institution, including at affiliated medical schools, hospitals, institutes, centers, etc., and they must apply to faculty, students, administrators, and academic professionals.

PRINCIPLE 24—Standing COI Committees: Every university should have one or two standing COI committees to oversee implementation of policies to address individual and institutional COI. At least one member should be recruited from outside the institution and approved by the faculty governing body. Members should be free of conflicts of interest related to their COI oversight functions. After faculty financial COI disclosure statements have been reviewed by an appropriate campus standing committee, they should be made available to the public, preferably on an easily accessible online database, as the AAUP recommends under Principle 27 below.

PRINCIPLE 25—Reporting Individual COI: Faculty members and academic professionals should be required to report to the standing campus COI committee all significant* outside financial interests relating directly or indirectly to their professional responsibilities (research, teaching, committee work, and other activities), including the dollar amounts involved and the nature of the services compensated—regardless of whether they believe their financial interests might reasonably affect their current or anticipated university activities. All administrators should report similar financial interests to both their superiors and the standing COI committee. Presidents and chancellors should report to the standing committee.

PRINCIPLE 26—University-Vendor Relationships and COI: Universities should ensure that vendor evaluation, selection, and contracting for university products and services are consistent with their academic mission and do not jeopardize the best interests of students. Vendors should never be persuaded or coerced into making financial contributions to the university, either through direct university donations or the recruitment of other contributing donors, in exchange for winning university contract bids. All university bidding for contracts and services related to such areas as banking and student loans should be conducted through a fair, impartial, and competitive selection process. Many universities currently have ethics policies banning gifts from vendors; the policies should also clearly prohibit institutions from accepting direct remuneration, or kickbacks, from vendors doing business with the university or its students. Direct profiteering can undermine public trust in the university and compromise the best interests of the students the university has pledged to serve.

PRINCIPLE 27—Inter-office Reporting and Tracking of Institutional COI: To keep track of institutional conflicts of interest (ICOI), every institutional COI committee should have a well-developed, campus-wide reporting system that requires the technology transfer office, the office of sponsored programs, the development office, the grants office, institutional review boards (IRBs), and reciprocal offices at affiliated medical institutions (in addition to its purchasing offices) to report, at least quarterly, to the standing ICOI committee on situations that might give rise to institutional conflicts.

PRINCIPLE 28—Strategies for Reviewing, Evaluating, and Addressing Financial COI: Disclosure of a financial COI is not a sufficient management strategy. The best course of action,

of course, is not to acquire financial COI in the first place. Strategies for addressing *individual financial COI* include: divesting troublesome assets, terminating consulting arrangements, resigning corporate board seats, and withdrawing from affected projects. Methods for addressing *institutional financial COI* include: the institution divesting its equity interest in companies doing campus research, placing conflicted equity holdings in independently managed funds with explicit firewalls to separate financial from academic decisions, recusing conflicted senior administrators from knowledge of, or authority over, affected research projects, and requiring outside committee review or oversight. Some university presidents decline to serve on corporate boards to avoid the appearance of COI. Because of conflicting fiduciary responsibilities, campuses should prohibit senior administrators from receiving compensation for serving on corporate boards during their time in office.

PRINCIPLE 29—Developing a Formal, Written COI Management Plan: If a university’s standing COI committee finds compelling circumstances for allowing a research project, or other professional activity, to continue in the presence of a significant financial COI—without the elimination of the conflict—the committee should document the circumstances and write a formal management plan for each case. The plan should detail how the university will manage the financial COI and eliminate or reduce risks to its constituents (students, faculty, patients), its pertinent missions (research integrity, informed consent, and recruitment of research volunteers), and its reputation and public trust. This recommendation is consistent with the Department of Health and Human Services (DHHS)-National Institutes of Health (NIH) rules implemented in 2011 to address financial conflicts, requiring all universities that receive DHHS grants to prepare and enforce such management plans.

PRINCIPLE 30—Oversight and Enforcement of COI Rules: All university COI policies should have effective oversight procedures and sanctions for noncompliance. They are essential to ensure compliance with university rules and public trust in the university’s ability to regulate itself.

PRINCIPLE 31—COI Transparency (Public Disclosure of Financial Interests and COI Management Plans): University COI policies should require faculty, administrators, students, postdoctoral fellows, and academic professionals to disclose to all journal editors all personal financial interests that may be directly, or indirectly, related to the publications they are submitting for consideration. The same requirements should apply to oral research presentations, presented in conferences, courts, and legislative chambers. After the university’s standing COI committee reviews faculty conflict of interest disclosure statements, they should be posted to a publicly accessible website. This is important to address growing demands from Congress, state governments, journal editors, the media, and public interest groups for increased reporting and transparency of faculty COI. It is also consistent with DHHS-NIH (2011) rules, which require universities to disclose all significant[©][®] financial COI (as per the DHHS-NIH definition) related to a faculty member’s DHHS-funded research on a public website or provide the information upon public request *within five days*. Disclosure of financial COI should also extend to affected patients and human research volunteers. (For details, see Principle 31 below.)

PART V—TARGETED PRINCIPLES: MANAGING COI IN THE CONTEXT OF CLINICAL CARE AND HUMAN SUBJECT RESEARCH

PRINCIPLE 32—Individual and Institutional COI and Human Subject Research: A “rebuttable presumption” against permitting the research should govern decisions about whether conflicted researchers or conflicted institutions should be allowed to pursue a particular human subject research protocol or project, unless a compelling case can be made to justify an exception. To maximize patient safety and preserve public trust in the integrity of the research enterprise, there should always be a strong presumption against permitting financial COI related to experimental studies involving human subjects.

PRINCIPLE 33—Institutional Review Boards (IRBs) and COI Management: An institutional review board (IRB) should review all proposed human clinical trial protocols, paying careful consideration to all related financial COI, before research is allowed to proceed. First, institutions should have clear policies, compliant with applicable federal regulations, to address reporting and management of financial COI associated with IRB members themselves. Policies should require conflicted IRB members to recuse themselves from deliberations related to studies with which they have a potential conflict. Second, the policies should require the institution’s standing COI committee to prepare summary information about all institutional and individual financial conflicts of interest related to the research protocol under review. The summary should accompany the protocol when it is presented to the IRB. The IRB should take the COI information into account when determining whether, and under what circumstances, to approve a protocol. Neither the IRB nor the standing COI committee should be able to reduce the stringency of the other’s management requirements. The double-protection system is consistent with the two sets of federal regulations governing clinical research and provides appropriate additional safeguards for research involving patient volunteers. Finally, if a research protocol is allowed to proceed, university policies should require the IRB to disclose any institutional and investigator financial COI as well as the university’s management plans for addressing them to (i) all patient volunteers in “informed consent” documents and (ii) all investigators and units involved with the research protocol.

PRINCIPLE 34—COI, Medical Purchasing, and Clinical Care: Academic medical centers should establish and implement COI policies that require all personnel with financial interests in any manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, to disclose such interests and to recuse themselves from involvement in related purchasing decisions. To the extent an individual’s expertise is necessary in evaluating a product or service, the individual’s financial ties must be disclosed to those responsible for purchasing decisions.

PRINCIPLE 35—COI Transparency in Medical Care: University policies should require all physicians, dentists, nurses, and other health professionals as well as investigators to disclose their financial COI to both patients and the broader public.

PART VI—TARGETED PRINCIPLES: STRATEGIC CORPORATE ALLIANCES (SCAs)

A Strategic Corporate Alliance (SCA) is a formal, comprehensive, university-managed research collaboration with one or more outside company sponsors, centered around a major, multi-year financial commitment involving research, programmatic interactions, “first rights to license” intellectual property, and other services. An SCA is frequently negotiated through a central university development office in tandem with a group of faculty, an entire academic department, or many different departments in unison. In broad SCA agreements, it is customary for universities, in each new grant cycle, to issue a formal request for faculty research proposals (RFP) on behalf of the outside corporate sponsor(s). In narrow SCA agreements, by contrast, all faculty members eligible for SCA funding and their projects are named and identified in advance, so a university-led RFP and research-selection process is not required.

PRINCIPLE 36—Shared Governance and Strategic Corporate Alliances (SCAs): Faculty senates or other comparable governing bodies should be fully involved in the planning, negotiation, approval, execution, and ongoing oversight of new SCAs formed on campus. The faculty’s academic senate or main governing body should appoint a confidential committee to review a first draft of a memorandum of understanding (MOU) pertaining to newly proposed SCAs. All parties’ direct and indirect financial obligations should be made clear from the outset. Before an agreement is finalized on a broad SCA, a full faculty senate or equivalent governing body should review it. Formal approval of broad SCAs should await both stages in this process. All approved SCA agreements should be made available to all faculty and academic professionals as well as the public. If the SCA designates specific funding for new full-time faculty appointments (FTEs), all normal university and departmental procedures for academic searches and hiring—as well as advancement and promotion decisions—must be followed to honor and protect academic self-governance. Temporary employees should not exclusively staff, administer, or supervise SCAs. Normal grievance procedures, under collective bargaining agreements where they exist, should govern complaints regarding interference with academic freedom or other faculty or academic rights that may arise under SCAs. In the absence of procedures, grievances and complaints should be reported to the SCA faculty oversight committee (see Principle 42 below for more details on this faculty oversight body) or to relevant college or university grievance committees for independent investigation. Standard safeguards regarding procedural fairness and due process must be respected and followed.

PRINCIPLE 37—SCA Governance and Majority Academic Control: The best practice in any academic-industrial alliance agreement—consistent with the principles of academic freedom, university autonomy, and faculty self-governance—is to build clear boundaries separating corporate funders from the university’s academic work. However, the current conditions of increasingly close university-industry relations make erecting strict walls unrealistic on some campuses. Instead, at a minimum, universities should retain majority academic control and voting power over internal governing bodies charged with directing or administering SCAs in collaboration with outside corporate sponsors. The SCA’s main governing body should also include members who are not direct stakeholders of the SCA and are based in academic disciplines and units that do not stand to benefit from the SCA in any way. A joint university-

industry SCA governing body appropriately may have a role in awarding funding, but it should have no role in exclusively academic functions, such as faculty hiring, curriculum design, course content, and academic personnel evaluation.

PRINCIPLE 38—Academic Control Over SCA Research Selection (For broad SCAs): In the case of broad SCAs, university representatives should retain majority representation and voting power on SCA committees charged with evaluating and selecting research proposals or making final research awards. These committees should also employ an independent peer review process (discussed under Principle 39 below).

PRINCIPLE 39—Peer Review (For broad SCAs): Using a standard peer-review process, independent academic experts should evaluate and award funding whenever SCAs issue a request for proposals (RFPs) in a new grant cycle. Any expert involved in the peer-review and grant-award process should be free of personal financial COI related to the area of research being reviewed to insure that research selection is scientifically driven, impartial, and fair. Appointees to committees charged with research selection should be prohibited from awarding commercial research funding to themselves, their departments, or their labs.

PRINCIPLE 40—Transparency Regarding the SCA Research Application Process: SCA agreements must clearly and transparently detail the methods and criteria for research selection and must explain how academic researchers may apply for SCA grant funding.

PRINCIPLE 41—Protection of Publication Rights and Knowledge Sharing in SCA Agreements: All the provisions of Principle 3, above, should apply to strategic corporate alliances as well.

PRINCIPLE 42—SCA Confidentiality Restrictions: To protect the university’s distinctively “open” academic research environment, restrictions on sharing corporate confidential information and other confidentiality restrictions should be minimized to the maximum extent possible in SCA agreements.

PRINCIPLE 43—SCA Anti-Competitor Agreements: Anti-competitor or noncompete agreements compromise the university’s academic autonomy, its ability to collaborate with other outside firms, and its commitment to knowledge sharing and broad public service. Restrictions in SCA agreements on faculty, academic professionals, postdoctoral fellows, and students interacting with and/or sharing information and research with private-sector competitors of SCA sponsors, or receiving separate research support from outside firms, should be avoided and/or minimized to the greatest extent possible.

PRINCIPLE 44-- Exclusive Licensing and SCA Agreements: All the provisions of Principle 12, above, should apply to strategic corporate alliances as well.

PRINCIPLE 45—Limits on Broader Academic Disruption by SCAs: Given the size and scope of many SCAs, a vigorous effort must be made to ensure that diverse areas of research (which pursue avenues of inquiry outside the purview of, not in conformity with, or even in opposition to the SCA’s research agenda) are not crowded out, and continue to enjoy institutional support,

resources, and sufficient financing. SCAs should be approved only if faculty and students within all academic units will, as a practical as well as a theoretical matter, retain the freedom to pursue their chosen research topics. All SCA agreements should strive to limit to the greatest extent possible negative financial, intellectual, or professional impacts on other academic units, colleges, and the university as a whole, as well as on faculty, academic professionals, postdoctoral fellows, and students engaged in research and activities outside the purview of the collaborative SCA arrangement. University policies should clearly affirm that no faculty member, postdoctoral fellow, academic professional, or student will ever be coerced into participating in a sponsored project; all participation will be entirely voluntary.

PRINCIPLE 46—Early Termination of SCA Sponsor Funding: With any large-scale SCA, sponsors may threaten termination of funding or limits on funding, or imply the threat, to pressure researchers in an effort to shape the research agenda or to express displeasure with the way the academic research is trending. To reduce this risk, all SCA legal contracts should include provisions to prohibit sudden, early termination of the agreement. If the negotiating process leads to inclusion of an early-termination option, it must prohibit the sponsor from arbitrarily or suddenly terminating the agreement or lowering pledged funding prior to the expected term, without at least three months advance notification. Salaries and research costs associated with the project must be continued for that period.

PRINCIPLE 47—Independent, Majority Faculty Oversight of the SCA, and Post-Agreement Evaluation: An independent, majority faculty oversight committee consisting of faculty with no direct involvement in the SCA should be established at the start of a new SCA agreement to monitor and at least annually review the SCA and its compliance with university policies and guidelines. A post-agreement evaluation plan should also be included in the formal SCA contract agreement so the campus can reflect on, and learn, best practices regarding the optimal organization for campus-based academic-industrial alliances. External evaluation may be appropriate for broad SCAs. Evaluation reports should be public documents.

PRINCIPLE 48—Public Disclosure of SCA Research Contracts and Funding Transparency: No SCA or other industry-, government-, or nonprofit-sponsored contract should restrict faculty, students, postdoctoral fellows, or academic professionals from freely disclosing their funding source. A signed copy of all final legal research contracts formalizing the SCA agreement should be made freely available to the public—with discrete redactions only to protect valid commercial trade secrets, but not for other reasons.

PART VII—TARGETED PRINCIPLES: CLINICAL MEDICINE, CLINICAL RESEARCH, AND INDUSTRY SPONSORSHIP

PRINCIPLE 49—Access to Complete Clinical Trial Data and the Performance of Independent Academic Analysis: All the provisions of Principle 5, above, should apply to clinical trial data as well.

PRINCIPLE 50—Registry of Academic-Based Clinical Trials in a National Registry: Universities and affiliated academic medical centers should adopt clear, uniform, written policies

to require all clinical trials conducted by their academic investigators to be entered into ClinicalTrials.gov (<http://www.clinicaltrials.gov/>)—the national clinical trial registry maintained by the US National Library of Medicine and the National Institutes of Health—at, or before, the onset of patient enrollment. The practice will help ward against manipulation of study results, suppression of negative findings, and improper altering of clinical trial protocols after the research has begun.

PRINCIPLE 51—Safeguarding the Integrity and Appropriate Conduct of Clinical Trials:

All clinical trials affiliated with academic institutions should be required to use independent data safety monitoring boards (DSMBs) and/or publication and analysis committees to protect the integrity and appropriate conduct of academic-based clinical trial research.

PRINCIPLE 52—Patient Notification: Neither industry-, government-, nor nonprofit-sponsored research agreements should restrict faculty or academic professionals from notifying patients about health risks and/or lack of treatment efficacy when such information surfaces and patients' health may be adversely affected.

PRINCIPLE 53—Undue Commercial Marketing Influence and Control at Academic

Medical Centers: Educational programs, academic events, and presentations by faculty, students, postdoctoral fellows, and academic professionals must be free of industry marketing influence and control. Both academics and administrators should be prohibited from participating in industry-led “speakers bureaus” financed by the pharmaceutical or other industry groups. Institutions should also develop funding systems for clinical practice guidelines and high-quality accredited continuing medical education (CME) programs free of industry influence.

PRINCIPLE 54—Appropriate Use of Facilities and Classrooms at Universities and

Academic Medical Centers: Universities, academic medical schools, and affiliated teaching hospitals should have clear and consistent policies and practices barring pharmaceutical, medical device, and biotechnology companies from distributing free meals, gifts, or drug samples on campus and at affiliated academic medical centers, except under the control of central administration offices for use by patients who lack access to medications. As a general principle, academic facilities and classrooms should not be used as for commercial marketing and promotion purposes, unless advance written permission from academic institutional authorities has been explicitly granted, with academic supervision required. (Commercial marketing of services would, for example, be appropriate at a job fair.) Campus policies should also prohibit marketing representatives from making unauthorized site visits. Finally, faculty, physicians, trainees, and students should be prohibited from directly accepting travel funds from industry, other than for legitimate reimbursement of contractual academic services. Direct industry travel funding for marketing junkets, trips to luxury resorts, and expensive dinners should be prohibited.

PRINCIPLE 55—Marketing Projects Masquerading as “Clinical Research”

Faculty, students, postdoctoral fellows, and academic professionals based at academic-affiliated institutions must not participate in marketing projects that masquerade as scientifically driven clinical trial research. When pharmaceutical firms fund these thinly disguised marketing studies,

they are often referred to as “seeding trials,” because they are designed primarily to expose doctors and patients to newer, brand name drugs.

PRINCIPLE 56—Predetermined Research Results: Faculty and other academic investigators should be prohibited from soliciting research funding from outside sponsors with the implied suggestion or promise of predetermined research results.

(a) This time limit of 30-60 days for delays on publication (for the purpose of securing proprietary protection through a provisional patent or other IP filing) is consistent with recommendations issued by the National Institutes of Health, which are discussed in further detail in the main report.

(b) Protecting access to “complete study data” is particularly important in the area of clinical research, where drug trials and other medical investigations are often conducted at multiple institutions simultaneously. If the sponsor grants only partial access to the study’s complete data sets and/or withholds other relevant research codes and materials, then the academic investigators and authors will not be able to perform a truly independent expert analysis of the study’s data and outcomes.

(c) The AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is *not* controlled and/or managed by an independent entity, such as a mutual or pension fund. This is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services under its 2011 conflict of interest disclosure rules. (Source: Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” *Federal Register*, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)

(d) The DHHS rule defines a “significant” financial conflict of interest as follows: “Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research... Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution’s FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution’s FCOI policy, the

institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; *income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles*; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.” [Emphasis added] (Source: Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” *Federal Register*, Vol. 76, No. 165, August 25, 2011, quotes on pp. 53283-53284.)

INTRODUCTION

An Overview of the Benefits and Risks of Heightened Academy-Industry Engagement

Why the AAUP Is Issuing This Report

In 1915, the American Association of University Professors called attention to the risks to higher education from the influence of “commercial practices in which large vested interests are involved.”

¹ The 1915 Declaration warned of “a real danger that pressure from vested interests may, sometimes deliberately, and sometimes unconsciously, sometimes openly and sometimes subtly and in obscure ways, be brought to bear upon academic authorities.” The Declaration’s framers never could have conceived of a corporation offering a university president hundreds of thousands of dollars to serve on a corporate board, or a start-up firm offering faculty members stock options and research funding to test products in which they have a direct financial stake.

By 2004, when the association adopted its “Statement on Corporate Funding of Academic Research,” contractual relationships between universities, university personnel, and corporations had become far more entangled. Nonetheless, a 2004 statement pointed out that the connection between industry and higher education “has never been free of concerns that the financial ties of researchers or their institutions to industry may exert improper pressure on the design and outcome of research.”² The 2004 language in fact echoes the association’s 1990 “Statement on Conflicts of Interest.” It admonished: “faculties should ensure that any cooperative venture between members of the faculty and outside agencies, whether public or private, respects the primacy of the university’s principal mission, with regard to the choice of subjects of research and the reaching and publication of results.”³ It goes on to say, “Faculties

should make certain that the pursuit of such joint ventures does not become an end in itself and so introduce distortions into traditional university understandings and arrangements.”

As early as 1965, in “On Preventing Conflicts of Interest in Government-Sponsored Research at Universities,” we urged “the formulation of standards to guide the individual university staff members in governing their conduct in relation to outside interests that might raise questions of conflicts of interest.”⁴ It is entirely appropriate that faculty play the leading role in formulating the standards. The 1966 “Statement on Government of Colleges and Universities”—formulated by the AAUP, the American Council on Education, and the Association of Governing Boards—recognizes that faculty should have “primary responsibility” for research matters.⁵ The expanding relationship between industry and institutions of higher education in funding faculty research threatens not only academic freedom and academic integrity but also faculty’s role in institutional governance. As noted in AAUP’s 1994 statement “On the Relationship of Faculty Governance to Academic Freedom,” the concepts of academic freedom and shared governance are “inextricably linked.”⁶ While reasserting the faculty’s primary responsibility for research may not be enough to resolve many of the issues identified in this report, faculty involvement is crucial for success.

As we report below, many academic and professional groups (such as the Association of American Universities, AAU; the Association of American Medical Colleges, AAMC; the Institute of Medicine, IOM) have already formulated more stringent and well-defined standards to address financial conflicts of interest and other threats to research integrity. Many of them explicitly seek to ensure the AAUP’s 1915 directive: “the scholar must be absolutely free not only to pursue his investigations but to declare the results of his researches, no matter where they may lead.”⁷ However, some of these professional guidelines, including ones put forward by the University-Industry Demonstration Partnership (UIDP), a project of the National Academies, focus narrowly on expanding academy-industry collaboration and managing intellectual property without paying sufficient attention to academic freedom, research integrity, and conflicts of interest.⁸

In this report, the AAUP has tried to draw together the most well articulated and effective of these prior guidelines and statements into a comprehensive set of “Recommended Principles and Practices” for all US colleges and universities to consider adopting. Where necessary, the

AAUP has expanded upon advice contained in existing guidelines in light of the values we have promoted for nearly 100 years.

Collaborations between industry and the academy present tremendous opportunities for advancing knowledge, applying it to real-world problems, and bringing about myriad social benefits. Cooperative research arrangements involving both university and industry scientists have proven critical to the development of numerous powerful technologies in medicine, agriculture, energy, and other fields. But the increasing number, financial scope, and complexity of these collaborations calls for more specific standards and principles than the AAUP has offered in the past. In putting forward these new guidelines, it should be clear, we do not aim to curtail collaborations between business and academia. Instead, we want to help higher education faculty and administrators manage these collaborations in a manner consistent with the long-term interests of both universities and the broader public, including private industry.

The report offers examples and case studies of university-industry relationships that have severely compromised the principles that should govern university life. We do not mean to suggest these anecdotal examples represent the norm. However, they demonstrate problems that can arise in the roles that both industry and the university play, and thus point to standards that could be designed to prevent future difficulties. In most instances, moreover, the AAUP has drawn together substantial empirical and quantitative evidence to support these case studies, and provide further documentation regarding the breadth and scope of these problems, and the possible consequences of ignoring them. Because the report addresses the growing challenges in academic-industrial relationships and does not survey all industry-academy relationships or summarize their accomplishments, we make no effort to report the entire history of such collaborations.

Although we focus on academy-industry collaborations, some of the problems and challenges we address can also arise with government and nonprofit contracts and alliances. We therefore note when a particular AAUP principle should apply to such collaborations as well. Indeed, the AAUP recognizes that any number of special-interest groups, mission-directed nonprofits, and even government agencies can pressure faculty for results that support their agendas, and to further their goals, can offer incentives, bias experiment design and analysis of data, harass contrary viewpoints, and delay release of results. Such pressures can arise within any organization and can lead to bias or misuse of academic research.

Of course, faculty investigators also have biases—whether they arise from scholarly debates, personal affinities, or political and religious commitments. Faculty status does not confer independence from the activities and interests of the communities in which faculty members live and work. The heart of the matter, however, is that faculty not be contractually obligated to represent positions at odds with their professional judgment and public commitments, or placed in compromised situations, financial and otherwise, that are more likely to produce bias.

A number of warning signs suggest particular sponsored research projects require extra scrutiny. Serious concerns are raised if, for example, proposed research design or reporting and publication protocols indicate university involvement is aimed primarily at helping a sponsor clear regulatory hurdles by supplying confirming or positive field data or analysis. Similarly, the risk of compromised research arises any time future investment depends on positive analysis or test results. The same issues arise when either investigators or institutions stand to benefit from additional research funding, licensing revenues, or the value of equity held in the sponsor or another company. Here in this report, we identify and put forward principles designed to help manage such problems.

The first step toward implementing these guidelines might be to have an AAUP chapter or a group of concerned faculty introduce a resolution in the faculty senate, or in a comparable campus governing body, to create a committee to compare campus-based policies, practices, and regulations with this report's recommendations. The committee would research and report on faculty-handbook recommendations, formal university policies, and other campus guidance documents. At universities in which faculty engage in collective bargaining, some of the policies could be incorporated into union contracts. In all cases, committees would consult widely with diverse groups of faculty across disciplines and build broad-based consensus around recommended language. Faculty governing bodies would benefit from working closely with knowledgeable administrators, many of whom will be equally interested in adopting clear campus guidelines.

As this report will show, university policies and procedures for managing academy-industry engagement and financial conflicts of interest remain highly variable, inconsistent, and overall too weak. As noted, many preeminent academic and professional societies agree with this assessment, and have already issued recommendations to strengthen both the management and

oversight of academy-industry relationships. However, with the exception of the AAU's 2001 recommendations, issued in its "Report on Individual and Institutional Financial Conflict of Interest,"⁹ most of these guidelines are drawn narrowly around biomedicine and human-subject research. Here, the AAUP draws together the best of these societies' recommendations, and contributes its own, to strengthen institutional oversight and protections *across the entire university*. This report also documents how recent developments have eroded faculty control over research as well as shared governance. It calls on faculty to take responsibility for strengthening the guidelines governing academy-industry relationships, thereby reaffirming the primacy of shared governance, faculty control over research, academic freedom, and research integrity.

Society traditionally has placed great trust in universities, faculty, physicians, and other health professionals and has granted considerable leeway for self-regulation. However, mounting concern from lawmakers, government agencies, and the public demonstrates the urgent need for stronger measures to protect public trust in academic research. A growing body of empirical evidence also shows that inadequate or misguided management of industry relationships threatens the very principles that universities hold most sacred: academic freedom, independent inquiry, the right to publish, research autonomy, scientific objectivity, research accuracy, broad dissemination of knowledge, independent analysis and research verification, and the development of products that serve the public good.

Faculty members and administrators often cite academic freedom to justify their objections to standards for regulating contracts. Their arguments obscure the fact that academic freedom evolved as a concept not only to protect individual rights but to insulate the academy and safeguard the discovery process from powerful social forces, initially the church and later big business. Some rules are necessary to preserve freedom of research, teaching, and inquiry. At stake are the standards that govern universities, their reputations, and public trust.

Academic freedom does not entitle faculty members to accept outside responsibilities that make it impossible to do their primary jobs. Academic freedom does not entitle faculty members to sign away their freedom to disseminate research results. Academic freedom does not entitle faculty members to ignore financial conflicts of interest that could dangerously compromise the informed-consent process and the impartiality of research. It follows, therefore, that academic

freedom does not guarantee faculty members the freedom to take money regardless of the conditions attached to receipt of the funds.¹⁰

At times, individual faculty rights, the institution's responsibility to protect research integrity, and the university's reputation for conducting independent research—indeed its very ability to carry out independent research—can dramatically conflict. The AAUP's 1992 statement, "An Issue of Academic Freedom in Refusing Outside Funding for Faculty Research," highlighted the friction. The statement noted that institutions have the right to decline grants offered faculty if unacceptable conditions are attached, when, for example, "the agency was imposing conditions on the research that violated academic freedom."¹¹

Elsewhere, when the AAUP was asked to consider prohibiting the whole category of tobacco-industry funding, the association argued that "a very different situation obtains, however, when a university objects to a funding agency because of its corporate behavior."¹² The AAUP reasoned that "the distinction between degrees of corporate misdeeds is too uncertain to sustain a clear, consistent, and principled policy for determining which research funds to accept and which to reject . . . A university which starts down this path will find it difficult to resist demands that research bans should be imposed on other funding agencies that are seen as reckless or supportive of repellant programs."

The AAUP clarified its reasoning in 2003, after faculty at two University of California campuses voted to refuse research awards from tobacco companies due to a growing body of evidence that the industry was trying to unduly influence and steer scientific research both on and off campus. The AAUP's Committee A on Academic Freedom and Tenure observed that its concerns about the restraints on academic freedom would not be lessened "if the initiative in calling for these bans on the funding of faculty research comes from the faculty itself."¹³ The AAUP based its reasoning on the conviction, no doubt widely shared by faculty across the United States, that the right of individual faculty members to choose what research they wish to conduct is fundamental, indeed foundational. The right is central to the AAUP's 1915 Declaration and to numerous policy statements issued since then. If faculty members are free to choose their own research projects and agendas, the reasoning goes, they should be free to accept the funding needed to conduct their research. Even a destructive industry like tobacco, moreover, will sometimes fund useful research—if for no other reason than the positive publicity it can generate. Should that research be prohibited? For most US institutions, the individual academic-

freedom argument has long covered the individual right to accept research funding. More recently, however, some colleges of medicine and schools of public health have asserted that, though individuals can pursue any research they choose, that does not give them the right to accept funding from an industry uniquely dedicated to undermining the advancement of science.

Clinicians at university hospitals, of course, regularly see the consequences on their patients of smoking. Departments of medicine, moreover, are more likely than other academic programs to experience the negative impact of tobacco-industry funding. Faculty members in medicine may feel more conflict between tobacco-industry campaigns and their core public health institutional mission than most other faculty members. American lawsuits and global treaties to curb tobacco-company influence have reinforced the medical college perspective.

In 2003, the World Health Organization adopted its Framework Convention on Tobacco Control. It soon became one of the most widely embraced treaties in the United Nation's history. Within a year, 168 nations signed the treaty aimed at responding to the "globalization of the tobacco epidemic." Guidelines for implementing the treaty, which took effect in 2005, recommend that public educational institutions and other government bodies prohibit "contributions from the tobacco industry or from those working to further its interests," and direct all signatories "to protect these policies from commercial and other vested interests of the tobacco industry."¹⁴

Meanwhile, as a result of litigation, immense archives of internal tobacco industry documents detailing the companies' suppression of internal research linking smoking with cancer and their decades-long campaign to manipulate public opinion became available for public review. Faculty members, health advocates, and government agencies alike began to wonder if tobacco companies were a special case. Weapons manufacturers could claim their products advance national security. Not so tobacco companies. Soon, academic research studies and careful reviews of litigation documents revealed how the tobacco industry had manipulated scientific evidence—including academic research—to suppress the truth about the health hazards of cigarettes and stave off regulation. In 2012, the National Institute on Drug Abuse (NIDA),¹⁵ a division of the National Institutes of Health (NIH), outlined how tobacco companies had colluded to fund science that would support their business objectives while suppressing scientific evidence of smoking's harmful effects. The NIDA website summed up the evidence:

Integrity and honesty in conducting research are essential to sound science and form the basis for public confidence and trust in the results of scientific research. Recent landmark judicial rulings against the tobacco industry found that prior tobacco industry-sponsored research was biased in support of the interests and goals of the tobacco companies. In 2006, a federal court [in *US Department of Justice v. Philip Morris USA Inc. et al.*¹⁶] found that the cigarette industry engaged in willful racketeering and conspiracy to conceal the dangers of smoking from the American public by improperly suppressing and terminating scientific research and destroying research documents. This ruling was upheld in 2009 by the US Court of Appeals and in 2010, the US Supreme Court denied further review of the ruling. In the final opinion in that case, the presiding judge ruled that nine manufacturers of cigarettes and two tobacco-related trade organizations had violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") by engaging in a lengthy, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the lack of health benefits from low tar and "light" cigarettes, and their manipulating the design and composition of cigarettes in order to create and sustain nicotine addiction.¹⁷

The NIH website went on to warn: "The tobacco industry manufactures, markets, and distributes products that are both addictive and lethal. In fact, cigarette smoking remains the leading cause of premature death in the US, killing approximately 440,000 people per year. Thus, it is the opinion of NACDA [the National Advisory Council on Drug Abuse] that the interests of the tobacco industry are *fundamentally incompatible* with the scientific goals and public health mission of NIDA."¹⁸ Finally, the NIH concluded that a history of prior tobacco-industry funding could jeopardize the success of new scientific grant applications filed with the agency.

Based on evidence of academy-industry collusion, a limited number of universities have revised their tobacco industry funding policies. After five University of California campuses voted to refuse tobacco funds in 2007, the UC Regents reasoned that accepting tobacco industry funding might undermine the university system's reputation and adopted a compromise policy (RE-89) identifying tobacco as a special case and requiring each campus chancellor to approve new tobacco funding. The Regents also requested an annual report detailing any new grants issued, but since the policy was adopted, no new tobacco funding has been received. Schools of public health at Arizona, Columbia, Harvard, Iowa, Johns Hopkins, North Carolina, South

Carolina and elsewhere, along with schools of medicine at Emory, Harvard, and Johns Hopkins now formally decline to accept tobacco funding. A similar movement is underway overseas. The University of Geneva, the University of Hong Kong, the German Cancer Research Center, London School of Hygiene & Tropical Medicine, and seventeen Australian universities now decline tobacco funding. Confronted with evidence that tobacco companies colluded to impede their universities' missions to develop and disseminate knowledge and to pursue scientific truth, these institutions adopted new policies. They recognized that the tobacco industry used universities to distort public understanding and delay research results, and the industry did so not only by misrepresenting science but also by sowing confusion in the scientific literature itself.

There is so far no evidence these efforts to prevent the tobacco industry's distortion of science to advance its business will spread more widely among American universities. Debate about the ethics of tobacco industry funding brings to mind arguments the AAUP itself advanced in 1915—that academic freedom entails responsibility not only to one's campus and one's profession but to the public good.

Financial conflicts of interests are not limited to tobacco-industry funding. When corporations, or nominally nonprofit funding agencies, effectively bribe faculty members to, for example, publish articles with doubtful product claims, dubious economic assessments, or attacks on well-established science, the faculty betray their professional and public responsibilities. No body of rules and guidelines can guarantee professional ethics. But principles, such as the ones offered in this report, can remind faculty members and institutions of their obligations to uphold standards of professional and personal integrity. The principles can also remind faculty of the broader social goals of their research and scholarship, a particularly important objective in disciplines that have a limited history of interrogating such issues collectively.¹⁹

This broad concern with professional ethics and the public good helps to explain why faculty members and students across all disciplines, not only those engaged in corporate-sponsored research, will have a keen interest in this report. A campus that compromises its core academic principles risks undermining the university's reputation, integrity, and its public trust. Whenever the potential for financial gains exist, such compromises, left unchallenged, are also arguably more likely to take place again. As this report will show, the potential for abuse also extends beyond those engaged in sponsored research. Historians, economists, statisticians,

business faculty, and lawyers are among those who have accepted lucrative consultantships to advise companies defending products proven to be dangerous to public health or to the national economy. Everyone on campus has a stake in the reputation of the institution and its success in upholding its core values and its mission.

The AAUP respects institutional autonomy. This statement offers baseline principles that universities and their faculty may use to formulate their own policies, while leaving room for adaptation to address specific, local, campus-based needs. Because comprehensive and rigorous national standards are urgently needed to safeguard academic freedom and research integrity, however, the AAUP is recommending specific policy guidelines covering the broad sweep of existing commercial interactions, recognizing that the principles sometimes will sometimes apply to nonprofit and government funding sources as well.

Universities have long relied on financial support from outside sources, including industry, to sustain their operations. The issue we seek to address here is not the funding source per se but conditions attached to the funding, as well as the effect that personal financial interests may have on professional decision-making and research integrity. Today, various new forms of academy-industry engagement are emerging that impose constraints on the historic autonomy of the university. Such arrangements may also limit faculty authority over academic matters (peer-reviewed research selection, curriculum design, and faculty hiring), and erode academic research standards (access to data, scientific objectivity, independent statistical analysis, and the ability to independently verify research).

The public trusts that universities and faculty members will remain professionally independent and maintain the highest standards of research and teaching. Universities cannot allow flagrant violations of professional academic norms and scientific standards to go unchecked lest the very foundation of academic freedom—indeed the justification for its existence—will become unstable, and eventually collapse. Even private corporations should recognize that the extraordinary value of the academy—its ability to carry out cutting-edge science, perform reliable research, and garner public trust—rests on the independence and perceived integrity of the university research culture. That, in essence, is why the AAUP has issued these recommendations: to protect academia’s distinctive academic culture and its public knowledge missions. Industries seeking genuine partnerships with the academy will welcome proof that university labs and company labs are not interchangeable.

The AAUP urges faculty senates or comparable governing bodies and universities to promptly review, update, and strengthen their written policies and guidelines for structuring and managing academy-industry alliances and sponsored-research agreements on their campuses. We also urge faculty to work actively with their administrations to update and strengthen campus-wide conflict-of-interest (COI) policies, covering both individual-faculty as well as institutional COI. The credibility and integrity of our nation's universities are now at stake.

Balancing the University's Diverse Missions

America's research universities, and many of its colleges and community colleges, have long sought to protect the integrity and independence of academic research and teaching and the distinctively open culture of the academy, while at the same time embracing collaborations with industry, government, and outside public-interest groups. The collaborations fund university research, advance and promote practical knowledge, and deliver tangible societal benefits. Land-grant universities have a proud tradition of nurturing working relationships with industry and providing other direct public service. Since their establishment well over a century ago, American land-grant universities have expressly sought to further economic development.

Today, virtually all American universities recognize economic development and community service as a vital part of their mission. It has long been argued that economic development comports with the more traditional missions of education and training and with universities' longstanding commitment to fundamental research, that, if managed wisely, these activities can be complementary. Nevertheless, notable tension between these missions has always existed.

Over the last thirty years or so, emphasis has grown on the economic contributions expected of universities. New state and federal laws and policies have sought to reorient the activities of universities to more closely meet economic objectives. States and the federal government now actively encourage cooperation between higher education institutions and the commercial and manufacturing sectors to promote advanced research, enhance innovation, and spur economic development. Encouraged by university administrators themselves, recent media

coverage has similarly focused on universities' potential to enhance American competitiveness and economic progress by generating new start-up firms, jobs, and high-tech regional growth. Finally, in recent decades, state financing of higher education, as well as federal funding of research, has shrunk to a fraction of university operating costs, leading the managers of many institutions to argue that they should strive to function more directly as engines of economic growth, expand their interactions with industry, and attract greater business support.

Despite a perennial hope that industry research funding will make up university operating shortfalls, there is reason to be skeptical. While the funding typically facilitates expansion of research into new areas or enhances existing ones, industry contracts, like those from government and nonprofit foundations, sometimes fail to cover the full indirect costs. Therefore, universities may actually lose money on them. In addition, the contracts can compromise teaching and research when other unsponsored work is curtailed to pay for the unreimbursed costs of sponsored research. According to the journal *Nature*, “[U]niversities are increasingly subsidizing grants from their own funds. . . . Between 1969 and 2009, the proportion of research funding supported by institutional money rose from 10% to 20%, according to the US National Science Foundation. Public universities and all but the wealthiest private ones are increasingly taking that money from tuition fees.”²⁰

While the lion's share of the interactions with industry are concentrated in distinct parts of the university—including agriculture, business, chemistry, engineering, biomedicine, economics, computer science—the ambiance and institutional assumptions associated with the emphasis on serving business and driving economic growth, are now pervasive. Buildings named after corporate sponsors or living donors contribute to the campus atmosphere. One alternative is to encourage sponsors and donors to name buildings or programs after admired deceased people. Pressure is mounting, even in the humanities and other traditional, nonmarket disciplines, to become more commercially “relevant” and to generate private revenue sources.

Balancing the need to protect academia's unique and distinct enterprise, while continuing to interact and engage with outside industries, interest groups, and diverse funding sources, has never been simple. However, universities continue to be responsible for upholding an array of well-recognized public knowledge missions, which no other private- or market actor has been capable of delivering so ably or effectively. Universities' public knowledge missions include:

- The delivery of a broad-based, liberal education, as opposed to narrow workforce training;
- Cultivation of critical thinking and civic understanding essential for any functioning democracy;
- Fundamental, “curiosity-driven,” or frontier science;
- Free and broad dissemination of new knowledge;
- Verification of new research discoveries and theories through publication, commentary, and/or actual testing and replication of reported research results;
- Space for social criticism and expression of unpopular viewpoints;
- Public-good research, such as research into climate change and occupational health, which generates enormous public and societal value but may not generate profit;
- Research and scholarly inquiry free from unwanted special-interest influence;
- Impartial expert advice for the general public, government agencies, industry, and other public constituencies;
- Preservation of a “public domain for knowledge” or a “knowledge commons”—the wellspring for all future creativity and invention;
- Preservation of past intellectual and artistic achievement;
- Continuous advancement of knowledge across all disciplines.

As a two-year investigation of academy-industry partnerships led by the Business-Higher Education Forum observed: “Corporations and universities are not natural partners. Their cultures and their missions differ. Companies’ underlying goals—and the prime responsibilities of top management are to make a profit and build value for shareholders by serving customers. Universities’ traditional missions are to develop new knowledge and educate the next generation.”²¹

University-industry ties, which date back to the mid-1800s, have produced numerous important benefits across many fields, from engineering and chemistry to agriculture and public health. A number of histories have documented the considerable accomplishments of academy-industry collaborations in agriculture, biotechnology, engineering, computing, and other academic fields.²² As previously noted, this AAUP report does not focus on the achievements. It instead addresses developments that over the past three decades have enhanced the variety,

pervasiveness, and importance of commercial relationships, while significantly raising the risk that financial conflicts of interest may unduly influence professionals' judgments about universities' primary educational, research, health, and other public missions.

A growing body of empirical research, as well as consensus statements from professional groups (discussed in detail in the Conflict of Interest section below) have concluded that conflicts of interest may threaten the integrity of the academic research enterprise, the objectivity of scientific investigations, the accuracy of published research results, and the quality of patient care. These issues warrant urgent scrutiny and attention.

Recent news stories, congressional investigations, litigation documents, reports by nonprofit activist groups, and academic research analyses have uncovered a variety of disturbing commercial conflicts, which could undermine public confidence in the academic enterprise. Here are a few examples:

- Physicians and researchers failed to disclose substantial payments from drug companies, as required by universities, government agencies, and medical journals;²³
- Agricultural industry groups employed a campaign to intimidate academic researchers and threatened to withhold university funding in an effort to undermine a report calling for reduced use of antibiotics in meat production and better waste-management practices;²⁴
- Companies and academic investigators failed to publish negative research results from industry-sponsored clinical trials, or delayed publication for a year or more after trial completion;
- Academics put their names on manuscripts, after the data were collected and analyzed and after the first drafts had been “ghostwritten” by industry-paid authors;
- ²⁵
- Private foundations endowed professorships and funded research centers under contracts requiring advance vetting of appointees and projects by the foundation's self-appointed advisory board;²⁶
- Nominally independent science organizations established and systematically funded to steer public discussion and debate, serve corporate business interests, and stall government regulation to the detriment of the university's overarching mission of developing and disseminating reliable public knowledge;²⁷
- Corporate gifts stipulated certain books must be assigned as required classroom reading;²⁸

- Corporate grants that permitted company employees to design new courses;²⁹
- Industry heavily funds clinical practice medical guidelines and the academics who write them.³⁰

The implications of these challenges to the university's historic autonomy, academic freedom, and research integrity are profound. Many books³¹ published in the last decade have expressed concerns about how commercial influences affect teaching, scientific objectivity, and the evidentiary foundations of medicine, as well as the role of universities as arbiters of reliable public knowledge and guarantors of the public interest.

This introductory report will explore in detail the benefits and risks associated with the growing academy-industry relationship. First, we begin with an overview of the: i) size and scope of the growing university-industry engagement; ii) the forces responsible for driving the trend; and iii) a description of the diverse types of academy-industry collaborations that now exist.

The Growth of University-Industry Engagement

Since the late 1970s, both the prevalence and scope of academy-industry engagements on campus have changed dramatically. Between 1970 and 2000, the share of private-industry paid university research funding tripled in the United States. The rise represents a tenfold increase in real research and development, or R&D, dollars coming from industry at a time when total university research and development funding increased only about 3.5 times.³²

Still, industry funding represents a relatively small fraction of overall university research financing. According to 2008 statistics, the latest available, from the National Science Board (NSB), the federal government continues to contribute 60 percent (or \$51.9 billion) of American university R&D funding,³³ while private sources provide only roughly 6 percent (or \$2.9 billion).³⁴

It is important to note, however, that the 6 percent figure represents industry-sponsored research only; it does not include industry funding that comes in the form of academic gifts,

endowments for new faculty appointments, faculty consulting, honoraria, seats on company boards, commercial licensing income, or equity and options in start-ups. Many of these other commercial funding streams are not tracked nationally by category, making it impossible to gauge the magnitude of their impact or how it may have changed over time.

It is also important to note that the latest available National Science Foundation data shows that in 2009, some colleges and universities obtained anywhere from 12 to 50 percent of their research and development budgets from industry sources. The data shows the University of Tulsa received 48.5 percent of its R&D budget from industry, Duke University and the State University of New York at Albany got 22.8 percent, Northeastern University 19.8 percent, Massachusetts Institute of Technology 14 percent, the University of Southern California 13.7, and the University of Maryland, Baltimore 12.6 percent.³⁵ The numbers fluctuate from year to year, particularly at less research-intensive universities, where a few large industry grants can markedly alter the share.

The impact of corporate funding is, of course, greatest in fields where it is most heavily focused, including medicine, biology, chemistry, engineering, economics, business, and agriculture.

Private industry now represents the largest source of funding for biomedicine in the United States. Between 1977 and 1989, the proportion of industry funding for clinical and nonclinical research grew from 29 to 45 percent.³⁶ Between 1995 and 2003, annual shares ranged from 57 to 61 percent.³⁷ (Federal government support for biomedicine remains quite substantial, however. In 2008, projects in the life sciences garnered 60 percent, or \$18.7 billion, of the federal R&D budget for university research.)³⁸

Not surprisingly, given this level of collaboration, relationships between academic biomedical researchers and industry are also extensive. A 2006 national survey of department chairs at medical schools and large teaching hospitals found that 67 percent of academic departments (as administrative units) had relationships with industry.³⁹ Also, 27 percent of nonclinical departments and 16 percent of clinical departments received income from commercial licensing of academic intellectual property.

A 2008 study shows industry's influence in biomedicine trending down. Overall, from 1995 through 2006, the proportion of biomedical faculty (clinical and nonclinical) who received

industry funding dropped from 28 percent to 20 percent. Faculty members getting industry support took a median of \$99,000 in 2006.⁴⁰

Academy-industry collaborations are by no means confined to biomedicine. They have been commonplace for a long time in engineering, chemistry, information technology, and business.⁴¹ In other fields ranging from agriculture and energy research to law, economics, and toxicology, academics rely heavily on industry funding and frequently engage with outside companies in other ways as well. For example, faculty consult and sit on company boards. However, compared to biomedicine, which has been studied extensively, minimal or no empirical analysis or scholarship has examined the size or possible influence of industry funding on other academic disciplines.

Sometimes university scholars report industry funding sources in conjunction with published academic research, but often they do not. The risks that unregulated—and often undisclosed—financial conflicts of interest can pose to research results, to universities' reputations, and to the public welfare was recently exposed starkly in the discipline of economics. Compromised medical research has obvious implications for public health and safety. The financial meltdown and recession of 2007 through 2009, though, literally affected millions of people worldwide. A 2010 study of academic financial economists examined a small but influential cohort of university professors and found extraordinarily limited public disclosure of professors' ties to banking and other financial services companies, although 70 percent of the surveyed economists worked with private financial institutions, and some held senior positions (co-founder, managing partner, chief economist, president). Even so, the professors rarely disclosed financial conflicts of interest that related directly to their economics research in presentations or publications.⁴²

When several prominent academic economists were interviewed about their industry ties in the Academy Award-winning 2010 film *Inside Job*, they repeatedly dismissed the need to disclose financial conflicts of interest. However, as the film illustrated, economists working for some of the nation's top-ranked universities played a central role in the global economic crisis. These economists argued against regulation of the financial-services industry, defended high-risk investment vehicles, and reassured government agencies and the public of the health of economic and financial systems up until the stock-market collapse, the wave of home foreclosures, and the resulting job losses. These professors opined while the same industry they were purportedly

evaluating with disinterested professional eyes paid them. The public outrage *Inside Job* generated helped persuade the American Economic Association to adopt new standards in January 2012 for the disclosure of authors' financial conflicts of interest in the association's journals. It was the first time the association had ever required authors to report industry income.

What Accounts for Rising Levels of Academy-Industry Engagement?

Numerous, diverse factors have been driving up levels of academy-industry engagement since the late 1970s. During the final years of the Carter and Reagan administrations, several policy measures aimed at stimulating R&D and innovation, broadly speaking, sparked new incentives for academy-industry collaborations. These included landmark congressional legislation sponsored by Senators Birch Bayh and Bob Dole, known as the Bayh-Dole Act (1980)⁴³; an R&D tax credit (1981, enhanced in 1986);⁴⁴ and relaxed antitrust rules for R&D joint ventures (1984).⁴⁵

After its passage, American universities widely interpreted the Bayh-Dole Act as granting them automatic intellectual property rights to all research results generated using federal funding, including the right to license products of the research to industry in exchange for a share of the resulting profits, royalties, equity, and other fees. However, in 2011, the US Supreme Court offered a different interpretation of the law. Bayh-Dole requires universities to secure faculty agreement to protect and honor the government's interest in federally funded inventions.⁴⁶ But nothing in the act compels faculty to give title to their own inventions to their university employers, nor must faculty "assign" invention management and intellectual property prosecution rights to their universities.

In 2011, the US Supreme Court⁴⁷ in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc. (Stanford v. Roche)* rejected longstanding university claims and clarified the law. In a successful amicus brief, the AAUP argued that "Bayh-Dole does not alter the basic ownership rights granted to inventors by law and that it simply helps bring inventions forward to benefit the public good by clarifying that the government assigns to universities and other grantees the claim to ownership over federally funded inventions . . ."⁴⁸

The high court agreed, ruling that US patent law has always favored, and should continue to favor, the rights of individual inventors, and that universities need explicit concurrence from researchers before claiming rights to their inventions. The AAUP viewed the ruling as a victory for faculty rights, demonstrating that “academic researchers and inventors are, and have traditionally been, much more than mere employees of their institutions.”

Soon after the *Stanford v. Roche* ruling, however, intellectual property experts predicted that US universities would respond by defensively including clauses in faculty employment contracts to assign patenting rights and ownership of faculty inventions to the institutions.⁴⁹ There is evidence that universities are doing exactly that, either by referencing the institution’s full IP policy within a contract or by posting the policy and declaring it applicable to all employees. Faculty with less bargaining power, including PhDs being offered their first tenure-track jobs, are vulnerable to pressure to sign away their invention rights, possibly for their entire careers. The AAUP believes faculty should have a vital role in the disposition of intellectual property derived from their research. All faculty assignments of intellectual property to host universities should be voluntary. (For a discussion of the AAUP’s recommended principles for faculty inventor rights and IP management, see Part III.)

Arguments underlying the compulsory assignment of faculty IP to the institution begin with the assumption that faculty members are no different from corporate employees, who owe their employers the fruits of their labor. However, the AAUP’s 1915 “Declaration of Principles on Academic Freedom and Academic Tenure” anticipated and disputed that claim. The declaration said faculty could not maintain academic freedom and the ability to serve the interests of society independently unless they were recognized as “appointees,” not employees.⁵⁰ It is now well established, indeed few academic administrators would disagree, that faculty members enjoy the right to direct and control their own research as well as classroom instruction. Academic freedom firmly secured these rights. By attempting to force assignment of faculty inventions and IP to universities, the institutions are effectively arguing that faculty lose academic freedom when they become inventors, at which point they become employees. The argument amounts to an assertion of employer control over faculty research, including the dissemination and possible future use of research results. Such a claim is as objectionable for faculty research as it is for instruction.

The *Stanford v. Roche* decision challenges a complex of practices university administrators

have imposed on faculty but which lack standing in law. Most of the developments in university research and invention policies over the past thirty years have had the effect of limiting, if not ending, the opportunity for faculty investigators and inventors to negotiate their own invention management, IP, and technology transfer terms. Some universities, such as the University of Washington, recite state ethics laws to exclude faculty investigators from participating in IP and invention-management transactions involving the state because, the universities argue, the faculty have a personal interest in the research agreement because they might receive pay from it (such as summer salary, which would not otherwise be allocated). Universities also commonly automatically insert institutional ownership clauses into standard sponsored-research agreements with industry and private foundations, claiming title and management rights to all faculty inventions created under the agreement. Now, as noted, universities are considering policies to make faculty assignments of invention rights a condition of employment. According to Gerald Barnett, a university IP expert, writing in a 2012 memo to the AAUP: “A compulsory ownership claim changes the relationship between faculty and administration from one of administrative governance and support to one of an employer with authority over the disposition of work of employees. . . . [This] is routine in companies, but is anything but routine, or acceptable, for university faculty.”

The Supreme Court’s *Stanford v. Roche* decision strongly affirms the AAUP’s position that faculty should be free to retain title to their own inventions and control their disposition. Flowing from this, faculty should also be free to choose how their inventions are managed (including how best to disseminate, license, and/or commercialize their discoveries, and which management agent is best equipped to handle negotiations). Under such a system, professors might choose to grant invention rights to their own institutions, but they could also choose to work with an outside IP expert or management agency (unless preexisting agreements or statutes prohibit it). Faculty’s ability to retain title to their inventions not only protects academic freedom and inventors’ rights, it requires universities to work more collaboratively with faculty, both in negotiations over individual faculty inventions and in developing shared protocols to guide invention management university-wide. Currently, most universities operate without shared written protocols to guide invention-management and technology-transfer operations, leading to widespread criticism (from faculty, industry, and private foundations) that they are unaccountable, overly focused on maximizing university profits, and often ineffective in

managing inventions.

One general caveat applies to all invention-management negotiations: no party to a contract is inherently immune to disabling motivations. Like administrators, inventors may be susceptible to greed or competition with other investigators. Inventors may also be generally indifferent about challenging intellectual property and contracting decisions, further strengthening the argument for shared governance and written protocols. Such protocols would benefit the community at large by articulating the university's and the faculty's academic, research, and public-interest obligations when transferring academic knowledge to society and would include safeguards for knowledge sharing, broad dissemination of new knowledge, protection of public health, etc.

The *Stanford v. Roche* decision opens the door for faculty to press for far stronger inventor rights than they currently enjoy as well as for stronger shared-governance systems around invention management. However, faculty face considerable opposition from universities, their associations, and technology-transfer officers deeply invested in the status quo. Propelled by the Bayh-Dole Act and other legislative reforms discussed above, US universities have invested heavily in technology-transfer and commercialization operations over the last three decades. From 1983 to 2003, patents issued directly to American universities grew by nearly an order of magnitude, from 434 to 3,259 patents.⁵¹ The overwhelming majority of the patents were concentrated in biomedicine, but they also covered software, agriculture, and numerous other academic fields. Total annual revenues from the licensing of university inventions increased from roughly \$200 million in 1991 to \$1.85 billion in 2006.⁵² In 2007, the Association of University Technology Managers (AUTM), composed primarily of university technology-licensing officers, reported a total of 3,148 cumulative, operational startup firms associated with US university patenting and licensing activities.⁵³

The figures look impressive. However, contrary to the assumptions of the vast majority of academic administrators following Bayh-Dole's passage, most universities have not generated substantial income from patenting and licensing activities. Only roughly two dozen US universities with "blockbuster" inventions generate sizable revenue from patents.⁵⁴ A 2006 econometric analysis found that, after subtracting the costs of patent management, US universities netted "on average, quite modest" revenues from 1998 until 2002, two decades after Bayh-Dole took effect. This study concluded: "universities should form a more realistic

perspective of the possible economic returns from patenting and licensing activities.”⁵⁵ Lita Nelsen, the head of technology licensing at MIT, commented similarly: “the direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research). . . . [M]ost university licensing offices barely break even.”⁵⁶ Difficulty breaking even is especially true for licensing offices less than twenty years old and for institutions with annual research budgets of less than \$100 million.

Supporters of Bayh-Dole hoped the legislation would unleash new incentives for universities to commercialize academic inventions and thereby speed the pace of technological innovation in the United States. Here too, however, the legislation’s economic legacy has been distinctly mixed. University patents on academic inventions soared after Bayh-Dole. But studies have found that academic patenting does not closely correlate with increased industrial use and/or commercial development of academic discoveries.⁵⁷ A 2002 study examining the patent portfolios of Stanford and Columbia universities found that of eleven major inventions, seven would have been commercialized without any assertion of patent rights or licensing by academic technology transfer offices, because “strategically located people in industry were well aware of the university research projects even before the universities began to market the inventions.”⁵⁸

Other surveys have found that patenting and licensing are not, in fact, the surest pathways for most industries to access academic knowledge and inventions.⁵⁹ A survey of firms in the manufacturing sector reported that the four highest-ranked channels for accessing university knowledge were all traditional, so-called open, academic channels: publications, conferences, informal information exchange, and consulting.⁶⁰ Even in pharmaceuticals, where patents and licenses are considered far more important to facilitate commercialization, firms still rely heavily on traditional open channels.⁶¹

The Bayh-Dole Act and subsequent tax incentives were not the only forces stimulating increased university patenting and commercial activity. Changes in US patent laws provided another stimulus by vastly expanding the types of basic academic knowledge eligible for patent protection to include genetic code, human genes, medical processes, and algorithms in computer code.⁶² Some have expressed concerns that increased academic patenting, and other types of intellectual property controls, could shrink the public commons for basic scientific knowledge,

long considered a wellspring for future invention and discovery. (This issue is discussed further below.)

The emergence of talk about a “knowledge-based economy” further spurred academy-industry engagement. In one 2004 study, industry representatives reported that universities had become more important to industry due to the locus of technical change moving closer to “science” in fields such as biotechnology and information technology. Business representatives have credited the decline in direct industry spending on basic research and the closing of industry-based R&D labs, following the wave of corporate restructuring in the 1980s, with being another driver.⁶³

The 2004 study also found universities’ primary motivation for industry partnerships stemmed from changes in federal research support levels: “The real growth in federal R&D funding for universities was 16% between 1953 and 1968 and 1% between 1969 and 1983, followed by an upturn to 5% between 1984 and 2000, but with substantial declines in non-biomedical areas.”⁶⁴ According to more recent data from the federal agencies, inflation-adjusted obligations for academic R&D peaked in 2004 at \$22.1 billion (in constant 2000 dollars) and have since declined by almost 7 percent to an estimated \$20.7 billion in 2009.⁶⁵ The federal declines, combined with declines in state funding as a share of overall expenditures, have left universities increasingly reliant on tuition, alumnae giving, endowment interest, private fundraising, research licensing, and funding from industry sources.⁶⁶

The evolution of science itself is another force driving academy-industry engagement. Both the biotechnology and information technology revolutions were born in academic laboratories. Moreover, the practice of science has become a far more collaborative enterprise. As the Business-Higher Education Forum observed in a two-year study of academy-industry partnerships: “the increasing volume and accelerating pace of knowledge creation has transformed the research process to the point where no one scientist, institution, or even nation can sufficiently conduct wholly independent research programs; rising costs, driven by increasingly complex research, make resource-sharing an imperative. Changes in the nature of innovation largely depend on multidisciplinary approaches and use tools from a range of seemingly unrelated fields.”⁶⁷

The US government has also been actively encouraging academy-industry-government engagement through its grant-allocation system.⁶⁸ Government-academy-industry partnerships

now span a wide range of sectors: electronic storage, flat-panel displays, turbine technologies, new textile manufacturing techniques, new materials, magnetic storage, next-generation vehicles, batteries, biotechnology, optoelectronics, and ship construction. According to one estimate, because of the federal government's growing preference for allocating R&D funds through corporate "matching grants" and other industrial cost-sharing research arrangements, private industry now directly influences 20 percent to 25 percent of overall university research funding.⁶⁹

In a 2007 interview with the Center for American Progress,⁷⁰ Jilda D. Garton, the associate vice provost for research at Georgia Institute of Technology—a top US engineering school—stated that roughly half the industry money that now pays for academic research at Georgia Tech comes from federal grants originally issued to corporations through various cost-sharing arrangements. After corporations receive federal research grants, they frequently contract with US universities to perform the actual research, though the federal government dictates terms. This way, US taxpayer funding that began as "public" in character effectively turns "private" by the time the money reaches academic investigators in their labs.

Public-private partnerships are now actively encouraged through a variety of federal grant programs, including the National Manufacturing Initiative; the National Science Foundation's "engineering research centers" and "science and technology centers;" National Institute of Standards and Technology's Manufacturing Extension and Advanced Technology Program (dual use programs run by the Department of Defense); Small Business Innovation Research (SBIR); Cooperative Research and Development Agreements (CRADAs).

Historically, according to a 2003 National Science Board survey, the National Institutes of Health (NIH) did not provide grants to industry. However in 1998-1999, NIH had 166 CRADAs providing access to government resources and supporting public-private research partnerships, and its SBIR program issued more than \$300 million to small companies. That same year, the Department of Energy (DOE) operated 700 CRADAs.⁷¹ In 2008, a DOE official told the Center for American Progress that the agency distributed roughly 80 percent to 90 percent of its federal funds for efficient and renewable energy R&D through some form of public-private cost sharing. Usually, corporate beneficiaries are asked to contribute matching grants of 20 to 50 percent, depending on the project and its potential commercial application.⁷²

Types of Academy-Industry Research Collaboration

Industry support of university research takes a variety of distinct forms, from smaller, more casual grants issued to individual researchers to larger, more institutionalized research consortia involving dozens of firms that pay fees to support a quasi-permanent research facility. As Bronwyn H. Hall, a UC Berkeley economist, observed: “The implication of this variety is that no one data source provides information on university-industry partnering, so that it is hard to get a picture of the system as a whole.”⁷³ Below are some of the main types of academy-industry relationships (AIRs):

Common Types of Academy-Industry Relationships (AIRs):

- 1. Research Contracts:** Industry support of a scientist’s or a group of scientists’ university-based research, usually in the form of a grant or a contract. These may be initiated by academic scientists, industrial sponsors, and/or company scientists. Institutions can benefit financially when research grants support salaries and facilities which otherwise would have to be supported by the institution, fund raising, or other grants.⁷⁴ Unfortunately, while research contracts, like federal and foundation grants, can facilitate expansion of investigations into new areas or enhance existing ones, research contracts often fail to cover full indirect costs. Universities, therefore, may actually lose money on them.
- 2. Consulting:** Academic faculty member provides advice, service, or information to a commercial firm or organization. Individual scientists retain consulting funds over and above their institutional salaries. Institutions can benefit financially when faculty use the money to support professional activities they would otherwise charge to the institution.⁷⁵

3. **Industrial Consortia:** Large laboratories funded through a consortia agreement involving several, or even dozens of, firms, such as the Stanford Center for Integrated Systems. Companies usually pay annual membership fees to participate in consortia, with academic research results and discoveries shared among all the consortia members under nonexclusive licensing terms.

4. **Quasi-permanent University-Industry Research Centers (UIRC)s and Engineering Research Centers:** UIRCs are partially funded by the federal government and partially by industry.⁷⁶

5. **Strategic Corporate Alliances (SCAs):** SCAs are multi-year, multi-million dollar sponsored-research alliances, commonly negotiated with just one corporation, set up to fund many campus-based labs and faculty research projects at once. SCAs have existed for a long time at MIT, Stanford University, and other campus, but in the last decade they have become more prevalent, especially in the pharmaceutical and energy research sectors. SCAs are further defined further and addressed in detail in the AAUP's accompanying "Recommended Principles and Practices" statement. Because SCAs often permit corporate sponsors to powerfully influence the university's research portfolio, resources, and internal governance systems, SCAs can raise distinct institutional conflict of interest concerns. As with other research contracts, SCAs may not cover full indirect costs, and they may also redirect core departmental teaching and research missions.

6. **Clinical Research Trials:** Pharmaceutical, biotechnology, and medical device manufacturers often finance academic investigators to test the safety and efficacy of their medical products. Clinical research trials are also discussed at length in the AAUP's accompanying "Recommended Principles and Practices" statement because a large body of empirical research has shown that corporate sponsors frequently exert undue influence over the conduct and reporting of university-based clinical trials, and faculty investigators also frequently have personal financial interests in their research.

7. **Licensing:** Licensing grants industry the rights to commercialize university-owned or co-owned technologies in exchange for royalties or other profit-sharing arrangements. Most universities now have dedicated offices of technology transfer or technology licensing, which handle all university-generated intellectual property and related patenting, copyright, and licensing matters. Most universities share some of the financial benefits of licensing with faculty inventors. As noted above, however, few licensing agreements make significant money for universities.

8. **Equity:** Academic faculty and academic institutions participation in the founding and/or ownership of new companies commercializing university-based research. Often these cash-poor companies provide equity or options to purchase equity as compensation for relationships, such as consulting and licensing relationships described above. Equity relationships are especially common in biotechnology, but occur in other fields as well.⁷⁷

9. **Training:** Companies provide support for graduate students or postdoctoral fellows, or contract with academic institutions to provide various educational experiences, such as seminars or fellowships, to industrial employees.

10. **Gifts:** The transfer of funding and/or resources (scientific or nonscientific), independent of an institutionally negotiated research grant or contract, between an industry group and an academic institution and or an individual faculty member. Gifts may include discretionary funding, equipment, biomaterials, support for travel to professional meetings, and entertainment (tickets to sporting events, cultural events, dinners, resort travel).⁷⁸

Strategic Corporate Alliances (SCA)

As noted earlier, biomedicine, including industry sponsorship of clinical trials, is one of the only areas of academy-industry collaboration that has received close scholarly scrutiny. Most other types of academy-industry collaboration have received little to no independent scholarly examination. In recent years, however, several university committees and faculty senates⁷⁹ have turned their attention to the emergence of large-scale, multi-year strategic corporate alliances (SCAs) on campus. Many universities have determined the alliances need more rigorous oversight due to their unique size, scope, and structure, and their tendency to grant industry sponsors an unusual degree of research influence and administrative or governing control.

For example, after the conclusion of the University of California, Berkeley-Novartis alliance—a five-year, \$25 million research collaboration from 1998 until 2003—independent researchers at Michigan State University performed a formal review and emphasized the need to “reassess in a comprehensive fashion the implications of non-financial and institutional conflicts of interest” associated with large-scale SCA agreements.⁸⁰ Cornell University’s faculty senate reached a similar conclusion after it convened a special panel to evaluate the emergence of SCAs on their campus. In the case of an SCA, “the essential quality of academic independence from the sponsor is more difficult to maintain at an institutional, as well as individual, level,” the panel wrote. “Therefore more formal decisional processes and oversight mechanisms are appropriate as continual self-checking and self-correcting mechanisms.”⁸¹

An independent analysis of ten SCA agreements signed by US universities and large energy firms—published in 2010 by the Center for American Progress, a think tank based in Washington, DC—found SCA legal agreements signed by academic institutions tend to grant industry sponsors substantial internal governing authority and research control, while providing few safeguards for research independence and academic freedom. (See the box below for details.)

Big Oil Goes to College

Center for American Progress, 2010⁸²

Summary of Findings:

- In nine of ten industry agreements, for example, university partners failed to retain majority academic

control over the central governing body charged with directing the SCA. Four of ten alliances granted the industry sponsors full governance control.

- Eight of ten agreements permitted corporate sponsors to fully control both the evaluation and selection of faculty research proposals in each new grant cycle.
- Only one of ten agreements required any specific management of financial conflicts of interest related to the alliance and its research functions. Most of the universities, in their written comments concerning the findings, stated that their standard campus-wide conflict-of-interest policy was sufficient.
- None of the ten agreements required use of independent expert peer review for evaluating faculty research proposals, the traditional method for awarding academic and scientific research grants fairly and impartially based on scientific merit. A given company evaluation may, of course, be sound, but peer review, however flawed, is more likely to be impartial. (Two universities reported that, in practice, they are using “independent peer review,” though the written contract does not require it. However, in one of these cases, the report documents how the SCA committee charged with final research selections is composed of faculty members who have nearly all received SCA grants themselves, raising serious questions about the selection committee’s impartiality.)
- Eight of ten alliance agreements failed to specify transparently, in advance, faculty application, evaluation, and selection procedures.

The Benefits of Academy-Industry Engagement

Dating back to the mid-1800s, enduring benefits have come from collaborations between American universities and private industry. Here, we briefly explore the benefits from the perspective of US universities.

In addition to providing critical financial support for universities’ educational and research missions, a 1995 Industrial Research Institute report identified the following academic opportunities from academy-industry collaborations: i) to fulfill the university’s service mission and demonstrate the value of academic research and expertise; ii) to broaden the experiences of

students and faculty; iii) to identify interesting problems and relevant applications for university research inquiry; iv) to enhance regional economic development; v) to increase employment opportunities for students after graduation.⁸³ Industry also brings new technology campuses and can advocate for state support for research at public institutions.

When working with industry, academic investigators often find that knowledge flows not only from the university to industry but also from industry to the university. Knowledge that flows both ways often benefits faculty research. The interaction between university faculty and companies can enhance the quality of research, ensure results stand up to reason and practice, and lead to substantially better understanding of the technology involved and the underlying research questions. Perhaps that is unsurprising. The breakthrough work underlying the questions university scientists ask has often arisen in practice and in industry. Companies, paradoxically, can both cause problems and be powerful agents in solving them. In that regard it is worth remembering that companies spend millions of dollars trying to replicate published claims of discovery based on university research, much of it publicly funded, sometimes without success. Efforts to evaluate and validate university research claims also contribute toward the advancement of knowledge. Innovation is by definition a learning process, ever testing the status quo and consensus responses to proposals for technological and social change. The give-and-take between industry and campus researchers plays a key role in the testing process.

According to a 2002 Business Higher Education Forum survey of university researchers, another benefit of corporate sponsorship is that it imposes less of an administrative burden than filling out the federal government's voluminous grant applications. Researchers also point out that additional visibility from academy-industry research collaborations can lead to greater peer recognition and, in some cases, enhanced consulting opportunities.⁸⁴

Furthermore, many entrepreneurial faculty report that they enjoy pursuing research with real-world applications and are highly motivated to translate ideas into applications with direct public benefits. These faculty relish their involvement with exciting new businesses, rapidly developing technology, and practical, market-relevant research. For many academics, collaborations with industry scientists provide invaluable access to know-how and expertise concerning the practical applications of academic discoveries, scaling for commercial production, and market considerations.

There is some evidence that industry partnerships may also enhance faculty members'

competitive positions for receiving federal research grant awards.⁸⁵ Industry support can be increasingly advantageous when more and more federal research funding is awarded in conjunction with corporate matching grants, on the basis of evidence that the research proposed already has evident commercial applications.

Collaborations also commonly facilitate faster commercial adoption of academic knowledge. One study found that faculty *with industrial research relationships* were significantly more likely than faculty *without* to report being involved with a start-up company (14% compared to 6%), applying for a patent (42% versus 24%), having a patent granted (25% versus 13%), having a patent licensed (18% versus 9%), having a product under review (27% versus 5%), or having a product on the market (26% versus 11%).⁸⁶ Of course, these associations do not necessarily prove causal relationships: industry may fund scientists who are already more productive or whose research areas already have a greater likelihood for commercial application. Alternatively, industry may provide funding that allows scientists to be more successful commercially or encourages them to be more commercially active.⁸⁷

Although some untenured faculty members see industry financing as an attractive opportunity, others, understandably, worry about the effect of the pressure to obtain industry funding on tenure decisions. The pressure to raise research funds in academia long predates the intensified pursuit of corporate funds. But declines in federal funding for research (in constant dollars) and state funding for basic operations (leading public institutions to shift resources away from research), often leave untenured faculty little choice but to accept available industry money. Institutional and monetary pressures also can lead tenure-track faculty members to seek grants from industry, rather than from the government or nonprofits, if the latter involve less funding. Rather than pursue topics based on academic merit, faculty may feel pressed to serve “the market.” Market forces can generate valuable research and serve public interests, but academic freedom and innovation benefit from greater freedom of choice.

Another related pressure arises when faculty (in medicine especially, but in other academic disciplines as well) are expected to use outside research grants to fund a portion of their own salaries. They may well feel extreme pressure to “serve the market.” The pressure can introduce unconscious bias into research selection. Faculty should not feel beholden to market pressures and should not evaluate research solely based on its potential short-term commercial value. They should be free to work on fundamental science, neglected areas of inquiry, and public-good

research, and they should feel free to contribute to the public body of knowledge (such as through the development of open source software), rather than to seek proprietary dissemination of the fruits of their research. Market pressures seriously threaten academic freedom. The threat emanates from outside the university as well as from within it.

For some students and more junior faculty members, however, industry collaborations may be a significant recruitment draw, with an increasing proportion of university graduates now moving into private-sector careers. Commercial research collaborations may provide students with valuable corporate research experience and lead to early job offers. Still, as the Business-Higher Education Forum survey cautions, “sponsored research also may pose risks” for students and junior faculty. “Universities should not divert graduate students toward efforts that will not advance their education or their thesis research,” the survey says. “If students’ work is hemmed in by corporate confidentiality requirements, they may find themselves barred from presenting their work at scientific meetings—or, even worse, unable to publish a Ph.D. thesis.”⁸⁸

Significantly, a growing body of empirical research has found that faculty with industry research relationships are more productive (even when measured in traditional academic terms) than faculty who do not. A 2009 survey of more than 3,000 faculty in the life sciences found that, across all measures, those with industry relationships were more academically productive.⁸⁹ They published significantly more and at a greater rate (in the past three years) than respondents unconnected to industry. The average journal impact factor of the most recent five articles was also significantly higher for respondents with at least one industry relationship. Earlier research corroborated the finding, showing that articles with joint academy-industry authorship have significantly higher citation rates than publications with single- or multiple-university authorships.⁹⁰ Moreover, researchers with at least one industry relationship conducted more service activities in their institutions or disciplines than respondents without industry relationships. Finally, academics with industry relationships spent significantly more weekly hours performing outside professional activities, such as giving external lectures and working with professional societies and advisory groups. The findings remained constant over time when the authors compared 1995 with 2006 survey data.⁹¹

A 2007 study,⁹² the first longitudinal analysis of medical school faculty patenting, also found that, despite public concern that the Bayh-Dole Act had transformed the ethos of medical schools by making them more proprietary, patenting activities are concentrated among a small

number of departments and faculty, and the most prolific academic patenters remain active in traditional scientific activities.

More subtle is the question of how sponsored research is designed or selected for funding. Might these industrial collaborations unduly influence the research agenda of the university or medical school as a whole, as well as individual researchers, pushing the focus from more fundamental to applied research? Or might the collaborations steer research toward more commercially profitable areas and away from “public good” research, (such as research on environmental toxins, third world diseases, or global climate change)? The latter question has not been examined empirically. However, the former has, and generally, studies have failed to document a sizable shift in the balance between basic and applied university research.⁹³

The Risks Academy-Industry Engagement Poses

In this section, we turn to the risks associated with heightened forms of academy-industry engagement. However, we should note that risks and benefits are often fundamentally two sides of the same coin. Many of the benefits highlighted above—including opportunities for service learning, applied or translational research, enhanced student job opportunities, contributions to economic development, increased research opportunities, and demonstration of the practical value of academic research—are the selfsame forces that can generate financial conflicts of interest and threaten the open culture of the university.

Most of the risks can be substantially moderated by adopting the principles we put forward in this AAUP report. However, we recognize that the risks will be difficult to eliminate entirely unless funding sources are concealed from researchers—a standard that would be in most instances impractical if not impossible to observe comprehensively.

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RISK 1: Violations of Academic Freedom and Researcher Autonomy

Some industry sponsors have tried to directly interfere with faculty members' core academic freedom by blocking or impeding their ability to carry out and publish truly independent research.

The proprietary nature of some sponsored research—including confidentiality restrictions, publication delays, or industry requests for editorial changes—may jeopardize the university's core commitment to free and open inquiry.

Most university sponsored-research contracts try to include provisions securing faculty's legal rights to publish. However, notable contracts that fail to secure basic academic publication rights have slipped through. And many more university contracts fail to properly secure these rights (see Risk #6 below) by allowing industry sponsors to control data access, write manuscripts, insert their own statistical analyses, and make final editorial revisions.

In recent decades, there have been numerous academic freedom disputes over professors' rights to publish or speak about what they believe to be true. Among the more well-publicized are the cases of Aubrey Blumsohn, Ignacio Chapela, Betty Dong, Tyrone Hayes, David Healy, James Kahn, David Kern, and Nancy Olivieri. All these cases came to light because faculty members, usually at great cost to their own careers and reputations, refused to tolerate industry interference with their professional work. First we will review a few of these clinical-research cases, and then we will turn to cases in other disciplines.

Thalassemia: The Case of Nancy Olivieri

In 1996, Dr. Nancy Olivieri, a University of Toronto professor, and her research colleagues, found that deferiprone, used to treat thalassemia, an inherited, potentially fatal blood disorder, could worsen hepatic fibrosis. When she moved to inform patients, the drug's manufacturer, Apotex Inc., prematurely terminated the clinical trials. Simultaneously, the company threatened legal action against Olivieri if she attempted to disclose the risk to her patients or the medical community. Several months later, after a thorough review of patients' charts, Olivieri identified a second, more serious risk. Again, Apotex issued legal warnings against disclosure.

The academic contract Olivieri and her hospital signed with Apotex was poorly drafted and

forbade disclosure of results for up to three years without the company's consent. The prohibition violated Olivieri's professional medical, ethical, and academic obligations.

Despite the threat of a lawsuit and ineffective assistance from her university and its affiliated hospital, Olivieri informed her patients and the scientific community of the risks she had identified. The dispute became public in 1998, when Olivieri published her findings in a leading scientific journal.

Since then, Olivieri has faced work restrictions and public criticism. Her hospital, Apotex and some colleagues have tried to discredit her. However, an independent investigation by the Canadian Association of University Teachers (CAUT),⁹⁴ found that Olivieri's academic freedom rights were violated. The investigators also found other serious violations of her professional rights and responsibilities.⁹⁵

Thyroid Conditions: The Case of Betty Dong

In 1987, the manufacturer of Synthroid (levothyroxine) contracted with Dr. Betty Dong, at the University of California at San Francisco, to study whether its drug was more effective than competing preparations for treating thyroid conditions. In 1990, Dong found Synthroid no more effective than other preparations, including cheaper generics. The sponsoring company, Boots Pharmaceuticals and later Knoll Pharmaceuticals, refused to allow the findings to be published. The pharmaceutical company's contract with UCSF required the manufacturer's consent before releasing information. The prohibition violated the university's own written policies.

Over the next four years, Boots/Knoll waged a vigorous campaign to discredit the study and prevent publication, claiming the research was flawed. Two university investigations found only the most minor and easily correctable problems in Dong's research and concluded that the company's attacks amounted to "harassment" designed to prevent publication. Eventually, the study passed the *Journal of the American Medical Association's* peer review process and was scheduled for publication on January 25, 1995. Shortly before publication, however, the company threatened a lawsuit.

At that point, it seemed unlikely that Dong's research would see the light of day. Then a *Wall Street Journal* reporter learned about the study and wrote an article exposing what had

happened.⁹⁶ Soon, pressure from the Food and Drug Administration forced Knoll to back off, and the study finally appeared in *JAMA* in 1997.⁹⁷ The lengthy delay was a huge victory for Boots/Knoll because it enabled the company to sustain Synthroid's dominant market position.⁹⁸ For the general public, it was not a good story. Dong and her colleagues estimated that if an equally effective generic or brand-name preparation were substituted for Synthroid, patients would have saved \$365 million annually in lower drug prices.⁹⁹

AIDS: The Case of James Kahn

In September 2000, Immune Response, a biopharmaceutical company, sued the University of California at San Francisco for \$7 million, after Dr. James Kahn and other researchers declared they were moving forward with publication of the findings from a clinical trial of the company's experimental acquired immunodeficiency syndrome (AIDS) vaccine, Remune, which they found ineffective.

The investigators refused to allow the company to insert its own statistical analyses into the manuscript.¹⁰⁰ The sponsor, Immune Response, demanded that the researchers not publish the article and withheld part of the study data in an effort to dampen publication prospects.¹⁰¹ However, the investigators persuaded the *Journal of the American Medical Association (JAMA)* to proceed with publication, with an explanation of the circumstances.¹⁰² After publication, Immune Response sued, and the legal battle ended only after the university countersued alleging that the contract did grant the researchers permission to publish.¹⁰³

Several well-publicized academic freedom cases have also arisen in fields outside of clinical research, including in occupational health, environmental toxicology, and agricultural research.

Environmental Toxicology: The Case of Tyrone Hayes¹⁰⁴

In 1998, the same year the University of California at Berkeley signed a \$25 million research alliance with Novartis, later renamed Syngenta, Tyrone Hayes, a biologist at Berkeley, accepted a \$100,000 grant from Pacific EcoRisk, a consulting firm Novartis-Syngenta hired to

study the effects of its most popular weed killer, atrazine, on frogs. Atrazine, among the most heavily applied herbicides in the United States, is widely used on agricultural croplands, golf courses, and lawns and leaves chemical traces in streams, waterways, and rainwater throughout the United States, especially after the planting season.

Not long after Hayes's research began, he turned up disturbing results. Exposure to atrazine appeared to disrupt male frogs' sexual development. Their voice boxes shrank, and they developed ovaries. The research suggested that atrazine was part of a family of chemicals known as endocrine disrupters. Even in minute traces, they can significantly interfere with hormones that regulate key biological activities in both wildlife and in humans. Hayes wondered if atrazine use might explain why fifty-eight amphibian species had disappeared or become extinct and another ninety-one had been listed as endangered in the past twenty years.¹⁰⁵

Although Hayes was eager to publish his research, he soon learned that his contract gave EcoRisk and Syngenta ultimate control over publication. Like in the Betty Dong case, the University of California grants office had overlooked this glaring breach of its own policy on publication. EcoRisk called in its own consulting group, the Atrazine Endocrine Risk Assessment Panel chaired by Texas Tech University Professor Ronald J. Kendall, to evaluate and analyze Hayes's results. Hayes suspected that the panel's true purpose was to forestall publication, and he quit.¹⁰⁶ Soon after, Hayes acquired enough new funding (from W. Alton Jones, the World Wildlife Fund, and the National Science Foundation) to continue his research, the first part of which he published in the April 2002 *Proceedings of the National Academy of Science*.

The study had an immediate impact because the US Environmental Protection Agency was, at that precise moment, reviewing the atrazine's safety to determine whether to reauthorize it for use as an herbicide. The EPA's scientific panel had been leaning in favor of reapproval until it saw Hayes's scientific results. They showed atrazine levels as low as 1 part per 10 billion in water could cause tadpoles to develop into frogs with both male and female sexual organs. If Hayes's results were accurate, serious hormone disruption was occurring at concentrations thirty times lower than the EPA's then-approved levels.¹⁰⁷ By 2002, much of Europe had already banned atrazine due to safety concerns.

Alert to the financial and political stakes involved, Syngenta and EcoRisk quickly tried to discredit Hayes' study. On June 20, 2002, they issued a press release announcing that "three

separate studies by university scientists have failed to replicate” his findings.¹⁰⁸ None of the studies had been published in peer-reviewed journals; Syngenta had underwritten them all. One study, written by Texas Tech’s James A. Carr, EcoRisk’s Kendall, and others, later appeared in the journal *Environmental Toxicology and Chemistry* (ET&C)—where Kendall was an editor. Prior to publication, Kendall was quoted in a press release saying: “As research on this issue continues, one thing is certain. No conclusions can be drawn at this time on atrazine and its purported effect on frogs.”

How independent were the studies? Syngenta informed the EPA that the Texas Tech study published in ET&C “was conducted under the direction and auspices of an independent scientific panel.” However, Goldie Blumenstyk, an investigative reporter with the *Chronicle of Higher Education*, challenged the study’s independence. She revealed that under the \$600,000 contract between Texas Tech and EcoRisk all research data and analyses belonged to EcoRisk “and/or its client.” Furthermore, any publication of the research required “appropriate review and written permission by EcoRisk.”¹⁰⁹

In October 2002, Hayes published a second study in *Environmental Health Perspectives*,¹¹⁰ and a shorter piece in *Nature*, based on field research examining native populations of frogs at eight sites, seven of which had detectable traces of atrazine. At one site in Wyoming, 92 percent of the male frogs actually had immature eggs inside of them. At six of the other sites, the researchers found 10 percent to 40 percent of the frogs were hermaphrodites. The only site where they found only normal males was the one where they detected no traces of atrazine.

Once again, Hayes’s research came under attack. This time, the EcoRisk panel, the Kansas Corn Growers Association, and an association of 1,000 growers and herbicide manufacturers called the Triazine Network challenged the validity of Hayes’s research. Under a law known as the Data Safety Quality Act of 2001, they petitioned the EPA to disregard all Hayes’s findings. Nevertheless, in June 2003, an EPA scientific advisory panel found “sufficient evidence” to hypothesize that the country’s most widely used herbicide, atrazine, causes sexual abnormalities in frogs. The panel called six studies showing a variety of defects, including the development of multiple testes and multiple ovaries, persuasive and significant.¹¹¹

Four months later, however, when the EPA issued its final ruling, it reversed course and reapproved atrazine’s use as a weed killer. Critics cried foul, noting that Kendall, who oversaw the \$600,000 Syngenta-EcoRisk grant at Texas Tech, also sat on the board of the EPA’s

scientific advisory panel on atrazine and its endocrine-disruptor screening committee, both of which would have had a say in a final decision on atrazine's reapproval.¹¹²

Occupational Health: The Case of David Kern

Dr. David Kern served as a faculty member at Brown University's School of Medicine for fifteen years, starting in 1984; during his last five years, he was an associate professor. He also worked as a clinician at Brown's affiliated Memorial Hospital, where he directed an environmental- and occupational-health clinic. The following account—drawn from a 2011 article in *Academe*¹¹³—is based upon primary documents that Kern provided to the AAUP¹¹⁴, an official Brown University investigation¹¹⁵ of Kern's case, and Kern's own account¹¹⁶ published in the *International Journal of Occupational and Environmental Health*.¹¹⁶

In the mid-1990s, Kern saw two patients suffering from a rare lung condition; both happened to work at the same factory run by Microfibres, Inc., a Rhode Island manufacturer of nylon-flocked fabrics. Microfibres was a hospital donor, and its owner and two family members sat on Memorial's board. With the company's permission, Kern and his students made one preliminary visit to Microfibres's factory to conduct air tests but turned up little. Fifteen months later, in March 1996, Kern proposed that Microfibres hire him as a consultant to conduct a more thorough health investigation, and the company agreed.¹¹⁷

Records show that Memorial Hospital processed Kern's consulting payments but did not negotiate a formal research contract with Microfibres. Kern states that he separately pressed Microfibres to sign his own clinic contract, but when the company refused, he pressed ahead with his investigation seeking to uncover the cause of his patients' illnesses.

Soon Kern identified 10 workers out of 165 at the Microfibres plant who were suffering from variations of the same rare condition, known as interstitial lung disease. He also identified a similar lung outbreak in a Canadian nylon-flocking factory and soon determined that he had sufficient evidence to publish an article about what he believed to be a new lung disease. Kern informed Microfibres of his plan to publish and present his findings at an American Thoracic Society meeting in May 1997. The company responded by threatening to sue, citing a confidentiality agreement Kern had signed fifteen months earlier, during his initial air-testing visit. Kern turned to Brown University for support, but

Brown officials told him not to publish or present his findings. In a document dated November 18, 1996, Peter Shank, Brown's associate dean of medicine and research, told Kern that, based on the earlier confidentiality agreement, "I see no way in which you can publish results of your studies at the company without their written approval. . . . You should immediately withdraw your abstract [from] the national meeting."¹¹⁸

Kern said he was shocked. Patients' lives were at stake. One had already died; two others were seriously ill. In Kern's view, Brown had a moral and medical obligation to make his research public and to ensure that workers under his care, as well as workers at other nylon-flocking plants, received appropriate preventive treatment and care. Besides, it was Kern's opinion—and that of his legal advisers—that the confidentiality agreement Kern had signed during his prior air-testing visit referenced only "trade secrets," which Kern's health investigation would not touch upon or disclose.

Then, in a December 23, 1996, memorandum, Memorial's president instructed Kern to "withdraw [his] abstract from publication or presentation before the deadline of Jan. 15, 1997." The hospital, he stated, was shutting down Kern's entire occupational-health program "effective immediately."¹¹⁹ Brown's medical school dean, Donald J. Marsh, initially stated publicly that he was never consulted about the closure of Kern's program, but in an April 30, 1997 letter to the hospital's president, he wrote that he was notified and "raised no objection."¹²⁰

Over the course of the spring and summer of 1997, Kern's case attracted the attention of high-profile public health professors, resulting in more than one hundred letters addressed to Brown protesting Kern's treatment. Kern also sought help from Brown's faculty senate and the AAUP, but an organized defense of Kern never materialized.

Kern proceeded with his publication¹²¹ and presented evidence at the thoracic society conference of what he considered to be a new lung disease. Brown issued a statement at the time noting that "many questions remain unresolved" about the case but expressing support for Kern "in his right to conduct research and in his academic freedom to publish results."¹²² Less than a week after the conference, however, Kern received letters from Brown's president, Vartan Gregorian, and from the president of Memorial Hospital, Francis Dietz. They said that, as a result of the closure of the occupational-health program, Kern's teaching and research were being eliminated. Kern would remain at the hospital until his five-year contract ended in 1999, but the closure of his program left him unable to seek research contracts within his field of occupational and environmental medicine. Memorial Hospital also barred him from treating his former Microfibres patients. Later that fall, Kern received a letter from the Centers

for Disease Control and Prevention officially recognizing the new disease he had identified: flock worker's lung.

More than thirteen years after his first publication¹²³ exposing the dangers of flock workers lung, in 2011, Kern published a follow-up study in the *Journal of Occupational and Environmental Health*.¹²⁴ The article examined a longer-range set of public health records for the original cohort of male Microfibres workers. The study uncovered a threefold increase in lung cancer incidence among the male workers. Kern completed the study without the benefits of an academic research appointment, while working as a clinician providing inpatient hospital services at Togus Veterans Administration Medical Center in Augusta, Maine. If Brown-Memorial had allowed Kern to retain his faculty position and not barred him seeing his Microfibres patients, this potentially grave cancer risk would almost certainly have been uncovered far sooner, potentially saving workers' lives.

Agricultural Research: The Case of Ignacio Chapela

In November 2003, Ignacio Chapela, a UC Berkeley microbial biology professor and an outspoken critic of its \$25 million research alliance with Novartis-Syngenta, was formally denied tenure. Almost immediately after the announcement, large numbers of faculty protested the decision and questioned whether an objective assessment of his scholarship or politics drove Chapela's tenure review.

When Michigan State University researchers were invited to the Berkeley campus to conduct a formal, external review of the UC Berkeley-Novartis deal, they devoted an entire section of their final report to Chapela's tenure case: "Regardless of whether [Ignacio] Chapela's denial of tenure was justified, there is little doubt that the UCB-N agreement played a role in it. First, the very existence of UCB-N changed the rules of the game. Certain faculty were denied participation in the process because of the agreement. Second, while the administration saw fit to avoid conflicts of interest (COI) among faculty, they ignored the potential for COI among administrators. Thus, regardless of its validity, the decision of top administrators to accept the decision of the Budget Committee was seen by many as a COI."¹²⁵

In 1998, when UC Berkeley's College of Natural Resources first planned to sign a five-year, \$25 million research alliance with Novartis (later Syngenta) public, Chapela served as the elected chairman of the College of Natural Resources's executive committee, a faculty governing body. The position put him directly at the center of a vibrant faculty debate about the proposed

Novartis alliance, the largest single academy-industry alliance ever negotiated on the campus. Although not yet tenured, Chapela orchestrated a campus survey to gather faculty viewpoints on the alliance and candidly voiced his own reservations about the deal, creating rifts with other scientists, including other microbiologists in the Department of Plant and Microbial Biology, the department slated to receive the Novartis funding.

In the fall of 2001, Chapela and his graduate student, David Quist, reported in the journal *Nature* that foreign DNA material from genetically modified (GM) plants appeared to be migrating into native varieties of corn in southern Mexico, although Mexico had banned the planting of modified corn as early as 1998.¹²⁶ Corn was first cultivated in Mexico 10,000 years ago and remains the center of corn genetic diversity around the world, which is why both the Mexican government and the environmental community reacted nervously to the study's findings.¹²⁷ Like all *Nature* papers, the Chapela-Quist study was rigorously peer-reviewed prior to publication. The moment it was released, it became the subject of unusual scientific debate. A petition calling on *Nature* and Chapela to retract the study appeared on AgBioWorld, a biotechnology LISTSERV to which more than 3,000 scientists subscribe.¹²⁸ This type of backlash is not unprecedented in the agriculture-biotech sector, where a number of scientists who have published research critical of GM agriculture have had both their research and their personal integrity attacked, often by large agricultural interests with profits riding on the research.¹²⁹

What was striking about the Chapela-Quist case was that many of their harshest scientific critics who wrote letters to *Nature* and posted comments on AgBioWorld were directly tied to UC Berkeley's plant and microbial biology department, the beneficiary of the \$25 million in Novartis funding. Numerous current and former researchers in the department, for example, signed two group letters *Nature* published challenging the validity of Chapela's study.¹³⁰ Michael Freeling, a plant and microbial biology professor, signed the petition calling for a full retraction of Chapela's paper.¹³¹ With each side accusing the other of impure motives, and the Novartis-alliance controversy lurking, judging the Chapel-Quist study on purely scientific grounds became increasingly difficult.¹³²

Few disputed Chapela and Quist's main finding that genetically modified plants had contaminated native maize in Mexico. They disagreed over its significance. Biotech supporters maintained the contamination posed no threat, while critics worried that genetic contamination could erode plant genetic diversity and create other long-term ecological problems. Chapela and

Quist's second conclusion, concerning the movement of foreign DNA around the corn plant, sparked more controversy, with critics attacking the testing method of the researchers as unreliable. In the end, *Nature* did not retract the peer-reviewed paper, but it did do something unparalleled in its 133-year history: The journal printed an editorial note stating that the "evidence available is not sufficient to justify" the original publication and calling upon readers to judge the science for themselves.¹³³

Not surprisingly, the *Nature* study controversy became a central issue in Chapela's tenure review. At first, the College of Natural Resources voted thirty-two to one (with three abstentions) in favor of tenure. Then, an ad hoc tenure committee with five experts chosen for their ability to evaluate Chapela's research voted unanimously in his favor again. However, when the final arbiter, the budget committee—with members from across the college—denied tenure. Immediately, Wayne Getz, an insect biology professor and a member of the ad hoc committee, charged that the process had "gone awry." Then the chair of the ad hoc committee, who originally voted in favor of tenure, rescinded his recommendation.

As it turned out, a member of the campus-wide budget committee, genetics Professor Jasper Rine, had ties to the biotech industry, raising conflict of interest concerns.¹³⁴ In the past, universities only had to monitor their professors' potential conflicts of interest, wrote the Michigan State reviewers. But the Berkeley-Novartis agreement "raised issues of a different sort. In this case, it is the *institution's* potential for conflict of interest relative to the funds it receives that is at issue."¹³⁵ After Chapela was formally denied tenure, he filed a lawsuit challenging the fairness and impartiality of his tenure review. In May 2005, the university reversed its decision and granted tenure.¹³⁶

All of these cases are troubling because they represent instances when universities themselves have compromised a faculty member's academic freedom in deference to an industrial partner's economic interests. Moreover, as Patricia Baird commented in the *Canadian Medical Association Journal*, such well publicized cases "are likely only the visible tip of a bigger iceberg" because many academic investigators probably are reticent to speak out when threatened. "For many academic researchers," Baird explains, "the future prospects of their laboratories and careers depend on renewed industry funding. They also may be understandably reluctant to speak out: if they trigger a legal action, it is time consuming and expensive, and it

disrupts work and harms reputations. Large pharmaceutical companies, on the other hand, may see such legal expenses as a ‘cost of doing business.’ Even if a company ultimately loses an action, in effect they win by delaying publication of adverse findings for lengthy periods, and the case serves as a deterrent to others from acting independently.”¹³⁷

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RISK 2: Restricted Access to Data and Suppression of Negative Results

Another concern, related to academic-freedom threats, concerns access to data. In industry-supported clinical trial research with multiple trial sites, many academic investigators lack access to complete study data and depend almost entirely on company statisticians for data analysis. The phenomenon has been well documented.¹³⁸

In one published review, six academic investigators interviewed cited cases in which corporate sponsors stopped publication of research articles or altered their content. In many instances, the suppression was not publicly reported at the time.¹³⁹ In one case cited, Dr. Curt Furberg, a professor of public health sciences at Wake Forest University School of Medicine, reported that he refused to place his name on the published results of a study in which he was the principal investigator because the sponsor was “attempting to wield undue influence on the nature of the final paper. This effort was so oppressive that we felt it inhibited academic freedom.”

In a pivotal trial of Celebrex for treatment of arthritis, the manufacturer Pharmacia Corporation selectively published¹⁴⁰ only six months of clinical trial data, though the original protocol called for a longer trial, and the twelve-month outcomes were available when the manuscript was submitted.¹⁴¹ At six months, the outcomes clearly seemed to favor Celebrex compared with competing drugs, but at twelve months, most of Celebrex’s advantages disappeared because of ulcer complications that arose largely in patients taking Celebrex in the second part of the study.¹⁴² When Dr. M. Michael Wolfe, a gastroenterologist at Boston University who had penned a favorable review of the six-month study, learned of the deception, he told the *Washington Post*: “I am furious. I looked like a fool. But . . . all I had available to me

was the data presented in the article.”¹⁴³ None of the original study’s sixteen authors, including eight university professors, spoke out publicly about the suppression of data. All the authors were either Pharmacia employees or paid company consultants.¹⁴⁴

In 2001, concerns about the integrity of clinical trial research grew so serious that leading medical journal editors and the International Committee of Medical Journal Editors (ICMJE) condemned the intrusive industry influence and, in an effort to curb abuses, revised their collective requirements for manuscript submissions.¹⁴⁵ The revisions call for full disclosure of an industry sponsor’s role in the clinical trial research, as well as assurances that investigators are independent of the sponsor, are fully accountable for the trial’s design and conduct, have independent access to all trial data, and control all editorial and publication decisions. The guidelines aim to promote integrity and preserve public trust in the clinical research enterprise.¹⁴⁶

However US universities have generally been slow to affirm these academic freedom and research integrity principles in their own sponsored-research agreements with industry. One 2002 survey of 108 medical schools found that only 1 percent would guarantee academic investigators access to complete trial data associated with a multi-site clinical trial; 50 percent would allow the industry sponsor to write the final manuscript and only allow the investigators to review it and suggest revisions; 35 percent would permit a corporate sponsor to store the study data, and release portions to the investigators; 41 percent would allow a sponsor to prohibit investigators from sharing raw research data with third parties after the trial was over.¹⁴⁷ (This study and others are discussed at greater length under Risk #6 below.)

Some experts suggest universities fear losing pharmaceutical industry funding for clinical trials, 70 percent of which private industry now funds, due to increased competition from the for-profit research sector, which has been garnering a growing share of the market.¹⁴⁸ However, most medical experts agree these battles over data ownership and control must be resolved, if the research mission of US universities is to be preserved. As Dr. Aubrey Blumsohn, a pathologist and osteoporosis specialist denied access to his own trial data by Procter and Gamble, wrote in 2006: “If the industry wishes to sell its products under the banner of science, it has to accept the rules of science. Most importantly, as academics we need to reassert the importance of data and the meaning of authorship. We also need to assert ‘old fashioned’ ideas of academic freedom, our right to speak the truth as we see it, and to allow that truth to be

subjected to open debate. In the words of George Orwell (1984), ‘Freedom is the freedom to say that two plus two make four. If that is granted, all else follows.’¹⁴⁹

Dr. Robert Steinbrook, who has reported on “gag clauses” that block the access of researchers to data, wholly agrees: “A basic tenet of research ethics is that the data from clinical trials should be fully analyzed and published. If the knowledge gained from trials is not shared, subjects have been exposed to risk needlessly. Moreover, participants in future studies may be harmed because earlier results were not available. These principles are reflected in federal regulations regarding the protection of human subjects, which define research as ‘a systematic investigation designed to develop or contribute to generalizable knowledge.’¹⁵⁰

Numerous recent, high-profile drug scandals dramatize how critical data access and independent academic analysis of data are for protecting not only academic freedom but public health and the evidentiary foundation of medicine as well.

The Case of SSRI (Selective Serotonin Reuptake Inhibitor) Antidepressant Drugs

One striking case involves clinical trials assessing the safety and effectiveness of a broad class of drugs, known as selective serotonin reuptake inhibitors (SSRIs), to treat depression in children and teens.¹⁵¹ SSRIs, including top-sellers such as Zoloft, Paxil, and Prozac, are also prescribed widely to adults.

In 2004 in a letter to the FDA, Dr. David Healy, a medical expert who published on an early SSRI-suicide link, wrote: “There is probably no other area of medicine in which the academic literature is so at odds with the raw data.”¹⁵² Indeed, one meta-analysis of the *published* medical literature¹⁵³ concluded, in 2004, that antidepressant drugs were safe and effective, but a more comprehensive meta-analysis¹⁵⁴ published the same year and considering *published as well as unpublished data*, reached the opposite conclusion: that elevated risks of suicide outweigh the benefits for all but one drug in the entire class of antidepressants.¹⁵⁵

After doubts about the validity of the trials were raised, several academic authors of the SSRI trials in children were reportedly denied access to unpublished suicide data from their own clinical studies. The reason, they told the *New York Times*, was that US medical schools, in agreeing to run the tests, had also consented to permit the manufacturers to keep the underlying data confidential.¹⁵⁶

In October 2004, the Food and Drug Administration (FDA) announced that the entire class of SSRI antidepressants was associated with an increased risk of suicidal thoughts and actions in children and teens. The FDA also stated similar concerns might be true for adults and issued new patient warning labels. Nearly one year earlier, the British equivalent of the FDA effectively banned the use of SSRIs, except for Prozac, in children and adolescents under eighteen years of age.¹⁵⁷

After the dust had settled, the editors of *The Lancet* summed up the antidepressant debacle as follows: “Confusion, manipulation, and institutional failure.”¹⁵⁸ It is unknown how many patients may have been harmed or committed suicide as a result of taking SSRIs. According to one source, in 2010, GlaxoSmithKline, the maker of Paxil, had paid nearly \$1 billion to settle Paxil lawsuits, including \$390 million for suicides and attempted suicides thought to be related to the drug.¹⁵⁹

The Vioxx Case

At least an estimated 50,000 people have died from risks obscured from doctors, academics, patients and regulators as a result of Vioxx, a widely prescribed painkiller.¹⁶⁰

According to numerous independent analyses¹⁶¹ of Vioxx clinical trials and litigation documents, Merck, the drug’s manufacturer, repeatedly suppressed data connecting Vioxx with serious cardiovascular risks, including heart attacks. In 2004, Merck removed Vioxx from the market due to the previously undisclosed heart risks.

In one 2008 analysis, researchers found that in addition to suppressing negative data, Merck had also marketed and promoted Vioxx by extensively using industry-paid ghostwriters. Based on a detailed review of court documents, the authors concluded: “review manuscripts were often prepared by unacknowledged authors and subsequently attributed authorship to academically affiliated investigators who often did not disclose industry financial support.”¹⁶²

According to litigation documents obtained by the *New York Times*, a major Vioxx trial known as the “Advantage Trial,” was riddled with problems. The trial was completed in 2000, but results were not published until 2003 in the *Annals of Internal Medicine*. The article’s lead author was listed as Dr. Jeffrey R. Lisse, a University of Arizona rheumatologist. However, the newspaper reported that Lisse later admitted he had not written the article. “Merck designed the trial, paid for the trial, ran the trial,” Lisse acknowledged. “Merck came to me after the study was

completed and said, ‘We want your help to work on the paper.’ The initial paper was written at Merck, and then it was sent to me for editing.”¹⁶³

The published article also reported false results: it stated that five patients taking Vioxx, compared with one patient taking a competing painkiller, suffered heart attacks during the trial—a difference that, the authors reported, failed to reach statistical significance. In actuality, three additional trial participants taking Vioxx had suffered cardiac deaths.

The Avandia Case

In many ways, the story of Avandia is the story of Vioxx all over again, as Robert Steinbrook and Jerome P Kassirer, former editors at the *New England Journal of Medicine*, commented in 2010.¹⁶⁴ Once again, the published research on Avandia—a top-selling diabetes drug—was dangerously at odds with the raw scientific data. And once again, the manufacturer, in the case of Avandia, GlaxoSmithKline, actively suppressed data.

In July 2010, an FDA medical officer reported that a GlaxoSmithKline clinical trial designed to study Avandia’s cardiovascular risks was riddled with errors that biased its conclusions. Dr. Thomas Marciniak, the FDA examiner, uncovered a dozen instances in which patients taking Avandia appeared to suffer serious heart problems, some requiring hospitalization, that the study’s final tally of adverse events failed to count. Such mistakes “should not be found even as single occurrences,” and “suggest serious flaws with trial conduct,” Marciniak wrote.¹⁶⁵ In September 2010, the FDA announced it would restrict sales of Avandia, due to serious, previously unreported heart risks associated with the drug.¹⁶⁶

Many years before the FDA acted, however, evidence of the Avandia’s health dangers—and manipulation of data—had begun to attract the attention of medical experts, the US Congress, and FDA regulators.

As early 2007, Dr. Steven Nissen, a cardiologist at the Cleveland Clinic, unearthed forty-two Avandia clinical trials—only fifteen of which had ever been published. Nissen was unaware at the time, but he found the trove of Glaxo data online because of a lawsuit New York attorney general Eliot Spitzer filed in 2004. The suit alleged Glaxo had concealed negative trial data associated with its popular antidepressant drug, Paxil, and as part of the settlement, Glaxo was required to post its clinical trial data on a public website.¹⁶⁷ Nissen’s paper, published in *The New England Journal of Medicine*, found that Avandia raised the risk of heart attacks in patients by

43%.¹⁶⁸ The news made front-page headlines. Two days later, the FDA, which had already been assessing Avandia's health risks imposed its toughest "black box" warning label on the drug.

Meanwhile, during a congressional hearing chaired by Congressman Henry Waxman, it came to light that the FDA had already considered a black-box warning years before. Rosemary Johann-Liang, a former FDA drug safety supervisor, testified that she had recommended a warning label for Avandia, due to its increased cardiovascular risks, a year before Nissen's publication. Glaxo's own meta-analysis, presented to the FDA in 2006, showed Avandia increased heart attack risk by 31%. But, according to Johann-Liang, "my recommending a heart failure box warning was not well received by my superiors, and I was told that I would not be overseeing that project."¹⁶⁹

Internal company documents released to the *New York Times* in July 2010 also revealed that GlaxoSmithKline "had data hinting at Avandia's extensive heart problems almost as soon as the drug was introduced in 1999, and sought intensively to keep those risks from becoming public." In one document, the company sought to calculate potential lost sales if Avandia's cardiovascular safety risk "intensifies." The cost: \$600 million from 2002 to 2004 alone, the internal document said.¹⁷⁰

Within the US Congress, the Avandia case generated sustained attention from Waxman as well as from senators Charles Grassley, Max Baucus and members of Congress who pressed for stronger federal regulation of clinical trials.¹⁷¹ According to a US Senate Committee on Finance report, GlaxoSmithKline actively tried to intimidate university physicians critical of Avandia and its safety profile. The committee's final report said:

In November 2007, for example, the Committee examined the case of Dr. John Buse, a professor of medicine at the University of North Carolina (UNC) who specializes in diabetes.¹ According to a formal Senate Finance Committee investigation released in 2010: "Based partly on internal documents from GSK, the Committee reported on what appeared to be an orchestrated plan by GSK to stifle the opinion of Dr. Buse in 1999. At that time, Dr. Buse argued at several medical conferences and in letters to the FDA that GSK's diabetes drug Avandia may cause cardiovascular problems."² According to GSK emails made available to the Committee, GSK executives labeled Dr. Buse a "renegade" and silenced his

concerns about Avandia by complaining to his superiors at UNC and threatening a lawsuit. The call to Dr. Buse's superiors was made by Dr. Tachi Yamada, then GSK's head of research. In discussions with Committee investigators, Dr. Yamada denied that his call was meant to intimidate Dr. Buse. Instead, Dr. Yamada argued that he had made the call to determine if Dr. Buse was making legitimate statements or if he was possibly on the payroll of a GSK rival.

Dr. Yamada also made a call to the University of Pennsylvania (Penn) regarding two physicians who were about to publish a case study that Avandia may have caused liver problems in one of their patients.³ . . . Both physicians also said that the calls placed by GSK officials, including Dr. Yamada, were highly unprofessional and had a chilling effect on their professional activity.¹⁷²

In 2006, Avandia was one of the largest-grossing drugs in the world, with sales of \$3.2 billion. According to a 2010 *Journal of the American Medical Association* study analyzing Medicare records, from 1999 to 2009, an estimated 47,000 people taking Avandia suffered heart attacks, strokes, heart failure, or died, most probably as a direct consequence of taking the diabetes medication.¹⁷³

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***Risk 3: Threats to Open Science, Knowledge Sharing,
and Timely Academic Publication***

Over time, the academic community has evolved a distinctive “open science” system, rewarding reputation, discovery, timely publication, and broad dissemination of research results, as the seminal 1957 writing of Robert Merton and later writing of Paul David and others have described.¹⁷⁴ The academic system contrasts starkly with the knowledge systems in private industry, which place a premium on keeping knowledge confidential to prevent leaks to competitors and to facilitate commercial investment and development.

With the growth of academy-industry relationships, many question how academia's open knowledge system can be preserved. Studies by Wesley Cohen and John Walsh,¹⁷⁵ have found that the effects of increased academic patenting on knowledge sharing inside academia have not been as onerous as some anticipated. Other empirical research by the same authors, however, found that increased commercialism on campus can lead to longer publication delays, more information withholding, heightened secrecy, and other potentially serious threats to open science.

Although the key concern is that academic research results be accurate and truthful, rapid publication can be of genuine social value in some fields. The importance of quickly disseminating knowledge in medicine, where it has a direct impact on public health treatments, is readily apparent. It is evident also in biotechnology, where the revolution would have been considerably delayed if a single company or set of researchers had hoarded a major scientific breakthrough like "gene splicing." Academic publication ensures that valuable knowledge be shared with others who may use it productively. Some research results have social benefits, and their delay or suppression has social consequences. The freedom to publish rapidly when appropriate, without sponsor constraint or prohibition, is thus of fundamental importance to academic freedom.

Industry and government have sometimes both sought to delay publication of research results. The two most widely publicized recent cases occurred after two of the United States' biggest environmental disasters—the 1989 Exxon Valdez oil spill in Alaska's Prince William Sound and the 2010 BP America oil spill in the Gulf of Mexico. Exxon and BP each sought to delay release of industry-funded academic research examining their respective environmental disasters. After the Deepwater Horizon explosion, BP initially asked university faculty and their departments to sign research contracts that gave the company's lawyers the right to delay any communication or publication of results for up to three years.¹⁷⁶ The US Natural Resource Damage Assessment (NRDA) procedures—which assess restoration needs, possible legal liability, and the scope of environmental and economic damages following disasters—prompted government agencies to use their contractual authority to impose publication delays on academic investigators as well. Knowing that the government and the oil industry would face one another in court, both the private corporation and the government agencies pressured academics to keep sponsored academic research results confidential to avoid giving additional advantage to their

opponent. However, timely publication of research results after natural disasters can be critical for the design of effective follow-up scientific research investigations, cleanup efforts, wildlife preservation, public health initiatives, and the litigation efforts of directly affected localities, individuals, and small businesses.

One further risk that is important to note is that of intimidation. Faculty members who critique powerful industries in published research may find that the industries vigorously defending their interests. As *The Nation* reported in 2005:

Twenty of the biggest chemical companies in the United States have launched a campaign to discredit two historians who have studied the industry's efforts to conceal links between their products and cancer. In an unprecedented move, attorneys for Dow, Monsanto, Goodrich, Goodyear, Union Carbide and others have subpoenaed and deposed five academics who recommended that the University of California Press publish the book *Deceit and Denial: The Deadly Politics of Industrial Pollution* by Gerald Markowitz and David Rosner.¹⁷⁷ The companies have also recruited their own historian to argue that Markowitz and Rosner engaged in unethical conduct.¹⁷⁸

Markowitz and Rosner based their book in part on an archive of company and trade association documents a Louisiana attorney obtained through the discovery process. The documents demonstrated that, as early as 1973, the chemical industry had learned that vinyl chloride—used in numerous consumer products—caused cancer in animals, but the industry failed to disclose the findings. After UC Press obtained eight reviews of the manuscript, the book's copublisher, the Milbank Memorial Fund, sponsored a two-day conference to bring together the reviewers and authors to discuss the manuscript. Talks came to a head when a worker exposed to vinyl chloride sued for damages after being diagnosed with liver cancer. The companies' paid historian, a Rutgers-Camden University business professor who had also testified for the asbestos industry, charged that the conference was unethical because it allowed the authors to know who reviewed their book. He also claimed it was inappropriate for the authors to recommend reviewers, a common academic practice. The accusations against Markowitz and Rosner were discredited, but only after the authors and the book reviewers were subjected to days of cross-examination in court. Had Milbank not provided legal representation

to the authors and reviewers, they would have faced significant personal legal costs. Meanwhile, the intimidation left a chilling effect on scholars whose research questions industry practices.

In 2009, the tobacco industry personally attacked Stanford University historian Robert Proctor. After Proctor emailed a colleague to confirm that a University of Texas-San Antonio faculty member had hired University of Florida graduate students to do research for an upcoming Florida trial in which the faculty member was scheduled to testify, tobacco industry attorneys argued that Proctor's email constituted an "improper" effort to "influence, interfere, or intimidate" a defense witness.¹⁷⁹ The judge ordered Proctor to submit his emails to the court, after which the tobacco lawyers dropped their accusations, because the emails were ruled harmless. Still, Proctor was forced to undergo sixteen hours of depositions under oath by twelve lawyers. The attorneys for R.J. Reynolds then subpoenaed Proctor's unfinished book manuscript on the history of the tobacco industry, a move the *Chronicle of Higher Education* characterized as having "major implications for scholars and publishers."¹⁸⁰ A judge eventually held "that an author has a constitutional right to choose when and where his writings are published."¹⁸¹ Academic freedom thus survived but only after considerable scholarly intimidation, time, and expense.

The Proctor and Markowitz and Rosner cases are far from isolated. However, some industry campaigns, such as one tobacco companies waged against Stanton A. Glantz, a UC San Francisco professor of medicine, are far more elaborate and only come fully to light when industry documents are made public. Glantz was certainly aware of tobacco industry opposition to his scholarship. On March 14, 1995, for example, a large display ad personally attacking him appeared in the *Washington Times*. The ad stated it was financed by "the 130/10 Club, a group of citizens who chip in \$10 a month to expose government waste." In fact, the president of the Philip Morris-funded American Smokers Alliance managed the group. The "waste" protested in the ad targeted a National Cancer Institute grant awarded to Glantz in part so he could track tobacco industry campaign contributions and correlate them with state legislators' votes on tobacco-related issues. Seven months later, former US Surgeon General C. Everett Koop and others signed a *New York Times* opinion-page ad defending Glantz's research. However, when Glantz typed his name into the Legacy Tobacco Documents Archive, in 2006, he was surprised to uncover 500 pages of internal documents showing that the tobacco industry's campaign to derail his academic research and reputation went far deeper than he had realized.

For example, after Glantz and a colleague presented a paper summarizing research on the dangers of secondhand smoke, and the *New York Times* published a full-page story on the presentation in May 1990, the tobacco companies' public relations arm kicked into full swing. The campaign included a far more elaborate plan to have Glantz's National Cancer Institute funding withdrawn. Glantz's archival research exposed industry efforts to recruit pro-tobacco legislators to the cause, as well as a covert campaign to recruit seemingly independent university faculty and others to write letters to academic journals and newspapers discrediting Glantz's academic work. The writers billed the tobacco companies roughly \$3,000 for each letter penned.¹⁸²

Publication Delays and Data Withholding

A fundamental tenet of academic life is that research should be published as rapidly as researchers and peer reviewers deem prudent so that it can be broadly shared, utilized, and independently verified or disproven. However, empirical work has consistently found that industry funding is associated with publication delays.¹⁸³

- A comprehensive 1996 study found that one-third of 210 life science companies surveyed reported disputes with academic collaborators over intellectual property, and 30 percent noted that conflicts of interest emerged when university researchers became involved with other companies. Nearly 60 percent of academic agreements signed with these life science firms also required that university investigators keep information confidential for more than six months—considerably longer than the thirty to sixty days that NIH considers reasonable for the purpose of filing a patent.¹⁸⁴

Numerous case studies¹⁸⁵ describe how industry sponsors have delayed, sometimes for years, reporting of clinical trial results and adverse-event reports. In one case involving the antidepressant drug, Paxil, negative clinical trial data were released publicly only after a lawsuit was filed against the manufacturer.¹⁸⁶

Industry imposed delays on, and interference with, publication are not limited to the field of medicine, although biomedicine has been more extensively researched than other fields. A

1994 Carnegie Mellon University study in the field of engineering found pervasive delays at joint university-industry research centers across the United States.

- The survey of 1,056 industry-academic centers (with more than \$100,000 in funding and at least one active industry partner) found that more than half of the university research centers reported that industry participants could force publication delays, and more than one-third reported that industry sponsors could delete [ok?] information from papers prior to publication.¹⁸⁷

Threats to Academic Knowledge Sharing

Another central tenet of academic science is that information, data, reagents, materials—especially when they are associated with an academic publication—should be freely shared with other academic investigators. Again, studies find industry relationships are associated with greater restrictions on knowledge sharing.

- In 1997, Harvard's David Blumenthal found that commercial activity, including but not limited to patenting, was associated with greater withholding of academic research results.¹⁸⁸
- A 2002 survey of university geneticists and life scientists found that one in four scientists reported the need to honor the requirements of an industrial sponsor as one of the reasons for denying requests for post-publication information, data, or materials.¹⁸⁹ Some 28 percent of geneticists reported having difficulty replicating published results, and 24 percent said they had their own publication significantly delayed.
- In 2007, Walsh et al. found that, among genomics researchers, the rate of withholding research materials appears to have increased from 10 percent of requests between 1997 and 1999 to 18 percent of requests in 2003 and 2004.¹⁹⁰
- The Walsh study also found that one in nine scientists had to abandon projects each year because of unfulfilled requests for materials or information.¹⁹¹

Exclusive Licensing & Other Proprietary Restrictions on Academic Knowledge

After passage of the Bayh-Dole Act, US universities became far more enthusiastic about patenting academic discoveries and imposing exclusive licenses and other legal restrictions, known as Material Transfer Agreements (MTAs), on the use of research reagents and other materials. This was driven both by a desire to commercialize the research, and by a desire to extract fees for the university. Some controversial MTA licenses require royalty fees be paid back to the university on products that might eventually be developed through use of its research tools (known as “reach-through” royalties).

According to a 2001 study in which the authors obtained rare access to university invention portfolios, 90 percent of all University of California discoveries and 59 percent of Stanford’s were licensed under reasonably “exclusive” terms.¹⁹² (“Exclusive” was defined as either global exclusivity or restrictive as to market or field of use.)

Many legal scholars, economists, and historians of scientific and industrial innovation have expressed concerns¹⁹³ that the Bayh-Dole Act may be fostering a significant, if somewhat more subtle, sea change in academic norms regarding the dissemination of academic knowledge. Industrial historian Richard Nelson and others have warned that increased patenting and other proprietary restrictions on academic knowledge sharing could lead to a “privatization of the scientific commons”¹⁹⁴—formerly an important basic science wellspring for future research and discovery. Patents, licenses, and MTAs are controversial because some scholars believe they could impose burdensome costs and impede downstream research, invention, as well as new product development.¹⁹⁵

Increased academic patenting and licensing activity have been particularly notable in the biotechnology and information technology sectors.¹⁹⁶ Some experts have expressed concern that Bayh-Dole may have created a dangerous incentive for US universities to put licensing profits ahead of other academic goals, including knowledge sharing, public health, and academic freedom.

A University of Utah professor patented two human breast cancer genes, and the university then licensed them *exclusively* to the professor’s own start-up company, Myriad Genetics, Inc. The company soon began to hoard the genes, using legal threats and other tactics to block other academic scientists and physicians in the US and abroad from using them in their own research and diagnostic testing. The case drew international attention and outrage; it also led to protracted

litigation before landing in the US Supreme Court. In March 2012, the high court ruled that a diagnostic test developed by Myriad was ineligible for patent because it was a simple application of a law of nature. The court ordered a lower appeals court to reconsider its decision to uphold the patents on the genes, which are associated with a high risk of breast and ovarian cancer.¹⁹⁷

Another controversial set of academic patents, filed by the University of Wisconsin, claimed broad rights to embryonic stem cell lines.¹⁹⁸ Biotechnology firms eager to do research on stem cells have complained about the Wisconsin's licensing fees and about "reach through" provisions calling for royalties on products developed from research on embryonic stem cells, with additional restrictions on use.¹⁹⁹ According to some outside observers, rather than promote commercialization, patents on basic research platforms constitute a "veritable tax on commercialization."²⁰⁰

The National Institutes of Health shares the concern. In 1999, it issued formal guidelines to remind universities to avoid seeking patents and other restrictive licenses on data, materials, and other "research tools," unless they are necessary to attract investors for commercial use and development.²⁰¹ In 2005, the NIH again issued guidelines seeking to prevent genomic inventions from falling under excessive proprietary controls.²⁰² The NIH guidelines also argued against "reach-through" royalties, and urged universities to license research tools with few encumbrances and at reasonable fees. However, the guidelines lack the force of law. In 2000, one year after the first guidance, Maria Freire, then-director of NIH's Office of Technology Transfer, reported that scientists were still having problems accessing research tools, particularly in negotiations between academia and industry.²⁰³

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RISK 4: Financial Conflicts of Interest

A number of recent scholarly books²⁰⁴—beginning with Stanton Glantz's collaborative *The Cigarette Papers*, and including Allan Brandt's *The Cigarette Century*, David Michaels's *Doubt is Their Product*, and Robert Proctor's *The Golden Holocaust*—credit the tobacco industry with inventing the modern corporate strategy of manufacturing scientific controversy to manipulate academic science, advance corporate interests, shape public opinion, and forestall industry

regulation. Because financial payments, and consequent financial conflicts of interest, have been a central tool in the strategy, the tobacco industry may also be credited with mounting a sophisticated and extensive campaign to buy university scientists and manipulate academic science.

As early as the 1930s and 1940s, epidemiological and laboratory evidence linked cigarette smoking and lung cancer, but the 1950s proved a watershed. More sophisticated and reliable laboratory experiments with animals demonstrated nicotine's addictive power and the carcinogenicity of the tars in cigarette smoke. In the early twentieth century, smoking rose dramatically in the United States, and, two to three decades later, lung cancer diagnoses climbed at comparable rates. Connections with coronary heart disease and other conditions would gradually be established as well.

While tobacco companies had been accused of collusion as early as 1911, the US Department of Justice's successful 2006 Racketeer Influenced and Corrupt Organizations Act (RICO) case²⁰⁵ against the tobacco industry began with memos documenting an infamous December 1953 meeting of tobacco company executives at New York's Plaza Hotel. There, the executives from six companies hammered out a public relations strategy—one they would vigorously pursue over the next half century—based largely on the advice of John W. Hill, president of the country's most influential public relations firm, Hill & Knowlton. Advertising alone, Hill argued at the meeting and in a written proposal later that month, could not counter the mounting scientific consensus that tobacco was harmful to public health. Rather than stand on the sidelines and try to contest the science, Hill urged the tobacco companies to start funding and controlling science themselves.²⁰⁶ University scientists, skeptical of the link between smoking and cancer—scientists who were in many cases smokers unwilling to admit they were killing themselves—proved key allies in the tobacco industry campaign to manipulate scientific evidence. Many academic faculty members received funding from the Tobacco Industry Research Committee (TIRC). Headquartered inside Hill and Knowlton's offices, the TIRC trumpeted its pursuit of scientific truth and its commitment to public health in 400 newspaper ads in January 1954.

The TIRC funded research cleverly designed to distract and confuse. Much of it had no bearing on the actual link between smoking and cancer. The TIRC promoted genetic predispositions to cancer. It even occasionally publicized the benefits of smoking, promoting

nicotine’s value as a “tranquilizer,” and in one study suggesting that secondhand smoke increased airline pilot alertness. Above all, as the scientific consensus about the hazards of smoking became decisive, the industry employed seemingly independent and objective faculty allies to create the fiction of an ongoing scientific controversy over whether smoking caused lung cancer. Although the number of university skeptics remained small, tobacco companies could rely on newspapers and other media, eager to report on controversy and demonstrate balance, to enable a perception of scientific doubt to trump the overwhelming scientific consensus that tobacco smoking was, indeed, hazardous. As a now famous 1969 internal tobacco industry memo observed, “Doubt is our product, since it is the best means of competing with the ‘body of fact’ that exists in the minds of the general public. It is also the means of establishing a controversy.”²⁰⁷

This lesson was not forgotten when tobacco companies later acted to sow doubts about research demonstrating the dangers of secondhand or environmental tobacco smoke. As David Michaels wrote, “No industry has employed the strategy of promoting doubt and uncertainty more effectively, or for a longer period, and with more serious consequences.”²⁰⁸ In time, other major industry groups adopted the “tobacco strategy” to cast doubt on the dangers of asbestos, power plant emissions, mercury in fish, lead in paint and gasoline, as well as the impact of impact of fluorocarbons on the ozone layer, and, of course, the worldwide threats posed by global warming.

University scientists were only the first wave of faculty members potentially compromised by tobacco industry funding. We now know—based on more than 80 million pages of tobacco industry documents known as the Legacy Tobacco Documents Library (<http://legacy.library.ucsf.edu>), which became fully digital and text searchable in 2007²⁰⁹—that literally thousands of university faculty worked for tobacco companies as paid researchers or consultants. Scientists, statisticians, and historians performed research, provided analysis, and advised the companies on advertising and litigation strategies. Some of the funding relationships were public, but many remained confidential. The confidentiality itself presents good reason to adopt the policies to manage financial conflicts of interest we recommend in this report.

Over the past three decades, changes in the academic research landscape—especially in biomedicine but in other academic fields as well—have dramatically increased the possibility of financial conflicts of interest (COI), like the ones stemming from extensive tobacco industry

involvement on campus. Contributors to the trend include increased industry funding and the more varied forms of academic-industrial engagement discussed above. Another contributor is the presence of dedicated patenting and technology-transfer offices on virtually every research university campus. Through equity, options, royalties, and licensing fees, patenting and technology-transfer offices have opened opportunities for faculty members and universities to have direct financial interests in campus-based research.

University owned and operated research parks, incubator programs, and venture-capital funds as well as direct faculty involvement in start-ups and other businesses may help to realize universities' technology-transfer missions. But these activities also lead to financial conflicts of interest. In 2005, for example, reporters revealed that an academic medical center, the Cleveland Clinic, and its chief executive officer had undisclosed financial interests in a medical device firm. The medical center used the firm's heart surgery device, and hospital surgeons promoted it. Patients were uninformed about the conflicts of interest. The medical center's board subsequently enacted tough policies to address the *institutional* conflicts.²¹⁰

Experts on ethics and professionalism have largely reached a consensus on the broad definition of a financial COI: A conflict of interest may be broadly defined as a situation in which an individual or a corporate interest has a tendency to interfere with the proper exercise of judgment on another's behalf.

An *individual* COI, more specifically, may be defined as a set of circumstances that creates a risk that a secondary interest, such as financial gain, will unduly influence professional judgment or action regarding a primary interest, such as research conduct, teaching, or patient welfare.²¹¹ A similar definition of an *institutional COI* comes from a joint Association of American Medical Colleges (AAMC)-Association of American Universities (AAU) 2008 report:

An institutional conflict of interest (institutional COI) describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's activities. The risks are

particularly acute in the context of human subjects research, when the protection of human subjects and the integrity of the institution's research may be threatened.²¹²

It is worth emphasizing that the COI definitions describe circumstantial situations; they do not imply confirmed wrongdoing. As the Institute of Medicine wrote in 2009: "A conflict of interest is not an actual occurrence of bias or a corrupt decision but, rather, a set of circumstances that past experience and other evidence have shown poses a risk that primary interests may be compromised by secondary interests. The existence of a conflict of interest does not imply that any individual is improperly motivated."²¹³ Because financial conflicts are a function of a situation, rather than a function of whether someone is actually biased, they are either present, or they are not. Thus, financial COIs should not be termed "potential," a qualifier that one hears frequently and usually incorrectly, because the word implies that the conflict does not currently exist and is only a future possibility, thereby seeming to diminish its risk or significance.

COI policies in many parts of society—in universities, in corporations, in government, and in the courts—are designed to be preventative. University COI policies, therefore, seek to prevent or manage situations that might compromise, or appear to compromise, the ability of a university administrator or a faculty member to make unbiased decisions (related to contract negotiations, evaluations, research, education, academic promotions, new faculty hires, or patient care). The policies also should attempt to prevent or manage relationships that might weaken public trust in a university's overall research or teaching integrity—a particular concern for public and private universities that depend on taxpayer support.

Obviously, financial COI are not the only "competing interests" that may distort academic decision-making or bias academic research. Other competing interests—such as, the desire for "priority of discovery," reputational or career advancement, scientific competition—are "an inescapable fact of academic life." As the Association of American Medical Colleges writes: "Most are managed through institutional policies and practices, and through the constraints imposed by the scientific method."²¹⁴ However, most experts on ethics and professionalism distinguish financial COI from other competing interests because: first, financial conflicts are discretionary, and, second, a growing body of empirical research has found that even gifts of small value are associated with bias and unreliability in research conduct and

outcomes, as well as bias in professional decision-making, although these effects are usually imperceptible to the investigator.

While we strongly endorse financial COI disclosure throughout our principles, we also recognize that disclosure alone is not enough. Indeed, in some contexts disclosure alone can be entirely inadequate. The risks are particularly notable in medicine with regard to patient care. Academics are relatively well versed in professional skepticism, though perhaps most so in their own disciplines. The same cannot be said of all members of the general public, especially with regard to professional advice. A 2012 editors' editorial in *PLoS Medicine*, building on research by Lisa Cosgrove and Sheldon Krinsky,²¹⁵ expresses concern regarding the high number of financial conflicts among psychiatrists who contributed to the fifth and most recent edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), the so-called “bible of psychiatry.” Based on faculty member self-disclosure, which may understate reality, nearly 70 percent of DSM-5 Task Force members had or have had, financial ties with the pharmaceutical industry, up from 57 percent for the manual's previous fourth edition. The rate is still higher for contributors to the psychotic disorders section—83 percent. The *PLoS Medicine* editorial expresses concern that doctors may strategically exaggerate to compensate for disclosure. The editorial also questions whether physicians who disclose may feel impervious to bias or, even worse, that disclosure absolves them of responsibility for managing their conflicts of interest. What's more, patients may not be inclined to discount professional advice in light of COI disclosure. While disclosure is essential, it is only a first step in reforming the problems created by financial conflicts of interest.

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RISK 5: Research Bias and Unreliability
Associated With Corporate Funding

Here, in the box below, is a summary of a growing body of empirical research (in the fields of psychology, neurobiology, and other social sciences) demonstrating that financial conflicts of interest, including gifts of relatively little value, are associated with bias and unreliability in

professional decision-making as well as in research conduct and outcomes, although investigators frequently fail to perceive their own bias.

Industry Sponsorship & Pro-Industry Findings

A large number of systematic reviews and independent studies show that industry-sponsored clinical trials, and trials with industry ties, are more likely to report results favoring the sponsors' products or interests:

- ▶ One meta-analysis found that clinical trials in which either the drug manufacturer funded the trial or the investigators had financial relationships with the manufacturer were 3.6 times more likely to find that the drug tested was effective compared to studies without such ties (Bekelman et al. 2003).
- ▶ Another meta-analysis that included non-English language studies (not included in the above-mentioned Bekelman study) found clinical studies favoring a drug were four times more likely to be funded by the drug maker than any other type of funder (Lexchin et al. 2003).
- ▶ A 2008 literature review found that seventeen of nineteen studies published since the preceding two meta-analyses reported “an association, typically a strong one, between industry support and published pro-industry results” (Sismondo, 2008, p. 112).
- ▶ Another 2008 review found that industry-funded studies were more likely than other studies to conclude that a drug was safe, even when the studies found statistically significant increases in adverse events for the experimental drug (Golder and Loke, 2008).

These studies do not prove funders caused research bias, and other explanations could be offered. Companies, for example, fund trials only when they predict a strong likelihood of success for their product. But the documented association between funding source and research bias, carried out now across diverse areas of clinical drug as well as tobacco research,²¹⁶ raises serious concerns about possible undue influence and skewed research results.

Gifts, Financial Inducements, & Biased Decision-Making

Extensive research in psychology and other social sciences has also demonstrated that financial inducements, including small gifts, have the potential to introduce bias and distort individual decision-making.²¹⁷ Much of this research has been in biomedicine, but the results have broader ramifications across an array of disciplines, including agriculture, energy, economics, environmental studies, toxicology, chemistry, occupational health, and epidemiology. In general, studies find that pharmaceutical and other biomedical firm gifts or financial inducements, such as free meals, travel expenses, drug samples, have a powerful affect on physician behavior and decision-making—even without an explicit contract or “strings” attached.²¹⁸

For example, these studies have identified the following effects:

- ▶ Physicians who request additions to hospital drug formularies are far more likely to have accepted free meals or travel funds from drug manufacturers.²¹⁹
- ▶ The rate of drug prescriptions physicians write increases substantially after they see sales representatives,²²⁰ attend company-supported symposia,²²¹ or accept free drug samples.²²²
- ▶ Receiving gifts is associated with positive physician attitudes toward pharmaceutical representatives.²²³
- ▶ Systematic review of the 2000 medical literature on gifting found an overwhelming majority of industry interactions negatively influenced clinical care.²²⁴

Neurobiologists have provided additional persuasive evidence on the impact of financial conflicts of interest on individual behavior. According to a 2010 Association of American Medical Colleges task force report, “inherent biological processes cause individuals to respond reciprocally—and typically unconsciously—to relationships that involve even simple gifts, sponsorships, or the development of personal relationships.”²²⁵ Neurobiology remains an emerging area of scientific discovery. However, according to the AAMC report, research “suggests that the neurobiological processes that engage the brain’s reward and decision-making circuitry can operate below the detection and overt control of higher cognition.”

Finally, a 2009 panel report from the Institute of Medicine summed up the research on investigator objectivity and industry funding and gift giving by quoting Jason Dana, a University of Pennsylvania professor of psychology.

This research shows that when individuals stand to gain by reaching a particular conclusion, they tend to unconsciously and unintentionally weigh evidence in a biased fashion that favors that

conclusion. Furthermore, the process of weighing evidence can happen beneath the individual's level of awareness, such that a biased individual will sincerely claim objectivity. Application of this research to medical conflicts of interest suggests that physicians who strive to maintain objectivity and policy makers who seek to limit the negative effects of physician-industry interaction face a number of challenges. This research explains how even well-intentioned individuals can succumb to conflicts of interest and why the effects of conflicts of interest are so insidious and difficult to combat.²²⁶

Much of the impetus to address financial conflicts in universities has focused on biomedical research. However, starting in the late 1990s, the Department of Health and Human Services, followed by the National Science Foundation, passed federal COI rules covering university grantees, not only to protect human research subjects but also to safeguard research objectivity, reliability, and integrity.²²⁷ Below, is a historical overview of efforts to address financial conflicts of interest at universities as well as in academic medical centers.

A Brief History of Efforts to Address Financial Conflicts of Interest at US Universities and Academic Medical Centers

In 1995, the US Public Health Service implemented the first federal rules addressing financial conflicts of interest at universities. The rules covered all Department of Health and Human Services (DHHS) funded research, including all National Institutes of Health research.²²⁸ Ten years earlier, California had moved to address conflicts inside universities.²²⁹ The federal government first attempted to push through COI rules for university grantees in 1989 but failed due to strong opposition from academic and professional groups. The Federation of American Societies for Experimental Biology, for example, asserted the proposed rules would “devastate productive relationships between university researchers and industry, deny scientists outlets for their discoveries at the bench and interfere with the technology transfer.”²³⁰

In June 1990, the AAUP approved its “Statement on Conflicts of Interest,” which strongly echoed this widespread academic opposition to federal mandates for disclosure of financial conflicts of interest:

Government proposals for policing possible conflicts of interest have been overwhelmingly rejected by the academic community as involving a massive, unneeded enlargement of the government's role on the campus. Faculties must be careful, however, to ensure that they do not defensively propose a similar bureaucratic burden differing only in the locus of administration. Any requirements for disclosure of potential conflicts of interests should be carefully focused on legitimate areas of concern and not improperly interfere with the privacy rights of faculty members and their families.²³¹

This AAUP statement reflected widespread faculty views at the time, and also embodied the association's longstanding commitment to faculty rights and autonomy. However, federal proposals to address COI in academia have since become federal rules. It is not only that the AAUP's earlier warning has as a result become moot; in reality there is now much wider recognition of the danger that COI present to research integrity and the reputation of the academy. And while the AAUP's insistence on limiting COI disclosure to "legitimate areas of concern" remains valid, these areas of concern have multiplied dramatically, since 1990, and now pose a significant threat to the university's educational, research, and public knowledge missions. As such, this report substantially revises and updates the AAUP position on the need to regulate and disclose financial conflicts of interest, both at the level of individual faculty and at the institutional level.

The 1995 Public Health Service rules required all DHHS grantee institutions to ensure that their research was not "biased by any conflicting financial interest of an Investigator."²³² The rules also required faculty members with related financial COI (greater than \$10,000 or 5 percent ownership in a single entity) to report their interests to university employers for internal review, reduction, elimination, and/or management, with some modest reporting back to the federal granting agency. However, the PHS rules provided little guidance on how universities should manage conflicts, and left the institutions considerable discretion to formulate their own policies and procedures. The same was true of COI rules the National Science Foundation issued in 1995 and the Food and Drug Administration adopted in 1998, although both sets of rules were even more limited.²³³ Most universities used these new federal rules as the baseline for developing their own COI policies. However, by early 2000, a series of independent surveys demonstrated

that university COI policies varied considerably from one institution to the next and were, overall, quite weak.²³⁴

Under the PHS rules, most public and private universities chose to keep information concerning their faculty members' financial conflicts confidential. However, over the next two decades, class-action lawsuits filed by tobacco and pharmaceutical firms, combined with heightened scrutiny by the media, Congress, and science journal editors, served to push these commercial conflicts into the open, generating widespread public concern.

A major wave of public scrutiny came in 1999 after a young man, Jesse Gelsinger, died in a University of Pennsylvania gene therapy experiment. Evidence revealed the experiment was riddled with financial conflicts and other potentially harmful breaches of federal safety rules as well. A 2009 Institute of Medicine summary of the Gelsinger case documents serious concerns about the university's oversight of the study. The university and several past and present faculty and officials had financial interests in the biotechnology company that developed the experimental medical intervention. The biotechnology company had contributed \$25 million to the annual budget of Penn's research institute conducting the study; it also held exclusive rights to develop products emerging from the trial and related research. The institute's director, who also served as the trial's lead investigator, maintained a significant financial interest in the biotech firm, which he had helped to found.²³⁵

The Gelsinger tragedy and its shocking financial conflicts led to a lawsuit, congressional inquiries, and other probing investigations, along with widespread calls to strengthen federal rules governing financial conflicts at US universities.²³⁶ However, when the DHHS released new proposed COI rules in January 2001,²³⁷ once again most major academic and medical groups strongly objected, just as they had in 1989, citing universities' preference for self-regulation.²³⁸ Soon the proposed federal rules were tabled.

Following Gelsinger's death, prominent academic and medical groups released a series of consensus reports seeking to provide more detailed guidance to US universities and academic medical centers on the appropriate management financial conflicts of interest. Among others, these reports issued from the Association of American Medical Colleges (AAMC, 2001, 2002, 2008c), the Association of American Universities (AAU, 2001), the AAMC and AAU jointly (AAMC-AAU, 2008), and the Council on Government Relations (COGR, 2002). However because adoption of these groups' recommendations was only voluntary, independent surveys

(reviewed in detail below) have found that U.S. universities overall have highly variable COI policies, most of which remain quite weak.

In 2001, just two years after the Gelsinger tragedy, medical journal editors also started to voice serious concerns about financial conflicts of interest and undue commercial influence over clinical research. That year thirteen editors of prominent medical journals published a high-profile editorial in *The New England Journal of Medicine*, expressing alarm concerning the growth and pervasiveness of financial conflicts in medicine. The article observed that industry sponsors were exerting excessive control over clinical-trial design, data access, and final analysis of reported research results. The editors concluded by announcing that the International Committee of Medical Journal Editors (ICMJE) would soon revise requirements²³⁹ for manuscript submissions, and call for full disclosure of financial COI. These new requirements would also mandate details concerning the industry sponsors' roles in the conduct of research, and require the study's lead authors to provide written assurances that they remained independent from sponsors, were fully accountable for trial design and conduct, had independent access to all trial data, and controlled all editorial and publication decisions. Additionally, the editors called on the medical community to restore academic and scientific standards that were customary in decades past. They noted that academic "contracts [with private sponsors] should give the researchers a substantial say in trial design, access to the raw data, responsibility for data analysis and interpretation, and the right to publish—the hallmarks of scholarly independence and, ultimately, academic freedom."²⁴⁰

In 2005, however, Senator Chuck Grassely, R-Iowa, spearheaded another wave of investigations into industry relationships with academic researchers and continuing medical education programs, which uncovered persistent financial conflicts of interest in federally funded academic research.²⁴¹ Grassley obtained documents pertaining to research at more than two dozen medical schools and found that several high-ranking academic physicians had accepted large amounts of money from private companies with direct financial interests in their research, but had neglected to accurately report this personal income to their own universities or the NIH, as campus and federal rules require.²⁴² Grassley's staff made separate inquiries of drug companies and universities and compared the data. In some cases, it appeared that the disclosures omitted from university documents involved companies whose products the researchers were investigating.²⁴³ The list read like a who's who of leading psychiatrists:

- Dr. Charles Nemeroff, an influential psychiatrist and then chair of the Psychiatry Department at Emory University, reportedly earned more than \$2.8 million in consulting arrangements with drug makers between 2000 and 2007, yet he failed to disclose hundreds of thousands of it to Emory in violation of federal research rules, according to documents provided to congressional investigators. In one telling example recounted in the *New York Times*, Nemeroff signed a letter dated July 15, 2004 promising Emory administrators that he would comply with federal rules and would earn less than \$10,000 a year from GlaxoSmithKline (GSK). But that very day he was at the Four Seasons Resort in Jackson Hole, Wyoming earning \$3,000 of what would become \$170,000 in income that year from GSK.²⁴⁴ Confronted with these unreported conflicts of interest and negative media attention, the NIH forced Nemeroff to step down from NIH-funded university research projects and froze funding for a \$9.3 million project he was leading on depression. Later, Emory removed Nemeroff from his seat as chair of psychiatry and restricted his outside activities. He then transferred to the University of Miami.²⁴⁵
- Dr. Alan Schatzberg, then chair of the Psychiatry Department at Stanford University, received an NIH grant to study the drug mifepristone for use as an antidepressant while owning millions of shares of founders stock in the drug's developer, Corcept Therapeutics,²⁴⁶ which was then seeking FDA approval to market the drug. Grassley's investigation questioned Stanford's oversight of the conflict. In comments and a letter to Stanford published in the *Congressional Record*, Grassley noted that Stanford had required Schatzberg to disclose stock valued at more than \$100,000, but Stanford did not require the psychiatry chair to report profits of \$109,000 from the sale of some of his Corcept shares in 2005, or the fact that his 2 million remaining shares were worth more than \$6 million. "Obviously, \$6 million is a dramatically higher number than \$100,000 and I am concerned that Stanford may not have been able to adequately monitor the degree of Dr. Schatzberg's conflicts of interest with its current disclosure policies," Grassley wrote in a letter to Stanford University President John Hennessy.²⁴⁷ An NIH oversight group later stepped in and recommended that Stanford's clinical trial on mifepristone be "terminated immediately and permanently," due to concerns over

conflicts of interest and patient safety, according to internal emails obtained by an outside public interest group. Stanford also asked Schatzberg to step down as chair temporarily.²⁴⁸ The recommendation was made because of concerns over conflicts of interest and patient safety, among other issues.

- A Harvard child psychiatrist, Dr. Joseph Biederman—whose work helped fuel an explosion in the use of antipsychotic medicines in children—earned an estimated \$1.6 million in consulting fees from drug makers between 2000 and 2007. For years, however, he failed to report much of the income to university officials, according to Grassley’s congressional investigators. According to the *New York Times*, two of Biederman’s colleagues also violated federal and university disclosure rules: “Dr. [Timothy E.] Wilens belatedly reported earning at least \$1.6 million from 2000 to 2007, and another Harvard colleague, Dr. Thomas Spencer, reported earning at least \$1 million after being pressed by Mr. Grassley’s investigators.”²⁴⁹ Harvard later disciplined the three physicians by requiring them to refrain from “all industry-sponsored outside activities” for one year, and afterwards only with permission. But some commentators questioned whether the punishment was sufficient,²⁵⁰ especially after court documents later suggested that Biederman may also have breached his research protocol²⁵¹ and solicited drug company funding by suggesting that his clinical trials would yield outcomes benefiting his corporate sponsor’s products and interests.²⁵²

This round of high-profile exposés and media attention precipitated renewed calls for enhanced federal oversight of financial COI at both the individual and institutional levels at US universities and greater public transparency. A 2008 report from the Office of the Inspector General at the Department of Health and Human Services criticized the NIH for inadequately overseeing grantee institutions and their management of faculty conflicts of interest and urged DHHS to implement *institutional COI* regulations as well.²⁵³

The following year, in 2009, Grassley and other senators pushed through the Physician Payment Sunshine Act.²⁵⁴ The landmark law mandates that drug, biologic, and medical device manufacturers disclose all gifts and other payments, including all “transfers of value,” to physicians, inside and outside of academia, and publicly post the payments on a national, online

database. Under the law, companies that failed to report face financial penalties. Several states and some private companies have adopted similar disclosure policies.²⁵⁵

Finally, on August 23, 2011, after a lengthy comment period, the US DHHS issued new rules for regulating financial conflicts of interest at universities and other external grantee institutions. The laws contain:

- New requirements for investigators to disclose to university employers all significant financial interests, not only those connected to specific research projects, related to their “institutional responsibilities.”
- A lowering of the threshold required for COI disclosure, generally dropping from a minimum of \$10,000 to \$5,000.
- More extensive university reporting to federal grant agencies regarding the scope of their faculty investigators’ financial COI and management plans the university has implemented to address them.
- New requirements that universities make information regarding faculty COI and university management plans accessible to the public.

It is too soon to gauge the effect of the 2011 DHHS conflict of interest rules and the 2009 Sunshine Act on academia. However, it is clear that public scrutiny of university and faculty COI will likely intensify due to more stringent financial disclosure requirements at leading science journals, new federal rules covering public disclosure of significant financial conflicts related to federal grants, and, lastly, Sunshine Act laws requiring public reporting of all industry payments to physicians.

However, as in 1995, the new federal rules fail to provide specific guidance on how US universities can or should review, reduce, eliminate, or manage their financial COI internally. Each university is left to implement the policies at its discretion, which if the past is any indication, could present problems. According to a 2009 Institute of Medicine panel review, “extensive variations” in university COI policies and procedures “raise concerns that some institutions may not have sufficient data to make determinations about the extent and the nature of an individual’s financial relationships or to judge the severity of a conflict of interest. . . . Absent outside pressures and oversight, variation in conflict of interest policies may encourage

an unhealthy competition among institutions to adopt weak policies and shirk enforcement.”²⁵⁶

Some universities have chosen to adopt more comprehensive COI policies. They should be emulated. However, studies indicate most US universities have been slow to heed academic associations’ calls following the Gelsinger tragedy to strengthen conflict of interest management policies and procedures. Independent surveys, some of which are listed below, have found that COI policies—even at academic medical centers, which have borne the brunt of recent public criticism—remain highly variable and, generally, too weak.

- In 2001, for example, the Association of American Medical Colleges called on universities to strengthen COI policies governing human-subject research. The association called for the establishment of a strong “rebuttable presumption” against investigators conducting research on people when investigators have a related financial COI, except in highly exceptional circumstances. However, a 2003 AAMC survey found that *only 61 percent* of medical schools had incorporated a “rebuttable presumption” into their policies, and, of those, only a minority had defined the compelling circumstances that would support an exception.²⁵⁷
- A 2006 analysis revealed that *only 48 percent of medical schools had policies to inform research participants about investigators’ financial COI*. The policies also varied regarding what information was to be disclosed.²⁵⁸
- In 2008, another AAMC membership survey found that, despite a 2002 joint recommendation from the AAMC and AAU that all universities implement *institutional* COI policies, *only 38 percent* of academic medical schools reported having one in place. Another 37 percent reported they were still in the process of developing one.²⁵⁹
 - In 2009, the Office of the Inspector General (OIG) at the Department of Health and Human Services reported serious deficiencies in how universities handle financial COI. After reviewing 184 separate financial conflict-of-interest reports that forty-one grantee institutions submitted to the NIH in 2006, the office concluded: “Vulnerabilities exist in grantee Institutions’ identification, management, and oversight of financial conflicts of interest.”²⁶⁰ The box, below, contains a summary of the OIG’s findings.

<p>“How NIH Grantees Manage Financial Conflicts of Interest” Office of the Inspector General, Department of Health and Human Services</p>

November 2009²⁶¹

Of forty-one grantee institutions, 90 percent rely solely on researcher discretion to determine which of their significant financial interests are related to their research and therefore need to be reported.

Grantee institutions fail to routinely verify information researchers do submit. Thirty of the forty-one institutions reported verifying information researchers disclosed, but only nineteen of the institutions documented how they did so.

To manage financial conflicts of interest, grantee institutions often require researchers to disclose conflicts in research publications; however, grantee institutions rarely reduce or eliminate financial conflicts of interest. (Grantee institutions reported that they managed 136 researcher conflicts, reduced 6 researcher conflicts, and eliminated 6 researcher conflicts. Another 17 researcher conflicts were handled using a combination of management, reduction, and elimination.) Other studies have corroborated the finding.²⁶²

Because nearly half of the grantee institutions do not require researchers to disclose specific dollar amounts of equity or other compensation on their financial disclosure forms, the specific financial interests of NIH-funded researchers are often unknown. Equity, including stocks and options, was the most common financial COI disclosed to the NIH on external grantee disclosure forms.²⁶³

Grantee institutions did not uniformly report conflicts to the federal government.

Grantee institutions fail to document their oversight of conflicts.

“Given the complex nature of researchers’ conflicts and the vulnerabilities that exist regarding their identification and management,” concluded the OIG, “[i]ncreased oversight is needed to ensure that (1) these conflicts are managed appropriately, (2) the research conducted using Federal funds is not biased by any conflicting financial interests of researchers, and (3) human subjects are not subjected to unnecessary risks.”²⁶⁴

Outside of biomedicine, much less is known about university COI management practices

because of a dearth of scholarly research in other areas. The NSF conflict of interest rules governing other disciplines are far less strong. No other federal grant-making agencies have COI policies covering their university grantees. In November 2003, the GAO issued a report tellingly titled: “Most Federal Agencies Need to Better Protect against Financial Conflicts of Interest.”²⁶⁵

In 2010, Francis Collins, then NIH director, and Sally Rockey, NIH deputy director of extramural research, published a commentary urging a “redoubling” of efforts to address financial COI for the good of the entire research enterprise: “*Clearly, investigators, institutions, and NIH need to redouble collaborative efforts to uphold the integrity of federally funded biomedical and behavioral research. If NIH-supported researchers fail to disclose the full extent of their financial interests, universities fail to comprehensively manage FCOI, or NIH fails to diligently oversee the entire system, public trust will be jeopardized in ways that may have far-reaching implications for the future of science...Consequently, for the good of the research enterprise and for our nation as a whole, it is imperative to take collective steps now to usher in a new era of clarity and transparency in the management of FCOI.*”²⁶⁶

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RISK 6: The Absence of Legal Protections to Safeguard Research Integrity and Academic Freedom in Industry-Sponsored Research Contracts

Finally, it is important to recognize that policies and procedures to address financial COI on campus are not the only, nor even the most important, mechanisms for managing academy-industry relationships. Another critical mechanism involves negotiating and drafting industry-university contracts to protect research integrity and faculty’s academic freedom.

All sponsored research (grants, contracts, or cooperative agreements) and a large portion of academic consulting as well, is done under the terms of legally binding contracts. The contracts set out specific terms and conditions for the university and its faculty to perform a certain scope of work under a specified budget. The legal contract usually spells out deliverables for each project and addresses other critical details related to ownership of intellectual property and the responsibilities of all parties. However, too often, these contracts fail to include specific legal terms that would better protect research integrity and secure core academic freedom rights of faculty members. This, too, is an area of growing public concern concerning universities’

management of productive academy-industry research relationships.

In 2002, for example, Kevin Schulman, a researcher at Duke University, surveyed senior administrators at the sponsored research offices of 108 medical schools to evaluate how well their legal contracts with industry sponsors conform to long-accepted standards of academic authorship and scientific research integrity. The International Committee of Medical Journal Editors (ICMJE) had reaffirmed the standards in 2001, and 500 scientific journals had adopted them.²⁶⁷ “Our findings,” Schulman wrote in his conclusion, “suggest that academic institutions routinely participate in clinical research that does not adhere to ICMJE standards of accountability, access to data, and control of publication . . . We found that academic institutions rarely ensure that their investigators have full participation in the design of the trials, unimpeded access to trial data, and the right to publish their findings.”²⁶⁸

Specifically, the study found the following standards for the conduct of industry-sponsored, multi-site clinical trial agreements:

Data Control: Only 1 percent of the site agreements between medical schools and industry sponsors required academic investigators to be given access to all the trial data in multi-site clinical trials. (Interestingly, this figure rose to 50 percent for “coordinating center agreements,” where one institution, department, or center agrees to be responsible for the conduct or administrative/coordinating functions of a multi-center study.)

Data Analysis: Only 1 percent of the site agreements required the use of independent executive committees or data-and-safety-monitoring boards (DSMBs) to provide independent oversight of the trial.

Publication: None of the site agreements required publication of trial results. Only 40 percent of the site agreements addressed the issue of editorial control over reported trial results.

Public Disclosure/Transparency: Only 17 percent of institutions in the site survey (and 36 percent in the coordinating-center survey) had a policy dictating limits on the duration of confidentiality. The median duration of confidentiality was five years, in both site and coordinating-center agreements.²⁶⁹

When the Schulman study was published, Jeffrey Drazen, editor in chief of the *New England Journal of Medicine*, commented: “This survey paints a bleak picture of the state of academic–industrial contracting. According to the results, very few centers included standard language in their contracts that guaranteed the investigators at a given center access to the primary data from the entire study. Without such a guarantee, the entities sponsoring the research can effectively implement a ‘divide and conquer’ strategy that allows each group of investigators access to their own data, but makes analysis of all the data in a multicenter trial a virtual impossibility.” He added that universities would do well to adopt standard, accepted contract language: “If universally adopted, such language would help safeguard the integrity of the research process.”²⁷⁰

Several more recent studies, however, have found a persistent dearth of academic research protections in university contracts with industry. A 2005 study led by Michelle Mello at the Harvard School of Public Health²⁷¹ surveyed research administrators responsible for negotiating clinical-trial agreements with industry at 107 US medical schools. The study concluded: “Standards for certain restrictive provisions in clinical-trial agreements with industry sponsors vary considerably among academic medical centers.” Although 85 percent of administrators reported that their offices would not approve contract provisions giving industry sponsors authority to revise manuscripts or decide whether results should be published, more detailed survey questions revealed the following gaps:

- 62 percent permit sponsors to alter study design after agreements are executed;
- 50 percent allowed industry sponsors to draft final manuscripts, with academic investigators’ roles limited to review and suggestions for revision, while 40 percent prohibited industry sponsors from drafting final manuscripts, and 11 percent were unsure whether to allow it;
- 24 percent permitted industry sponsors to insert their own statistical analyses into final manuscripts, another 29 percent were unsure whether to allow it, and 47 percent disallowed it;
- 41 percent allowed industry sponsors to bar academic investigators from sharing data with third parties after trials were complete, another 24 percent were unsure whether to allow this, and 34 percent disallowed it;
- 80 percent of the agreements allowed sponsors to own research data;

- 35 percent permitted sponsors to store the data and release portions to investigators;
- 62 percent of medical schools keep the terms of clinical-trial agreements confidential;
- After trials end, 21 percent of agreements prohibit investigators from discussing research results, including presentations at scientific meetings, until sponsors consent to dissemination;
- After the agreements had been signed, disputes with industry sponsors were common. Disagreement most frequently centered on payment (75 percent reported at least one payment dispute in the previous year), intellectual property (30 percent), and control of or access to data (17 percent).
- 69 percent of administrators perceived that competition for research funds created pressure on administrators to compromise on the language in their industry contracts, with 24 percent of those describing the pressure as great.

A final study that bears mentioning is a 2011 survey of clinical-care policies governing US universities' interactions with industry, led by Susan Chimonas at Columbia University's Institute on Medicine as a Profession (IMAP). This study examined U.S. medical school policies and procedures addressing a range of academy-industry relationships, sometimes described as "marketing relationships"—e.g. receipt of industry gifts, free drug samples, free meals, and positions on industry-led "speakers bureaus"—which empirical research (discussed earlier) has shown to be associated with bias in both research and professional decision-making. Many professional medical groups—including the IMAP and the American Board of Internal Medicine (ABIM) Foundation, publishing in the *Journal of the American Medical Association*;²⁷² the Association of American Medical Colleges (AAMC),²⁷³ and the Institute of Medicine (IOM)²⁷⁴—have already issued consensus recommendations urging US university medical schools to restrict biomedical industry gifts, meals, ghostwriting, and speakers' bureaus. These same associations have also urged universities to establish central repositories for free drug and product samples and have called for full transparency in university consulting and research contracts. The differences among the groups' recommendations are minor. However, the Chimonas study found that, as of December 2008, US medical schools' adoption of these policy recommendations covering physician-industry interactions was "notably incomplete."²⁷⁵

- The absence of any policy was the most prevalent finding in seven of eleven areas

examined;

- Even the most frequently regulated areas—industry gifts and industry consulting— had “no policy” rates of 25 percent and 23 percent, respectively;
- Faculty involvement in industry-led ghostwriting—which has become prevalent on campus and also highly controversial—was the most neglected policy area: 70 percent of medical schools had no explicit policies to address ghostwriting. (However, at nineteen institutions where policies did address ghostwriting, it was usually strongly prohibited.)
- The study also considered the “stringency” of the policies and found “very low adoption of stringent policies (less than 5 percent)” addressing consulting, honoraria, and faculty participation in industry speakers’ bureaus.
- Medical school policies had higher rates of stringency for gifts (30 percent), meals (26 percent), industry-vendor site access (19 percent), free drug samples (17 percent), and continuing medical education (16 percent)

Part I.
❖
**General Principles (1-7):
Principles & Standards To Guide
Academic-Industry Engagement University-Wide**

The AAUP recommendations offered here include:

GENERAL PRINCIPLES (these are principles that may be applied university-wide; they cover core academic norms and standards, such as authenticity of authorship, publication rights, and academic autonomy; they also address broad areas of academic-industry engagement, such as Student Education & Training, Financial Conflicts of Interest, and Intellectual Property Management), and

TARGETED PRINCIPLES (these Principles address specific types of academic-industry engagement, including Strategic Corporate Alliances, Industry-Sponsored Clinical Trials, and Academic-Industry Interactions at Academic Medical Centers). Some repetition has been necessary to preserve in what follows, so the principles appropriate to each category remain comprehensive.

**❖ Principle 1:
Faculty Governance**

The university must preserve the primacy of shared academic governance in the planning, development, implementation, monitoring, and post-hoc assessment of all donor agreements and collaborations, including those with private industry, government, and nonprofit groups.

• Threats to shared governance and violations of good shared-governance practices run throughout many of the case studies and risk categories associated with academic-industry engagement that we reviewed in the Introduction. The key threats to shared governance may be summarized as follows:

- Approval of sponsored research contracts without review and consent by faculty governing bodies;

- Involvement of senior administrators who hold approval or supervisory authority and who are compromised by financial COI;
- Faculty grant awarding processes dominated by, or influenced by, representatives of funding sources and or by faculty who are already recipients of corporate sponsor funding;
- Involvement of faculty, administrators, or governing board members with financial COI at any level;
- Analysis and review of completed projects compromised by involvement of faculty or administrators with financial COI;
- Non-disclosure of university foundation engagement with industry, including negotiations over gifts, contracts, or program initiatives;
- Loss of faculty control over key areas of authority and professional expertise—including curriculum planning and faculty hiring;
- Faculty selection of students for admission to graduate programs overly influenced by the goals of corporate contracts;
- Diminished faculty influence over departmental and institutional priorities;
- Diminished faculty influence over institutional mission.

The AAUP recommends the following corrective and preventative measures:

- No external relationships, donor agreements, or university-industry collaborations should be allowed to intrude on academic governance, or contravene existing academic policies or collective bargaining agreements.
- The faculty senate or other equivalent faculty governing bodies should be explicitly involved in the overall development and final approval of any new, large-scale, multi-year Strategic Corporate Alliances (SCAs) on campus (See Part VI, below, for a more complete discussion of the AAUP's recommended principles relating to SCAs).
- University faculty through their academic senates, or other governing bodies on campus, also should be actively involved in drawing up baseline principles and standards to guide all

forms of university engagement with outside sponsors, including corporate sponsors, the central focus of this AAUP report.

- Establishing these baseline standards will strengthen, and make more coherent, university policymaking in this area; safeguard academic professionalism; and engender greater campus-wide support and public trust.

- These guiding policies should draw on the AAUP’s recommendations offered here, and build upon them. To ensure that all forms of academic-industry engagement are addressed in an effective and comprehensive manner across the whole campus, these policies should cover the university as well as any affiliated medical schools, hospitals, institutes, and centers.

Discussion:

Too often, today, faculty governing bodies are shut out of policy-making and other negotiations surrounding the formation of academic-industry partnerships, even when these partnerships have a direct bearing on research and other institution-wide academic matters that have traditionally fallen under the purview of the faculty. Often these university-industry alliances emerge from one particular department or institute, but are not subject to any supervision, oversight, input, or evaluation by collective faculty governing bodies.²⁷⁶

This is the case with multi-year, multi-million-dollar partnerships—known as Strategic Corporate Alliances (discussed in detail under Part VI of this report)—which, due to complex negotiations and confidentiality concerns, are frequently presented to faculty senates or other faculty governance bodies as largely “fait accompli” deals, thus permitting minimal faculty input or consultation.²⁷⁷ The faculty should regard such end runs around shared governance as unacceptable.

Simply keeping track of academic-industry engagements on campus can be tricky, since these activities usually take place under the auspices of a variety of different offices (the Office of Sponsored Programs, the Office of Research Administration, the Office of Technology Transfer, etc.) and may be negotiated primarily by a relatively small handful of university and company representatives.

At many state-funded universities, meanwhile, a sizable portion of this private-sector and

corporate- gift and grant administration has been transferred over to legally separate, university-affiliated, non-profit foundations, which are highly opaque because they often claim exemptions from normal academic governance procedures and from state open record laws.²⁷⁸

Not surprisingly, as the private assets of these less transparent university-affiliated foundations have grown, so too has their influence and the potential for abuse. Allegations of misuse of university foundation assets have already led to civil suits, as well as state and federal criminal investigations at numerous universities. Here is a brief summary of just a few of these cases prepared by the Student Press Law Center, which tracks these university-affiliated foundations and their handling of donor funds.²⁷⁹

Misuse of University-Affiliated, Non-Profit Foundation Funding

- At the University of Idaho a former university vice president pleaded guilty to misuse of state funds and was sentenced to probation for his role in secretly diverting foundation money to prop up the financially troubled \$136 million project.²⁸⁰
- In 2005, the *Atlanta Journal-Constitution* reported that University System of Georgia Foundation donor lists—which were disclosed only after a legal battle—revealed that colleges within the system awarded companies lucrative contracts after they had made large donations to a special fund that supplemented the university chancellor’s salary.²⁸¹
- At Iowa State University, an independent audit in 1999-2000 revealed that the ISU Foundation was still paying a former football coach, who resigned in 1994, over half-a-million dollars a year as part of a deferred compensation contract payable over 20 years. (While actually employed by the university, the coach’s annual salary was \$111,197.)²⁸²
- At Florida Atlantic University, a 2003 investigation revealed that its foundation had set aside \$42,000 to purchase a red Corvette for the school’s outgoing president.²⁸³

Given these trends, it is imperative for faculty to protect shared academic governance by drawing up stronger consensus documents—containing baseline principles and standards to guide academic-industry relationships on campus—so all forms of academic-industry

engagement (whether advanced by the Vice President for Research, a small handful of faculty investigators, the Office of Sponsored Research, or a university-affiliated foundation) will be governed by a common set of clear academic standards.

This principle on Faculty Governance helps to clarify and strengthen AAUP recommendations already issued in the “Statement on Government of Colleges and Universities” and the “Statement on Corporate Funding of Academic Research.”²⁸⁴

Academic-industry partnerships play a vital role in funding research, and bring many additional benefits. However, in the face of mounting financial conflicts of interest, and other commercial threats to academic freedom, research integrity, and public trust, the time has come for stronger faculty input and guidance in this broad area.

❖ Principle 2: Academic Freedom, Autonomy, and Control

The university must preserve its academic autonomy—including the academic freedom rights of faculty, students, postdoctoral fellows, and academic professionals—in all its relationships with industry and other funding sources by maintaining majority academic control over joint academy-industry committees and exclusive academic control over core academic functions (such as faculty research evaluations, faculty hiring and promotion decisions, classroom teaching, curriculum development, and course content).

- No academic institution should accept any financial support that is either explicitly or implicitly conditioned on the donor’s ability to influence or control such core academic functions.

- This statement builds on the AAUP’s 1990 “Statement on Conflicts of Interest,” which reads in part as follows:

Because the central business of the university remains teaching and research unfettered by extra-university dictates, faculties should ensure that any cooperative venture between members of the faculty and outside agencies, whether public or private,

respects the primacy of the university's principal mission, which regard to the choice of subjects of research and the reaching and publication of results.²⁸⁵

- It also draws on a 2007 statement issued by the AAUP's Committee A on Academic Freedom, asserting that academic institutions surrender their autonomy and authority—and diverge with the principles of academic freedom—when they accept outside funding that is “conditioned on a requirement to assign specific course material that the faculty would not otherwise assign.”²⁸⁶

- In exchange for academic freedom and professional autonomy, faculty have a collective responsibility to uphold the highest standards of academic scholarship, research integrity, and public trust. These pillars of academic freedom and professional responsibility are further elaborated on in many of the detailed principles offered below.

Discussion:

In the last decade, a number of corporate- and private-foundation partnerships that impinge on core areas of faculty autonomy—including faculty hiring, research direction, and curriculum design—have been publicly reported on in the media. Here, in the U.S., recent cases have involved IBM, BB&T, and the Charles G. Koch Foundation; in Germany, a prominent case arose involving Deutsche Bank.²⁸⁷ Here is a brief summary of the U.S. cases:

- As of 2011, the Charles G. Koch Foundation (a libertarian foundation founded by one of the heirs to Koch Industries, a major U.S. oil, gas, and chemical conglomerate with annual revenues of \$110 billion) reported issuing grants to more than 180 colleges and universities.²⁸⁸ Many of these agreements contained highly controversial restrictions, which became public only after the underlying contracts were disclosed by faculty members and the news media. From 2007 to 2009, for example, Utah State University received more than \$700,000 from the Koch Foundation to supplement the salaries of five business school faculty. After stating these appointments would be subject to standard hiring procedures, the actual written contract required the Foundation to approve all faculty members hired. Another 2008 agreement between the Koch Foundation and Florida State University, which became public in 2011, also cedes control over faculty hiring. Under the FSU contract, an advisory committee of faculty members selected by the Koch Foundation is charged with vetting and approving (or disapproving) prospective faculty

appointments. This advisory committee is also charged with evaluating overall ideological conformity with the Foundation's libertarian economic and political goals.²⁸⁹

- In 2006, North Carolina State University inaugurated a new academic concentration, "Services Management," open to graduate students pursuing either a Masters in Business Administration or a Masters of Sciences in Computer Networking, whose coursework was co-developed by IBM. According to the *Wall Street Journal*, in exchange for IBM granting the university five faculty awards of \$30,000 each, plus the time of its employees, IBM was permitted to co-create the curriculum and co-teach five university courses.²⁹⁰

- At the University of North Carolina-Charlotte and more than two dozen other colleges across the nation, BB&T, a large southern banking giant, made donations to humanities and business programs contingent on Ayn Rand's free market theories being incorporated into the curriculum, and her books assigned as required reading.²⁹¹

Academic independence has always been rooted, historically, in the university's core belief that it must retain the ability to control its own internal academic affairs. This is referred to as academic self-governance or academic autonomy. Since the birth of the academic freedom movement in the early 1900s, U.S. universities and their faculty have worked vigorously to prevent outside donors (whether a wealthy benefactor, a commercial sponsor, or a federal grant-making agency) from exercising undue influence and control over faculty teaching, research, hiring, and other internal academic decisions. The rationale for this remains straightforward: If universities allow themselves to be guided by the narrow dictates and interests of their outside financial supporters, they could not simultaneously—or credibly—perform their core academic and public-interest missions to: advance high-quality scholarship and research across all disciplines; generate reliable public knowledge; engage in dispassionate inquiry; offer expert advice free from the influence of special interest groups; and deliver a broad-based education as well as advanced specialized training.

❖ Principle 3: Academic Publication Rights

Academic publication rights must be fully protected, with only limited delays (a maximum of thirty to sixty days*) to remove corporate proprietary information, confidential information, and/or to file for patents prior to publication. Sponsor efforts to obstruct, and/or sponsored research agreements that do not permit, the free, timely, and open dissemination of research data, codes, reagents, methods, and results are unacceptable. Sponsor attempts to compel a faculty member, student, postdoctoral fellow, or academic professional to edit, revise, withhold, or delete contents in an academic publication (including a master's thesis or PhD dissertation) or presentation (beyond these legally justified claims to protect explicit trade secrets) must be clearly prohibited in all written sponsored research contracts and in written university policies. A funder is of course free to make editorial suggestions, but the researcher must be free at all times to accept or reject them.

**This time limit is consistent with the National Institutes of Health recommendation discussed below. This time limit of 30-60 days for delays on publication (for the purpose of securing proprietary protection through a provisional patent or other IP filing) is consistent with recommendations issued by the National Institutes of Health, which are discussed in further detail below.*

Discussion:

As a condition of research sponsorship, it is common for a corporate sponsor to insist on “first look” rights to insure that any academic publications and/or public presentations stemming from this sponsored funding does not disclose proprietary information that has not yet been secured through intellectual property protection.

The National Institutes of Health generally recommends granting sponsors no more than a 30-to-60-day window for pre-publication review, which it considers sufficient time for the corporate sponsor, or the university, to file a provisional patent claim and/or remove any sensitive proprietary information.²⁹²

Publication is the lifeblood of the university; it guarantees the rapid diffusion of new academic knowledge and insures that all new knowledge will be independently scrutinized and

verified for accuracy. In some research fields, an enforced delay of even thirty days is hugely significant. These “first look” rights should be restricted to 30 days wherever possible (60 days maximum). They should also clearly specify that delays can be invoked only for the purposes of securing the sponsor’s intellectual property, not to suppress undesirable results temporarily, or for the purposes of amending or editing the content, substance, or conclusions contained in an academic publication or presentation.

Corporate sponsors should also be encouraged to agree to “rapid clearance procedures” for more time sensitive materials and academic presentations, so expedited reviews of two weeks or less are also possible. Delays in releasing research results that bear on natural disasters, industrial accidents, product safety, or immediate medical needs are examples of work that may require such rapid clearance procedures.

❖ **Principle 4:** **The Authenticity of Academic Authorship**

To protect the authenticity of academic publishing, universities and their affiliated academic medical centers should prohibit faculty, students, postdoctoral fellows, medical residents, and other academic professionals from engaging in practices variously described as industry-led “ghostwriting” or “ghost authorship.” Ghostwriting occurs when private firms or industry groups publish journal articles supporting commercial interests without publicly disclosing that the company initiated and often performed the initial drafting of the articles and recruited and/or paid university professors (sometimes referred to as “academic opinion leaders”) or others to sign on as nominal “authors.” Although ghostwriting has been especially widespread in academic medicine, prohibitions on ghostwriting should be applied university wide and should cover all faculty and researchers because the practice violates scholarly standards and is unacceptable in any academic setting.

• Numerous prestigious academic societies and journals have already endorsed such a recommendation. In the field of medicine, the Institute of Medicine (2009),²⁹³ AAMC (2006),²⁹⁴ and the Association of American Universities 2008²⁹⁵ have called for unambiguous prohibitions on faculty participation in ghostwriting. Starting in 2001, medical journal editors, through the International Committee of Medical Journal Editors (ICMJE) and the World Association of

Medical Editors (WAME), also took clear steps to try to better detect and prohibit ghostwriting.²⁹⁶ Concerned about threats to the integrity of clinical trials in a research environment increasingly controlled by private interests, the ICMJE revised its “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” to call for full disclosure of the sponsor’s role in the research, as well as assurances that the investigators are independent of the sponsor, are fully accountable for the design and conduct of the trial, have independent access to all trial data, and control all editorial and publication decisions. These ICMJE-WAME authorship principles are now widely seen as the “gold standard.” All universities should hold their faculty members clearly responsible for upholding these authorship standards, just as they would other academic regulations prohibiting fraud, plagiarism, and other serious violation of accepted scholarly practice.

- Despite the prevalence of ghostwriting documented in the academic literature (see the discussion and citations below for details), university policymaking in this area remains astonishingly weak: A 2010 study published in PLoS Medicine found that only 13 of the top 50 U.S. medical schools have policies that specifically prohibit ghostwriting.²⁹⁷

- Two of the hallmarks of academic integrity are intellectual independence and accountability; both are egregiously violated when a faculty member assumes credit as the “author” of a manuscript prepared by an unacknowledged, or inadequately acknowledged, industry-paid writer.²⁹⁸ Adequate acknowledgment would have to specify the role played by these industry-paid writers, as the preparers of the first draft, as well as the specific roles of all stated authors. Faculty have a special obligation to demonstrate and protect their intellectual independence, uphold the highest standards of scholarship, and act as role models for their students. Any faculty member who is found, and proven, to have engaged in ghostwriting should be appropriately disciplined, as this constitutes serious academic misconduct.

Discussion:

Studies have documented that industry-led ghostwriting in academia is prevalent, especially within the field of medicine.²⁹⁹ Investigations, based on litigation documents and other sources, have shown how pharmaceutical companies used behind-the-scenes ghostwriting techniques to market sertraline³⁰⁰, olanzapine³⁰¹, gabapentin³⁰², estrogen replacement therapy³⁰³, rofecoxib³⁰⁴, paroxetine³⁰⁵, methylphenidate³⁰⁶, milnaciprin³⁰⁷, venlafaxine³⁰⁸, and dexfenfluramine.³⁰⁹

One survey of major biomedical journals found that 13 percent of all research articles had “ghost” authors; that is, people who filled the criteria for authorship, but were not listed as authors.³¹⁰ None of these ghost authors was ever even acknowledged in the paper. Other estimates of ghostwriting prevalence run higher.³¹¹ However, because the practice of ghostwriting has not been investigated thoroughly beyond medicine, its true scope remains unknown.

Another variant on ghostwriting has been pervasive in the field of tobacco research, for example. Numerous studies have shown how the tobacco industry influences academic authors by carefully vetting who will receive its funding, shaping study design, and then making “suggestions” about what investigators should and shouldn’t say in their papers.³¹²

Industry efforts to manipulate and influence academic authors have drawn ire from public officials and the media. A *New York Times* article recently characterized medical ghostwriting as “an academic crime akin to plagiarism.”³¹³ Senator Charles Grassley (R-IA), a longtime-ranking member of the Senate Committee on Finance, spearheaded a series of investigations into financial relationships between drug and device companies and academic physicians, with an especially critical eye trained on ghostwriting.³¹⁴ Ghostwritten articles and reviews, in addition to compromising the authenticity of authorship and undermining peer review for faculty appointments and promotions, can also introduce pervasive commercial bias and distortion into the scientific literature. According to Drs. Jeffrey Lacasse and Jonathan Leo, the authors of a 2010 survey of ghostwriting, this may, in turn, be “dangerous to public health.” The authors conclude their study with the following passage, quoting from various studies (cited in the endnote that follows):

“[G]hostwritten articles on [the pain killer, Vioxx] rofecoxib probably contributed to... ‘lasting injury and even deaths as a result of prescribers and patients being misinformed about risks.’ Study 329, a randomized controlled trial of [the antidepressant drug, Paxil] paroxetine in adolescents, was ghostwritten to claim that paroxetine is ‘generally well tolerated and effective for major depression in adolescents,’ although data made available through legal proceedings show that ‘Study 329 was negative for efficacy on all 8 protocol specified outcomes and positive for harm.’ Even beyond frank misrepresentation of data, commercially driven ghostwritten articles shape the medical literature in subtler but important ways, affecting how health conditions and treatments

are perceived by clinicians.”³¹⁵

❖ Principle 5: Access to Complete Study Data and Independent Academic Analysis

University codes of conduct should prohibit faculty and others from participating in sponsored research that restricts investigators’ ability to access the “complete study data”* related to their sponsored research and/or that limits investigators’ ability to conduct unfettered, free, and independent analyses of complete data to verify the accuracy and validity of final reported results. All universities should also secure these basic academic freedom rights within the legal terms of all sponsored research contracts.

This principle is reaffirmed under Principle 44 (under Part VII, which addresses Clinical Medicine and Clinical Research).

**Protecting access to “complete study data” is particularly important in the area of clinical research, where drug trials and other medical investigations are often conducted at multiple institutions simultaneously. If the sponsor grants only partial access to the study’s complete data sets and/or withholds other relevant research codes and materials, then the academic investigators and authors will not be able to perform a truly independent expert analysis of the study’s data and outcomes.*

- This AAUP Principle is in keeping with recommendations already issued by the AAMC (2001³¹⁶ and 2006³¹⁷), the International Committee of Medical Journal Editors, ICMJE (2001),³¹⁸ and the World Association of Medical Editors, WAME.³¹⁹

- In 2001, the AAMC issued conflict of interest recommendations that emphasized the need for academic investigators to retain control over both data access and data analysis:

- “The [conflict of interest] policy should affirm an investigator’s accountability for the integrity of any publication that bears his or her name. ***The policy should also affirm the right of a principal investigator to receive, analyze, and interpret all data generated in the research, and to publish the results, independent of the outcome of the research.***

Institutions should not enter, nor permit a covered individual to enter, research agreements

that permit a sponsor or other financially interested company to require more than a reasonable period of pre-publication review, *or that interfere with an investigator's access to the data or ability to analyze the data independently*" [Emphasis added].³²⁰

- In 2002, the New England Journal of Medicine (NEJM) published a survey of 108 medical schools which found that only one percent of university-industry contracts to multi-site clinical trials required the academic authors to have independent access to the complete study data.

Commenting on this piece, NEJM editor Jeffrey Drazen wrote:

"This survey paints a bleak picture of the state of academic–industrial contracting...[T]he [academic medical] system would be better served if there were universally accepted contractual language that protected patients' confidentiality and any proprietary aspects of the data, while ensuring that academic investigators participating in clinical trials have full and unfettered access to the data. If universally adopted, such language would help safeguard the integrity of the research process."³²¹

- A more recent 2005 analysis of 107 medical schools found that industry sponsor control over data access and data analysis remains widespread. The survey concluded that 50 percent of medical schools would allow their industry sponsors to draft the final manuscript, with the academic investigators' role limited to review and suggestions for revision; 24 percent would permit the industry sponsors to insert their own statistical analyses into the final manuscript (another 29 percent were not sure whether to permit this or not); 41 percent would allow industry sponsors to prohibit academic investigators from sharing data with third parties after the trial was over (another 24 percent were not sure whether they should allow this practice, and 34 percent disallowed it).³²² In addition to the problem of bias, there are problems with delegating statistical analysis to industry employees not trained in statistics.

Discussion:

Today, it has become common for pharmaceutical and other biomedical companies to assert "proprietary control" over the complete study data associated with a particular clinical research trial (which is often conducted at multiple testing sites simultaneously), as well as the corresponding statistical codes (which are frequently used to "blind" the study's investigators from any possible bias, based on advance knowledge of patient outcomes or results and which

are required to interpret that data). Not infrequently, the industry sponsor will assert that this data and any related codes must be guarded on company computers, and may only be analyzed by company chosen statisticians.³²³ One academic physician has dubbed such industry-controlled drug trials “ghost science,”³²⁴ because they effectively permit the sponsor to control both the analysis and final interpretation of all study results, making independent academic authorship effectively meaningless. Attaching one’s name to industry-generated analyses raises serious issues of misconduct, since the academic researcher can claim no genuine intellectual responsibility for the reported results.

The prevalence of this industry practice is not known, and difficult to quantify. When Procter and Gamble Pharmaceuticals (P&G) blocked researchers at Sheffield University in the United Kingdom from analyzing data related to an osteoporosis drug trial, the company told the media that it was “standard industry practice”³²⁵ to deny authors access to raw data in drug studies.

The clearest indication of the prevalence of these problems came in 2001 when, (as noted already under Principle 5), the International Committee of Medical Journal Editors (ICMJE) announced it was revising its “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” to try to prevent undue industry influence over trial design, access to data, final data analysis, and the final reporting of study results.³²⁶ These ICMJE requirements now have been adopted by 500 science journals, however compliance is voluntary and not all high impact journals across all academic disciplines have adopted similar, rigorous submission standards, nor do all academic journals have well defined financial-conflict-of-interest disclosure policies.³²⁷ Moreover, as the studies cited above indicate, many universities and their medical schools are not enforcing these standards in their own sponsored research contracts with industry. It is not sufficient for journals alone to adopt these standards; universities must do so as well. Indeed, universities with strong sponsored research contracts and COI reporting systems are in a better position to enforce them.

❖ Principle 6: Confidential and Classified Research

Classified research, as well as confidential corporate, government, or nonprofit research that may not be published, is inappropriate on a university campus and should not be permitted. Many institutions currently have written policies that ban “classified” government research on campus; the bans should be reviewed to ensure that they also clearly cover confidential corporate research. Universities employ a variety of mechanisms for moving confidential and classified research off campus, sometimes using governing structures less subject to academic oversight. Sorting through multiple categories of “national security,” “classified,” and “sensitive but unclassified” (SBU) information requires special monitoring by faculty governing bodies. These faculty bodies should presume that research results are always made freely available, absent a compelling case to the contrary, to determine which research will be confidential and thus cannot be performed on campus. As historical precedent suggests, the special circumstances of a formal congressional declaration of war against specified nation-states may justify exceptions to the policies for the duration of the conflict.

- Given the university’s open culture and its longstanding commitment to the broad dissemination of new knowledge, any sponsored research project that would restrict free and open publication, presentation, and discussion of the results is not acceptable.

- Sorting through the U.S. government’s multiple categories of “sensitive but unclassified” (SBU) information will require special monitoring, as noted above, in order to determine what research will be confidential and cannot be conducted on campus. In line with this principle, the AAUP recommends against establishing secure buildings or facilities within buildings on campus to conduct secret sponsored research.

- This is a general principle with broad academic endorsement. The AAUP has addressed this issue on numerous occasions (see Appendix A for sources and details). In 1967 the national AAUP approved the following resolution: “The Fifty-third Annual Meeting of the American Association of University Professors believes that all secret arrangements entered into by academic institutions or individuals in an academic capacity threaten the integrity of the academic community. The agreements between academic individuals and organizations and the Central Intelligence Agency constituted such a threat. Accordingly, the Annual Meeting calls

upon all elements of the academic community to scrutinize any and all arrangements with public and private organizations and individuals to make certain that such arrangements are consistent with the basic principles upon which higher education in this country rests.”³²⁸ The following year the principle was reaffirmed: “The Fifty-fourth Annual Meeting of the American Association of University Professors reaffirms the concern of previous meetings about secrecy in research. Any arrangement with an outside agency that places restrictions on the open publication of results of research raises serious questions of academic integrity. Accordingly, the Annual Meeting calls upon the academic community to examine with great care the nature and consequences of research relationships with all outside agencies to make certain that such activities are consistent with the basic principles upon which higher education in this country rests.” The resolution was again reprinted in the AAUP Bulletin.³²⁹ The AAUP took up the matter again most recently in a 2003 statement titled “Academic Freedom and National Security in a Time of Crisis,” which explores the sweeping set of legal changes that the U.S. Congress adopted regarding domestic and foreign intelligence gathering and secrecy following the September 11, 2001, terrorist attacks:

“There may be points where some of our freedoms will have to yield to the manifest imperatives of security. What we should not accept is that we must yield those freedoms whenever the alarm of security is sounded. Given the extensive historical record of governmental overreaching and abuse in the name of security, we are right to be skeptical. Even at the height of the Cold War, when we faced the prospect of nuclear annihilation, the government did not institute security measures as far reaching as some now proposed... Accordingly, when the government invokes claims of security to justify an infringement of our civil or academic liberties, the burden of persuasion must be on the government to satisfy three essential criteria. 1. The government must demonstrate the particular threat to which the measure is intended to respond, not as a matter of fear, conjecture, or supposition, but as a matter of fact... 2. The government must demonstrate how any proposed measure will effectively deal with a particular threat... 3. The government must show why the desired result could not be reached by means having a less significant impact on the exercise of our civil or academic liberties.... Under certain circumstances, academic research can directly affect national security, and in those circumstances, a system of classification may be necessary, as it

has been in the past. The hazards of a dangerous world cannot be ignored. At the same time, secrecy, an inescapable element of classified research, is fundamentally incompatible with freedom of inquiry and freedom of expression... Not only are fewer restrictions better than more, but restrictions on research, to the extent that any are required, must be precise, narrowly defined, and applied only in exceptional circumstances. These seem to be the lessons the academic community has drawn from its past experiences with classified research.”³³⁰

- An earlier AAUP report has special relevance here because the arguments it mounts against classified research also raise issues of concern in negotiating approval for confidential corporate research. In a 1983 Committee A report “The Enlargement of the Classified Information System” responding to the Regan administration’s Executive Order 12356 (April 2, 1982), the organization asserted that the executive order “significantly abridges academic freedom beyond the needs of national security” and added that “insofar as academic freedom is improperly curtailed, the nation’s security is ill-served” and that “open and free scientific communication is essential for ensuring national security.”³³¹ Indeed, “freedom to engage in academic research and to publish the results is essential to advance knowledge and to sustain our democratic society . . . secrecy . . . is fundamentally incompatible with open inquiry.” (p. 11a) And finally, “classification [as secret] defeats its own purpose . . . if it imperils the freedoms it is meant to protect.” The report looked forward to “the bleak prospect of academic researchers who are walled-off from each other . . . thus forestalling mutual enrichment through the exchange of ideas and constructive criticism.”³³² At that point, research classified for national security reasons shares consequences with confidential research conducted for corporations.

- Many prominent universities now have policies in place banning confidential and/or classified research from their campuses, including Cornell, MIT, and U.C. Berkeley (see the discussions below), however not all of these policies were designed to address commercially funded research.

- Cornell’s policy seeks to protect public access to new knowledge by explicitly prohibiting classified research on campus. The policy reads as follows:

“Given the open nature of Cornell University, research projects which do not permit the free and open publication, presentation, or discussion of results are not acceptable... In particular, research which is confidential to the sponsor or which is classified for security purposes is

not permitted at Cornell University.”³³³

- The Massachusetts Institute of Technology (MIT) also has a written policy that strongly discourages any classified or unpublishable research from being performed on campus. There are some exceptions to this policy, but these are rare (see this endnote for MIT’s precise policy language).³³⁴ In 2002, a specially appointed MIT faculty committee, mindful of U.S. national security needs following the September 11, 2001 terrorist attacks, and of MIT’s history of national service, recommended that the university provide off-campus facilities to help faculty perform classified public service, or other research requiring classification. However, the committee also strongly reaffirmed MIT’s long-standing policy in defense of intellectual openness:

“We recommend that no classified research should be carried out on campus; that no student, graduate or undergraduate, should be required to have a security clearance to perform thesis research; and that no thesis research should be carried out in [intellectual] areas requiring access to classified materials.”³³⁵

- U.C. Berkeley also has a written policy banning the performance of classified and/or non-publishable research on campus. Berkeley’s policy states: “classified projects are not consistent with the teaching, research, and public service missions of the Berkeley campus.”³³⁶ The policy goes on to assert: “The University of California at Berkeley is committed to maintaining a teaching and research environment that is open for the free exchange of ideas among faculty and students in all forums—classrooms, laboratories, seminars, meetings, and elsewhere...There can be no fundamental limitation on the freedom to publish as the result of accepting extramural research support.”³³⁷

However, it is worth noting that the Energy Biosciences Institute (EBI)—a ten-year research alliance between U.C. Berkeley, Lawrence Berkeley National Laboratory, the University of Illinois (Urbana-Champaign), and BP, the oil giant—does appear to circumvent this policy. The EBI contract expressly permits BP employees to carry out “private, confidential, and proprietary research,” and to keep that research secret, despite their physical presence inside a university-owned academic building.³³⁸ U.C. Berkeley has stated that because this policy only applies to BP employees working at the EBI’s academic labs, it does not violate the U.C. ban on confidential research. However, because those same BP scientists’ have extensive collaborations with U.C. Berkeley professors and students, some critics remain skeptical.³³⁹ A similar

confidentiality provision in the 2006 draft EBI proposal prompted the editorial board at the *San Francisco Chronicle* to observe: “On the face of it, this arrangement conflicts not only with the ‘open’ nature of a university, especially a public one, but also with Berkeley’s prohibition against classified research on campus.”³⁴⁰

❖ Principle 7: Academic Consulting

To address the potential for conflicts of commitment* and other financial conflicts of interest, all consulting contracts worth \$5,000 or more a year should be reported to and reviewed and managed by the university’s standing conflict of interest committee(s), charged with addressing both individual and institutional conflicts of interest (see Principle 24, below, for more discussion of these committees). Neither faculty nor administrators should sign a consulting contract that undercuts their professional ability to publicly express their own independent expert opinions, except when consulting with industry, government, or other parties on explicitly classified or proprietary matters. All such consulting agreements should be secured in writing.

**A “conflict of commitment” arises whenever a faculty’s or administrator’s outside consulting and other activities have the potential to interfere with their primary duties, including teaching, research, time with students, or other service and administrative obligations to the university.*

- In accordance with a guidance issued jointly by the Association of American Universities and the Association of American Medical Colleges, AAU-AAMC (2008),³⁴¹ the AAUP recommends that an institution may wish to consider exempting certain clearly defined types of consulting and fees from their definitions of reportable financial interests:

- fees for serving on grant review committees (study sections),
- fees given as honoraria by another academic institution for an academic activity, public lecture, seminar, or grand rounds presentation.

- This AAUP principle on Academic Consulting is very similar to a recommendation issued by the Institute of Medicine (2009): “Faculty should engage only in bona fide consulting arrangements that require their expertise, that are based on written contracts with specific tasks and deliverables, and that are paid for at fair market value. As part of their administration of

conflict of interest policies, university review of faculty consulting and other contracts is prudent and desirable.”³⁴²

Academic Consulting and Financial Conflicts of Interest:

- Today it is common for both faculty and university administrators to accept outside consulting positions working for a variety of groups, including industry. Consulting is an important and vital part of university life. However, the terms of these consulting contracts, and any financial remuneration received, should not interfere with the recipient’s primary institutional, academic, and professional obligations and commitments. Certain types of outside corporate consulting—i.e., board of director seats, seats on corporate scientific advisory boards, faculty participation in corporate “speakers bureaus” (discussed under Principle 48(a) below)—raise distinctive financial conflict of interest concerns, due to possible irreconcilable conflicts between the recipients’ academic duties and the commercial and fiduciary obligations required by these outside positions.³⁴³ These types of consulting arrangements may warrant close oversight, and/or possible prohibition by the university’s standing COI committee.

- Both administrators and faculty should be held to the same standards of disclosure with respect to outside consulting, however campuses may want to consider a more restrictive policy for senior administrators in order to avoid the appearance of institutional conflicts of interest.

- At a minimum, senior administrators should be prohibited from sitting on the boards of corporations that are seeking (or already have in place) research contracts with campus faculty. The responsibility for administrative oversight can be seriously compromised by such arrangements.

Discussion:

The advantages of outside consulting can outweigh the risks if conflict-of-interest rules are in place and enforced, if the freedom to publish and express independent opinions is guaranteed, if the consulting work itself remains a small proportion of a faculty member’s or an administrator’s overall time, and if any single consulting responsibility represents a small proportion of his or her total income.

Outside consulting enables faculty to improve their understanding of various social, industrial, health, and other real-world problems and processes, to develop more interesting and

relevant research questions, and to apply their academic expertise and knowledge to real-world circumstances. This is extremely important. However, currently, codes-of-conduct and conflict-of-interest policies at many leading universities do not prohibit faculty from signing consulting agreements that explicitly conflict with the faculty member's ability to engage in free expression and free inquiry—the core pillars of academic freedom. This is an area that warrants serious policy attention on every campus.

Consulting terms that infringe upon these basic rights are cropping up in diverse fields from pharmaceutical research to energy research. Here are a few examples:

- In July 2010, shortly after BP's massive Deepwater Horizon oil spill, the *Press-Register* of Mobile, Alabama reported that BP was racing to sign consulting contracts with many marine ecology and other departments, located at universities in the Gulf of Mexico region, to aid it with its legal defense case. Some university scientists complained that the terms of these lucrative contracts violated their basic academic freedom rights. At the University of South Alabama in Mobile, for example, Russ Lea, the university's vice-president for research, reported that, under BP's proposed contract, data collected by academic scientists would be held confidential, and could not be published for up to three years without BP's permission.³⁴⁴ The contract also contained other onerous restrictions on scientists' freedom to work with other companies, or public agencies engaged with similar areas of research.³⁴⁵ Later, *Nature News* reported that a number of scientists felt ensnared by a larger legal scramble by BP and the U.S. federal government (which was then preparing its own official assessment of the oil spill, known as the Natural Resource Damage Assessment, NRDA), in which both sides were seeking to round up expert witnesses, sequester data, and impose gag orders on scientists.³⁴⁶

- According to a professor at Harvard's School of Public Health, writing in the *Chronicle of Higher Education*, similar industry restrictions on academic consulting have also surfaced in the field of epidemiology. This professor reported that he had received a contract request from a large pharmaceutical company, to assist in the design of a clinical trial, whose proposed terms "seemed to require that I sign away my right to criticize the product."³⁴⁷ He explained: "One provision would prohibit me from entering into 'any agreement or relationship to render services as ... adviser or consultant to, any other individual, firm, or corporation that would be inimical to or in conflict with' the aspects of the company's business covered by the agreement. Another

would forbid me to engage, in any capacity, directly or indirectly, in ‘any business,’ with or without compensation, relating to the class of products under discussion—not just for the term of the contract, but for the year after as well. Those provisions could restrain me from providing candid advice to a regulator, a government official, or the editor of a peer-reviewed journal about the class of products on which I was consulting, even if the advice were based on publicly available information. I objected to those terms, as did a colleague who was offered the same arrangement.”³⁴⁸

U.S. university administrators and faculty must not allow their quest for research revenue or, increasingly, their quest for earnings from the transfer and commercialization of academic research to distort their core academic and public-knowledge functions.

Part II.

❖

General Principles for Student Education and Training (8-10)

Opening Discussion:

Today it is not uncommon for students, postdoctoral fellows, and more junior researchers and faculty to participate in a wide variety of industrial-sponsored activities, both on and off campus. Such collaborations—working in an industry-sponsored lab on campus, a start-up company off site, or a corporate lab—offer attractive opportunities to graduate students working toward a master’s or doctoral degree, especially since a growing proportion of these students now move on to careers in the private sector. These collaborations can enhance students’ exposure to and understanding of the commercial research environment, and potentially also foster relationships that will lead to full employment after these students graduate.

However, in addition to these clear benefits, such collaborations also present serious risks. Faculty mentors who are involved with an outside company may divert graduate students toward efforts that will not appropriately advance their education, or their thesis research. If students’ work is hemmed in by corporate proprietary constraints (confidentiality requirements, non-compete agreements, non-disclosure terms, secrecy restrictions), students may find themselves barred from presenting their work at scientific meetings—or, worse yet, from completing their PhD dissertations in a timely manner.

Disputes can, and often do, also arise over the ownership of new ideas, resulting in difficult, complex, and often damaging intellectual property battles that undermine mentor-student relationships. When a senior faculty member has a significant personal financial conflict of interest, this may also bias his or her ability to give impartial advice, or appropriately supervise younger investigators’ research.³⁴⁹

A panel on conflicts of interest at the Institute of Medicine recently observed that exploitation of students and untenured investigators by conflicted senior advisers “is unethical and also has the potential to bias research design, conduct, or findings. Areas that may raise problems with undue influence include decisions about an individual’s inclusion or exclusion from a research project; the focus, design, and conduct of a study; the publication of research

findings (including the suppression of publication); and the treatment of intellectual property interests.”³⁵⁰

These men and women are, first and foremost, students and trainees. The university, therefore, has a responsibility to ensure that their primary academic interests are not compromised because of participation in sponsored-research collaborations. The following AAUP recommendations are intended, therefore, to better safeguard the interests of students, postdoctoral fellows, and other untenured and junior investigators, while simultaneously protecting the university’s core commitment to education—the most vital of the universities’ public obligations.

❖ **Principle 8:** **Recruiting and Advising** **Graduate Students, Medical Residents, and Faculty**

The admission of graduate students to degree programs and the appointment of medical residents and faculty should not be based on their potential to work under a particular donor agreement or a particular collaborative research alliance, whether commercial, governmental, or nonprofit. A PhD student’s main advisor should not have any significant* financial interests, including equity, in a company that is funding or stands to profit from the research. Exceptions should evaluate both conflicts of interest and potential conflicts of commitment, all of which should be disclosed orally and in writing to all affected parties and periodically reviewed by an appropriate faculty body.

**The AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is not controlled and/or managed by an independent entity, such as a mutual or pension fund. This is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services under its 2011 conflict of interest disclosure rules. (Source: Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” Federal Register, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)*

- This recommendation is drawn from one issued by the University of California at San Diego Academic Senate, Administration Committee on University Interaction with Industry.³⁵¹ It is also influenced by recommendations issued by the AAMC (2001),³⁵² and by

recommendations, issued by the AAMC (2008),³⁵³ noting that advisors should “recognize the possibility of conflicts between the interests of externally funded research programs and those of the graduate student.”

- Faculty advisors should be careful not to place undue pressure on a student to take on a thesis topic that reflects the priorities of a faculty start-up company or corporate research sponsor, rather than advancing that student’s best educational and personal interests.

- Faculty and student advisors should vigorously guard against any situation in which an M.A. or Ph.D. candidate finds that his or her thesis research is unpublishable, due to corporate non disclosure agreements, or other secrecy constraints.³⁵⁴

- This recommendation is not meant to bar an advisor who, say, gets modest benefits, like receiving an honorarium for discussing research at an industry meeting or public conference.

Discussion:

To date, surprisingly little scholarly attention has focused on the financial COIs that can and do arise in mentor- or supervisor- relationships, even though anecdotal evidence and scholarly discussion of problems has been mounting in recent years.³⁵⁵ According to a two-year analysis of university-industry partnerships conducted by the University-Industry Research Collaboration Initiative,³⁵⁶ it is not unusual for a student involved in an industry-sponsored project to take six months longer to earn a Ph.D. than would be the case in a purely academic research effort. If such delays are likely, students must be fully informed and willing to make this additional commitment of time.³⁵⁷

❖ Principle 9: Impartial Academic Evaluation

Students, postdoctoral fellows, academic professionals, and junior colleagues should always be entitled to impartial and fair evaluations of their academic performance. Because of the risk of both real and perceived bias, faculty members with a significant* personal financial interest in the outcome of their students’ research should not have sole responsibility for evaluating student progress toward a degree.

**The AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is not controlled and/or managed by an independent entity, such as a mutual or pension fund. This is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services under its 2011 conflict of interest disclosure rules. (Source: Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” Federal Register, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)*

- Because of the risk of both real and perceived bias, faculty members with a personal financial interest in the outcome of their students research should never be given primary responsibility for evaluating student progress toward a degree, or junior faculty progress toward tenure. Whenever a senior faculty advisor has a financial conflict of interest, any students, postdoctoral fellows, and untenured faculty colleagues working under that faculty member should always be assigned another senior advisor (with suitable expertise and no financial interest in the work) who can provide impartial oversight of all academic evaluations.

- This Principle is adapted from the AAMC (2001,³⁵⁸ 2008³⁵⁹) recommendations, and from an IOM (2009) proposal cited just below. In 2008, the AAMC cautioned that when a faculty advisor has a related financial conflict of interest, the university should carefully assess whether “the roles of students, trainees, and junior faculty and staff [are] appropriate and free from exploitation,” and whether special protections are needed for “vulnerable members” of the research team.³⁶⁰ In such a scenario, the Institute of Medicine, IOM (2009) proposed that “one protection might be to provide such individuals with access to independent senior faculty members for independent review and guidance when questions and concerns arise.”³⁶¹

❖ Principle 10: Grievance Procedures

Universities should establish effective, well-publicized grievance procedures for all students, postdoctoral fellows, academic professionals, and faculty, tenured and untenured, so they may freely and safely report obstacles encountered while pursuing their educational objectives. Obstacles may

include, but are not limited to, inappropriate commercial or other sponsor influence over the conduct of research and/or research analysis, unwarranted delays to degree completion, financial conflicts of interest, conflicts of commitment, and conflicts over ownership of intellectual property. Faculty with financial conflicts related to a grievance filing should recuse themselves from its adjudication in formal proceedings. Informal resolution of grievances, when possible, is often preferable.

Discussion:

Students and others depend on their faculty mentors' or supervisors' guidance, support, and goodwill to advance their own academic careers. This situation works well under normal circumstances, but these mentoring relationships are fragile and people can, and do, find themselves in vulnerable situations when outside commercial conflicts arise. This is why all universities need to implement clear channels for graduate students, postdoctoral fellows, and untenured faculty to report problems and seek help from objective third parties, should the need arise.

Anonymous complaints about contract provisions, financial conflicts of interest, and inappropriate commercial consequences should be given full consideration, but complaints regarding violations of individual rights need to be signed, as the right to confront an accuser is fundamental to due process.

When negotiating intellectual property agreements with outside commercial sponsors, universities must honor their commitment to the free and open exchange of academic data, research, and discoveries for the benefit of the public and the advancement of reliable knowledge.

Part III.
❖
General Principles
for Management of Intellectual Property, IP, (11-20)

The management of inventions, patents, and other forms of intellectual property in a university setting warrants special guidance, because it bears on so many aspects of the university's core missions and functions, including scholarship, research, and the transmission and use of academic knowledge by the broader society.

Intellectual property (IP) refers broadly to patents, copyrights, trademarks, and (according to some definitions) trade secrets,³⁶² in addition to the underlying subject matter that is controlled by the owner of these property rights established by statute (namely inventions, works of authorship, and identifiers that distinguish goods and services in the marketplace). Patents provide the owner with the right to exclude others from practicing an invention. Unlike the case of copyright, where exclusions follow copying and modification of particular instances of expression, a patent permits the exclusion of work created independently, and it has no "fair use" exception, even for non-profit purposes. Thus, patents may have a substantial impact on university research, may affect the value and role of scholarly publication, and may interfere with collaborations and the transfer of technology developed or improved in other research settings.

The management of intellectual property is complex and carries significant consequences for those involved in direct negotiations (faculty inventors, companies, university administrators, attorneys, invention management agents), as well as those who may be affected (competing companies, the public, patients, the research community).

Whether ownership of a particular invention is personal with the inventors, or is assigned by the inventors to an organization for management (a university technology transfer office, a university-affiliated foundation, an independent invention management agency), it is essential that all those involved recognize the distinctive role that inventions arising out of scholarly research should have. Faculty investigators and inventors, together with university administrators, must communicate this role and hold those involved accountable when they are engaged in the development and deployment of patent rights.

Inventions are owned initially by their own inventors, as has been established by both the U.S. Constitution and U.S. federal patent law. In a university setting, faculty inventors are also the initial owners of their inventions, as the U.S. Supreme Court affirmed in its 2011 decision in the *Stanford v. Roche* case (discussed at some length in the Introduction). Ownership of patent rights that may attach to an invention, however, may be transferred to another party by a written instrument. Thus, control of patent rights may be distinguished from ownership, since the initial patent owner may choose to contract (or transfer title) to another entity to manage those patent rights on their behalf. A university may become the owner of patent rights in a faculty invention by voluntary assignment, as was the case at most universities prior to the Bayh-Dole Act of 1980 (also discussed in the Introduction). A university may also become the owner of patent rights to faculty inventions if assignment of those rights is required as a condition of employment, or use of facilities, or participation in extramural research—an emerging practice that is increasingly preferred by many universities.

One fundamental problem that arises from university ownership of patent rights to faculty inventions is that it tends to create institutional conflicts of interest between the university's governance role and its potential financial and competitive interests in exploiting those patented inventions for its own benefit. This institutional conflict of interest is particularly challenging to manage because it is all too easy for universities to conflate royalty income with their public service mission to enhance economic growth, failing to perceive, or to acknowledge, the conflict that arises with other institutional responsibilities pertaining to academic governance and scholarship .

When faculty inventors and university administrators agree to use patents only for defensive purposes, and to allow general access to create technology platforms readily available for adoption, there generally is minimal organizational conflict of interest. When an invention is to be used to seek financial gain through the exploitation of monopoly positions in a marketplace, as necessary as this may be at times, faculty inventors and administrators alike may find themselves in a far more institutionally and financially conflicted position. In such instances, it may be beneficial for the university and the faculty inventor to use an external invention management agent, placing conditions on the actions of that agent to preserve the focus on the development and use of the underlying inventions, while simultaneously protecting broad access and use of the invention in research and education.

Inventions—despite distinctions often drawn in university policy statements—are a natural outgrowth of scholarly activities, and have enjoyed a symbiotic role in faculty research for over a century. The scholarly nature of university-based inventions does not simply disappear with the addition of a potential patent or other intellectual property rights. A patent is simply a specialized way of transmitting knowledge to society, which teaches a new invention to the world, in exchange for limited rights to exclude others from practice, in order to promote investment, development, and exploitation of the invention. As such, patented inventions and other discoveries, subject to intellectual property protection, should properly be viewed as extensions of scholarship that are equally subject to the principles of academic freedom and faculty rights.

Commercial development of university knowledge to stimulate economic growth and bring public benefits is unquestionably good. However, some practices associated with patenting and licensing operations—such as, narrow exclusive licensing, speculative reselling and relicensing of patent rights, assert licensing, and trolling activities, aggressive “reach through” provisions³⁶³— may negatively affect scholarship and the public interest and educational purposes of the university. Other activities associated with commercialization may be consistent with scholarship and academic norms, particularly when broad access to university inventions and research is protected through low-fee, non-exclusive licensing, and there is a broad reservation of rights for research and experimental practice.

Faculty investigators and inventors must have a strong voice in decisions involving patent management, where they desire to have such a voice. And university administrations and faculty collectively have an obligation to ensure that both institutional and individual interests in using patents to seek financial and logistic advantages are conducted within the broader context of the university’s scholarly and public research missions, and are subordinate to those missions.

Both IP contracting and licensing may be managed directly by the university, or through an outside agent (including a research foundation working under contract with the university, or a private invention management agency). Licensing may also be undertaken by inventors acting privately; such transactions take place regularly, for instance, in the area of open source software. When negotiating sponsored research agreements, university administrations and their contracted invention management agents must address the management of intellectual property and proprietary information and materials that may be provided by the sponsor, as well as the

disposition of any inventions or discoveries that may arise in the course of the sponsored project (these may include intended deliverables of the project; unexpected discoveries still of interest to the sponsor; or findings unrelated to the sponsor's commercial activities entirely).

University administrators and faculty also have an obligation to ensure that research funded by the federal government and other non-industry sources are available and managed for public benefit: this might occur through broad dissemination of the research (as happened with the gene splicing technique, developed at UC San Francisco and Stanford, that launched the biotechnology revolution), or through more targeted exclusive licensing, which gives one firm (say a pharmaceutical company) monopoly rights to a discovery so the company will invest the substantial resources required to develop an embryonic discovery into a viable new drug.

Finally, universities and their management agents are responsible for upholding academic, educational, and research obligations (taking into account their non-profit status, and their reliance on public funding). These obligations include, for example: the advancement of scientific research and academic inquiry; the exchange of academic data, research tools, inventions, and information for broad research and public use; and the production and dissemination of reliable knowledge. These obligations necessarily shape the licensing and financial opportunities that may be considered by faculty and administrators in their choice of licensing models, invention management agents, and acceptable licensing terms and practices.

The key to proper IP management is consultation, collaboration, and consent. That does not guarantee that invention licensing and management negotiations will be easy, but it does promote a system of checks and balances that has the potential to produce better results. All parties to such negotiations can exercise bad judgment. Faculty may have a sound understanding of the science and technology underlying their inventions without being able to gauge their marketability. University technology transfer offices, on the other hand, may not understand the underlying science equally well and thus may also overstate an invention's commercial value and misjudge how to disseminate it most effectively. Each party in these negotiations (a university technology transfer office, a sponsoring company, or a faculty member) can be motivated by the narrower goal of maximizing profits and fail to focus on the best interests of the public. That is partly why the faculty through its governing bodies needs to be involved collectively in setting policy, and why Principles 11 through 13 (below) are interdependent and equally necessary.

The dangers in having institutions or their agents exercise unilateral authority over patenting negotiations are illustrated by a cautionary tale summarized by Siddhartha Mukherjee in his book The Emperor of All Maladies. In the late 1980s, Brian Drucker, a young faculty member at Boston's Harvard-allied Dana-Farber Cancer Institute, was investigating chronic myelogenous leukemia (CML) to determine whether drugs might intervene in cancer's genetics. Scientists had synthesized a number of potentially promising compounds now held in Ciba-Geigy's freezer in Basel, Switzerland. Drucker proposed a collaboration between Ciba-Geigy and the Dana-Farber Cancer Institute to test those compounds in patients but, according to Mukherjee's account, "the agreement fell apart; the legal teams in Basel and Boston could not reach agreeable terms . . . scientists and lawyers could not partner with each other to bring these drugs to patients."³⁶⁴ It was not until Drucker moved to Portland's Oregon Health and Science University in 1993 that he was able to get straightforward cooperation from an academic institution.

One of the Ciba-Geigy compounds showed dramatic results in the lab, but because CML afflicts but a few thousand patients a year in the US there were questions about whether it was worth the company's investment. Ciba-Geigy had fused with Sandoz to form Novartis, and eventually the new company agreed to synthesize the experimental drug—Gleevec—for patient testing. The results were dramatic: Drucker witnessed dozens of deep remissions from patients treated with Gleevec. Prior to this, there was no effective treatment for CML, which usually had a maximum three to five year life expectancy after patient diagnosis. Today the drug is so effective that the cumulative number of surviving patients is significant: "As of 2009, CML patients treated with Gleevec are expected to survive an average of thirty years after their diagnosis . . . within the next decade, 250,000 people will be living with CML in America."³⁶⁵

The faculty collectively has an important role to play in establishing the university-wide protocols that will guide the management of faculty inventions, while also advancing the best interests of the university, science, national research communities, technological innovation, public health, economic development, and other public objectives. The AAUP recommends the following Principles 11-20 to ensure that academic inventions and IP management advance these public interest goals while also protecting the academic freedom of the faculty.

❖ Principle 11: Faculty Inventor Rights and IP Management

Faculty members' fundamental rights to direct and control their own research do not terminate when they make a new invention or other research discovery; these rights properly extend to decisions involving invention management, intellectual property (IP), licensing, commercialization, dissemination, and public use. As such, faculty inventor "assignment" of an invention to a management agent,* including the university that hosted the underlying research, should be voluntary and negotiated, rather than mandatory, unless federal statutes or previous sponsored research agreements dictate otherwise. Faculty inventors and investigators retain a vital interest in the disposition of their research inventions and discoveries and should, therefore, retain rights to negotiate the terms of their disposition. The university, or its management agents, should not undertake intellectual property or legal actions directly or indirectly affecting a faculty member's research, inventions, instruction, or public service without the faculty member's and/or the inventor's express consent.

**The term "invention management agent" covers all persons tasked with handling university generated inventions and related intellectual property, including, for example, university technology transfer offices, affiliated research foundations, contract invention management agents, and legal consultants.*

- The purpose of this Principle is to protect the professoriate's academic freedom rights, including the fundamental right to control academic research and instruction, which should logically encompass the faculty's right to control how their inventions are managed, licensed, commercialized, and otherwise transferred to society.
- If faculty have genuine control over their own research, they should not be asked to sign university employment contracts that require them to give away these rights. Such employment contracts—which make the assignment of faculty inventions to the university and its invention and IP management agents compulsory, rather than voluntary—abrogate the faculty's academic freedom by compelling them to represent positions, relating to their own academic research inventions, which may be at odds with their professional judgment and/or their assessment of public interest commitments.

❖ Principle 12: Adjudicating Disputes Involving Faculty Inventor Rights

Just as the right to control research and instruction is integral to academic freedom, so too are faculty members' rights to control the disposition of their research inventions. Inventions made in the context of university work are the results of scholarship. University policies should direct all invention management agents to represent and protect the expressed interests of faculty inventors, along with the interests of the institution and the broader public. Where the interests diverge insurmountably, the faculty senate, or an equivalent governing body, should adjudicate the dispute with the aim of selecting a course of action to promote the greatest benefit for the research in question, the broader academic community, and the public good.

Discussion:

Professors in fields ranging from information technology to medicine have reported that their academic freedom rights were restricted or infringed upon when university technology transfer officers made managerial decisions or took legal actions that they alleged impeded their research and/or inhibited its use and dissemination. In 2002, for example, the online magazine *Salon.com* reported on several such cases involving professors in the fields of computing and information technology. Cynthia Gibas, a bioinformatics professor at Virginia Tech, told *Salon.com* she was concerned about the way her university and others were using the Bayh-Dole Act to prevent professors from contributing to open-source software projects. Steven Brenner a computational biologist at U.C. Berkeley reported that it took several months and hundreds of dollars in legal fees to reach an agreement with his own U.C. office of technology licensing that would allow him to apply an open-source contract for dissemination of his software inventions.³⁶⁶

More recently, in June 2009, Dr. Robert Shafer, a bioinformatics and HIV expert, filed a formal grievance³⁶⁷ with Stanford University's faculty Advisory Board, which alleged that the university's invention management/IP agents had violated his academic freedom rights when they negotiated, without Shafer's knowledge, a settlement of infringement charges brought by an outside company (a French firm, Advanced Biological Laboratory, ABL) that directly impacted

on his HIV research, including a public website that he had developed to help HIV researchers throughout the world. Shafer asserted that this Stanford/ABL settlement agreement, which compelled him to post legal language on his free online HIV Drug Resistance Database (concerning a commercial licensing agreement signed by Stanford and ABL), would mislead and possibly intimidate database users (who themselves might fear patent infringement), and thereby impair his ability to fund, maintain, and operate the database. The HIV database Shafer developed is used extensively by scientists, drug companies, and treating physicians throughout the world to track and anticipate new mutations of the HIV-AIDS virus, and identify suitable drug treatments.

In April 2010, Stanford's faculty Advisory Board ruled that the university had indeed taken IP actions that "imposed a burden" on Dr. Shafer's academic freedom rights. In the words of the Advisory Board:

"The board concluded that actions taken in connection with the agreement with ABL were not consistent with the general principles set forth in the preamble of Statement on Academic Freedom which provide that: 'Stanford University's central functions of teaching, learning, research, and scholarship depend upon an atmosphere in which freedom of inquiry, thought, expression, publication and peaceable assembly are given the fullest protection. Expression of the widest range of viewpoints should be encouraged, free from institutional orthodoxy and from internal or external coercion.' The board concluded it was a mistake to enter into the binding agreement with ABL without consulting Professor Shafer and expressed deep concerns about some of the subsequent actions taken by the university to comply with the binding agreement. The board concluded that these actions were inconsistent with the general principles of academic freedom."³⁶⁸

❖ Principle 13: Shared Governance and the Management of University Inventions

Faculty have a collective interest in how university inventions derived from academic research are managed Through shared governance, they also have a responsibility to participate in the design of university protocols that set the

norms, standards, and expectations under which faculty discoveries and inventions will be distributed, licensed, and commercialized. The faculty senate, or an equivalent governing body, should play a primary role in defining the policies and public-interest commitments that will guide university-wide management of inventions and other knowledge assets stemming from campus-based research. These management protocols should devote special attention to the academic and public interest obligations covered in the AAUP Principles recommended here. They should also require the formation of a specially assigned faculty committee to regularly review the university's invention management practices, ensure compliance with these Principles, represent the interests of faculty investigators and inventors to the campus as a whole, and make recommendations for reform when necessary.

❖ Principle 14: IP Management and Sponsored Research Agreements

In negotiating outside sponsored research agreements, university administrators should make every effort to inform potentially affected faculty researchers and to involve them meaningfully in early-stage negotiations concerning invention management and intellectual property. In the case of large-scale corporate sponsored research agreements like SCAs, which can impact large numbers of faculty, not all of whom may be identifiable in advance, a special faculty governance committee should be convened to participate in early-stage negotiations, represent collective faculty interests, and insure compliance with related university protocols. Faculty participation in all sponsored research agreements should always be voluntary.

- Without this vital check on research accuracy, the university's ability to advance reliable public knowledge is dangerously impeded.
- As noted in the discussion above, a virtually identical "academic use" recommendation has already been endorsed by more than 50 universities (as well as the AAMC and AUTM) in a consensus statement, titled "In the Public Interest: Nine Points to Consider in Licensing University Technology," originally released in 2007.³⁶⁹ However, it appears these academic-use exemptions are not widely utilized in practice, even by universities that were original signatories to this statement, so written policy implementation and follow-through remain critically

important.³⁷⁰

❖ Principle 15: Humanitarian Licensing, Access to Medicines

In matters of IP and invention management, the university and its contracted agents should prohibit pursuit of institutional profits at the expense of the university’s academic, research, and public interest missions. When lifesaving drugs and other critical public health technologies are developed in academic laboratories with public funding support, universities have a special obligation to license such inventions in a manner that will ensure broad public access in the developing as well as the industrialized world. Exclusive university licenses to companies for promising drugs or other critical agricultural, health, or environmental safety inventions should include provisions to enable distribution of drugs and other inventions in developing countries at affordable prices.

- Doing this has little negative financial impact on the company issued the exclusive license (since most companies see no viable commercial market for their products in these underdeveloped countries). However, this humanitarian license opens the pathway for generic manufacturers, non-profits, and government agencies to find innovative ways to lower prices and broaden access, potentially saving millions of lives.

- Humanitarian licensing has already been endorsed by the Association of University Technology Managers (AUTM), the Association of American Medical Colleges (AAMC), and 50 universities in their consensus statement titled, “In the Public Interest: Nine Points to Consider in Licensing University Technology,” which recommends that universities address the need to make lifesaving medicines and other critical technologies broadly available in underdeveloped nations:

Point 9: Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.³⁷¹

- In 2009, AUTM and its university members further elaborated on this critical public health goal in their “Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies” (SPS),³⁷² endorsed by many top universities as well as by the National Institutes

of Health (NIH) and the Centers for Disease Control (CDC).

- In a detailed 2011 analysis of patenting, citation, and other data, Frank Lichtenberg (Columbia Business School) and Bhaven Sampat (Columbia University Mailman School of Public Health) examined both the *direct* and *indirect* role of government funding in new drug development. The researchers found that government-funded research, much of it performed at U.S. universities, played a powerful *indirect role* (i.e. generating the underlying basic research required) in the development of almost half of the drugs approved by the FDA between 1988 and 2005, and in close to two-thirds of the most innovative drugs (using the U.S. Food and Drug Administration’s definition of innovative).³⁷³ This is why it is critically important for universities to reserve these humanitarian rights, which are so necessary to ensure broad access to these lifesaving inventions.

- Universities currently hold key patent rights on drugs to treat HIV/AIDS, cancer, hepatitis B, and other major diseases. Stavudine (sold under the brand name Zerit)—a critical drug in the treatment of HIV/AIDS—was developed originally at Yale University and later became the centerpiece of a major student-led, human-rights campaign to broaden access to medicines in developing countries (for more on this story, see this endnote).³⁷⁴ So far, however, many drug compounds licensed by universities have remained largely out of reach for millions of patients in the developing world.³⁷⁵

- The Uniform Administrative Requirements for Grants and Contracts with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations³⁷⁶ (2 CFR 215) require universities to act as a trustee for the beneficiaries of the project or program under which the intangible property was acquired or improved. As a trustee, a university might take its role seriously and consider dedicating its share of the proceeds from licensing to advance the welfare of patients affected by the disorder the invention is intended to treat.

❖ Principle 16: Securing Broad Research Use and Distribution Rights

All contracts and agreements relating to university-generated inventions should include an express reservation of rights—often known as a “research exemption”—to allow for academic, nonprofit, and government use of

academic inventions and associated intellectual property. Research exemptions should be reserved and well publicized prior to assignment or licensing so faculty and other academic researchers can share protected inventions and/or research results from sponsored projects (including related data, reagents, and research tools) with scientists located throughout the host university or at any other nonprofit or government institution. The freedom to share and practice academic discoveries, for educational and research purposes, whether patented or not, is vitally important for the advancement of research and scientific inquiry. It also enables investigators to replicate and verify published results, a practice essential to the academic enterprise and to the integrity of science.

- Without this vital check on the accuracy of published research, the university's ability to advance reliable public knowledge is dangerously impeded.

- This research exemption should clearly cover three distinct categories of research: "Evaluation of," which refers to the practice of an invention or research tool to evaluate the claims made and replicate the procedures used in published findings; "Research on," which covers efforts to study how the invention or tools work, and make improvements or modifications; and "Research with," which covers the use of such inventions/tools in conducting one's own research, which may involve similar or entirely different subjects and uses from the ones under which the invention was created.

- After the *John M.F. Madey v. Duke University*³⁷⁷ decision of 2002, university and government researchers could no longer assume that they would continue to enjoy what had long been referred to, in the science community, as "a research or experimental use exemption," allowing use patented inventions for purely academic and research purposes without threat of a lawsuit. This decision put all universities, non-profits, and government agencies on notice that a patent ownership position could now place their researchers (and their institutions) at risk of an infringement action, if they practiced a claimed invention. That is why it has become increasingly urgent for universities and their faculty to reaffirm and secure these research exemption rights, to the greatest extent possible, by requiring all sponsored research agreements and IP management contracts to include this exemption from infringement suits in writing. Since universities themselves have vastly expanded their own intellectual property claims over

the last few decades, it is incumbent on them to protect knowledge sharing to the greatest extent possible.

• A similar recommendation to support this “research exemption” has already been endorsed by more than 50 universities (as well as the AAMC and AUTM) in a consensus statement, titled “In the Public Interest: Nine Points to Consider in Licensing University Technology,” originally released in 2007.³⁷⁸ This provision reads as follows:

Point 1 Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so. In the spirit of preserving the ability of all universities to perform research, ensuring that researchers are able to publish the results of their research in dissertations and peer-reviewed journals and that other scholars are able to verify published results without concern for patents, universities should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations:

- to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and
- to transfer tangible research materials (e.g., biological materials and chemical compounds) and intangible materials (e.g., computer software, databases and know-how) to others in the non-profit and governmental sectors.

• However, as noted earlier, these research exemptions have not been widely utilized in practice, even by universities that were original signatories to this Nine Points statement, so written policy implementation and follow-through by the faculty remain critically important.³⁷⁹

❖ Principle 17: Exclusive and Nonexclusive Licensing

Universities, their contracted management agents, and faculty should avoid exclusive licensing of patentable inventions, unless such licenses are absolutely necessary to foster follow-on use of an invention or to spur investment in the development of an invention that would otherwise be incapable of realizing its public benefit. Exclusive or monopolistic control of academic knowledge should be used sparingly, rather than as a presumptive default. When exclusive licenses are granted, they should have limited terms (preferably less than eight years), include requirements that the inventions be developed, and

prohibit “assert licensing,” sometimes referred to as “trolling.” Exclusive licenses made with the intention of permitting broad access through reasonable and nondiscriminatory sublicensing, cross-licensing, and dedication of patents to an open standard may be expected to meet public access expectations. However, the preferred methods for disseminating university research are nonexclusive licensing and open dissemination, to protect universities’ public interest mission, open research culture, and commitment to the advancement of research and inquiry through broad knowledge sharing. To enhance compliance and public accountability, universities should require all invention management agents to publicly and promptly report any exclusive licenses issued together with written statements detailing the necessity for the exclusive license and why a nonexclusive license would not suffice. The faculty senate, or a comparable governing body, should have the authority to periodically review exclusive licenses and corresponding statements for consistency with the principle.

• A compatible recommendation, favoring non-exclusive licensing, is contained in a 2011 National Academy of Sciences committee report addressing the management of university IP, which reads as follows:

Universities should pursue patenting and licensing practices that, to the greatest extent practicable, maximize the further development, use, and beneficial social impact of their technologies. Exclusive licenses generally should be reserved for technologies that require significant follow-on investment to achieve commercialization, or where exclusivity is needed to confer a competitive advantage (so-called rival-in-use technologies). For technologies that are not rival-in-use or require little or no follow-on investment, nonexclusive licenses are generally warranted.³⁸⁰

• The AAMC, AUTM, and over 50 universities have also endorsed a recommendation warning against an overreliance on exclusive licensing in a consensus statement, titled “In the Public Interest: Nine Points to Consider in Licensing University Technology”:

When significant investment of time and resources in a technology are needed in order to achieve its broad implementation, an exclusive license often is necessary and appropriate. However, it is important that technology transfer offices be aware of the potential impact that the exclusive license might have on further research, unanticipated uses, future commercialization efforts and markets. Universities need to be mindful of

the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology.”³⁸¹

❖ Principle 18: Upfront Exclusive Licensing Rights for Research Sponsors

Universities should refrain from signing sponsored research agreements, especially multi-year, large-scale strategic corporate alliance (SCA) agreements, granting sponsors broad title, or exclusive commercial rights, to future sponsored research inventions and discoveries unless such arrangements are narrowly defined and agreed to by all faculty participating in, or foreseeably affected by, the alliance. If this is infeasible, as in the case of larger SCAs, the faculty senate (or a comparable governing body) should review and approve the agreement and confirm its consistency with academic freedom, faculty independence, and the university’s public interest missions. Special consideration should be given to the impact exclusive licenses could have on future, as-yet unimagined uses of technologies. When granted, exclusive rights should be defined as narrowly as possible, restricted to targeted “fields of use” only, and every effort should be made to safeguard against abuse of the exclusive position.

- Similar recommendations are contained in the university consensus statement, “Nine Points to Consider in Licensing University Technology,”³⁸² referenced above, and in a Cornell University faculty senate statement on principles and best practices for guiding large-scale university-industry alliances.³⁸³

- These recommendations are also consistent with the objectives of the Bayh-Dole Act (35 USC 200), which expect universities and other nonprofit organizations to use inventions to promote free competition and enterprise.

- Any such arrangements involving title or exclusive rights must also conform with applicable tax laws regarding private use of facilities constructed with tax-free bonds.

❖ Principle 19: Research Tools and Upstream Platform Research

Universities and their contracted invention management agents should make available and disseminate research tools and other upstream platform inventions (in which they have acquired an ownership interest) as broadly as possible. They should avoid assessing fees, beyond those necessary to cover the costs of maintaining the tools and disseminating them, and other constraints that could hamper downstream research and development. Relatedly, no sponsored research agreement should make contractual obligations that prevent outside investigators from accessing data, tools, inventions, and reports relating to scholarly review of published research, matters of public health and safety, environmental safety, and urgent public policy decisions.

- In December 1999, the National Institutes of Health issued guidelines for U.S. universities covering research tools developed in whole, or in part, with federal funding, which reinforce this AAUP Principle . The NIH guidelines discourage the patenting of research tools, and urge that these tools be licensed with as few encumbrances and as broadly, as possible.³⁸⁴ The NIH, for example, cautions against the use of commercially aggressive “reach-through rights,” a legal provision that enables a university owner to claim royalty rights to any future product developed through the use of its research tools. The NIH also discourages use of restrictive “material transfer agreements” (MTAs), for the exchange of basic research materials, which can slow the pace of research progress and significantly raise the cost of doing research.

- The AAMC, AUTM, and over 50 universities—in their consensus statement titled, “In the Public Interest: Nine Points to Consider in Licensing University Technology”—have also endorsed a similar recommendation:

Consistent with the NIH Guidelines on Research Tools, principles set forth by various charitable foundations that sponsor academic research programs and by the mission of the typical university to advance scientific research, universities are expected to make research tools as broadly available as possible...Through a blend of field-exclusive and non-exclusive licenses, research tools may be licensed appropriately, depending on the resources needed to develop each particular invention, the licensee’s needs and the public good.”³⁸⁵

- Such goals are also consistent with the Bayh-Dole Act (35 USC 200), which warns against

use of patent rights that unduly encumber future research and discovery, and with the federal Uniform Administrative Requirements for Grants and Contracts with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations³⁸⁶ (2 CFR 215), which requires universities to act as a trustee for the beneficiaries of the project or program under which the intangible property was acquired or improved (2 CFR 215.37), and also requires public access to research data relating to published research findings produced under a federal award that were used in certain federal agency rule-making (2 CFR 215.36(d)).

Discussion:

Access to publicly funded research tools has become one of the most contentious areas of university IP management. At issue is whether these tools should be exclusively licensed to one company (sometimes a faculty start-up firm), or licensed non-exclusively so they can be utilized more broadly, or not be subject to intellectual property ownership claims at all. In some cases, research tools also have been withheld by faculty investigators or administrators to advance their competitive position, for example in anticipation of future grant funding.

Many academic researchers, of course, still freely share new research tools, including software, laboratory reagents, and animal disease models. However, today, because of universities' heightened focus on patenting, licensing, and revenue generation, research tools and other basic platform inventions may become tied up by intellectual property considerations, which may place commercialization or financial benefit ahead of access and use. Critics in academia, government, and industry contend these restrictions on tool sharing lead researchers to forgo otherwise promising lines of research and hamper the evaluation and replication of published research claims.

Research tools can be highly complex entities that require significant follow-on research to develop. As the University-Industry Research Collaboration Initiative, a project of the Business Higher Education Forum, explained in a 2002 report: "At the heart of the research-tool problem... is the fact that one person's research tool can be another person's key strategic product. Tool developers, which often later emerge as biotechnology firms, claim that without exclusive licenses, they cannot secure venture capital funding, thus stifling innovation."³⁸⁷ However many experts on innovation, and companies in the information technology sector and other industries, complain that restrictive university IP practices are undermining the open

academic research culture, and inhibiting broader commercial use and development of academic research.³⁸⁸ It should be noted that some of the most lucrative revenue generating patent licenses for universities have involved research tools; thus, it is to be expected that university administrators, and some faculty inventors, will balk at fully implementing this principle. However, most of those “big hit” licensing programs involved non-exclusive licenses, including the Cohen-Boyer,³⁸⁹ Axel,³⁹⁰ and Hall³⁹¹ inventions.

❖ Principle 20: Diverse Licensing Models for Diverse University Inventions

Universities and their invention management agents should develop multiple licensing models for diverse categories of academic inventions, reflecting differing objectives and commitments made by faculty investigators and inventors, varying practices in the wider community and in different industries, and models appropriate for the conditions that present at different stages of the development of those specific technologies. Licensing models commonly used to address opportunities in biotechnology, for example, should not be established as defaults in institutional policies or used indiscriminately across other areas of innovation. Faculty investigators/inventors and their management agents should work cooperatively to identify effective licensing and/or distribution models for each invention with the goal of enhancing public availability and use. This may involve more established models (exclusive or nonexclusive licensing), or more emergent ones (patent pools, open sourcing, and public licensing, offered by institutions like Creative Commons for copyright-based work).

- To cite but one illustration of this problem, there is robust evidence that exclusive licensing plays a more limited role in the development and commercialization of information technology than it does in certain pharmaceutical and biotechnology sectors, yet according to experts many U.S. universities often fail to draw adequate distinctions.³⁹² In August 2000, the Office of the President of the University of California system recognized this fact when it announced a program to exempt Computer Science as well as Electrical and Computer Engineering IP from the standard UC system-wide licensing policies, and authorized giving licensing officers greater flexibility when licensing IT discoveries. After the President’s Engineering Advisory Council

reviewed the matter, it observed:

“[T]he rapid rate of technological change in the engineering fields of electronics, communications technology, [and] computer hardware and software results in new products with a typical lifetime of a few years or less. Competitive success rarely is based upon the statutory protection of intellectual property as requirements for conformance with industry wide standards reduce the value of proprietary technology. Rapid product development and early market entry with innovative products are the keys to market leadership and successful products.”³⁹³

Principle (21): Rights to “Background Intellectual Property” (BIP)

University administrators and their agents should not act unilaterally when granting sponsors rights to university managed background intellectual property (BIP) related to a sponsor’s proposed research area but developed without the sponsor’s funding support. Universities should be especially mindful of how BIP rights will affect faculty inventors and other investigators who are not party to the sponsored research agreement. University administrators and managers should not obligate the BIP work of one set of investigators to another’s sponsored-research project, unless that BIP is already being made available under nonexclusive licensing terms, or the affected faculty inventors and investigators have consented. To do otherwise would have a chilling effect on professorial collegiality and on the willingness of faculty to work with university licensing agents.

• This recommendation draws from the “Background Rights” section of *Working Together, Creating Knowledge: The University-Industry Research Collaboration Initiative*, a report based on a two-year study of academic-industry partnerships published by the Business-Higher Education Forum in 2001.³⁹⁴ The Research Collaboration’s members included 37 university presidents, senior officers at major corporations, and heads of major business and educational associations. For a deeper exploration of these issues, see the discussion below:

Discussion:

“Background rights” are the licensing rights that universities may provide to an industry sponsor to cover “background intellectual property” (BIP) that may be related to the proposed research project the sponsor plans to undertake. By definition, this BIP consists of research inventions that were created by university employees outside of the current sponsored project, using funding from other sources, including in many cases the federal government. Frequently, companies will seek the rights to this BIP, in advance, in order to complete their intellectual property portfolios, so they will have access to all the licensing rights they anticipate needing in the future to commercialize the results of their sponsored research.

Universities face a number of problems when they offer to provide background rights. Many faculty members feel strongly that the intellectual property belonging to one faculty member should not be mortgaged for the benefit of another, or be leveraged to help the institution to secure sponsored-research funding. Merely identifying intellectual property that might be relevant to the sponsor is both time-consuming and expensive. Agreements on background rights usually include provisions that the parties offer a “good faith effort” or use “reasonable efforts to disclose in the field of use” in order to identify potential background conflicts. These are legal terms whose interpretation will require the involvement of legal counsel and could hold the university liable for any oversight. “The only way you should even begin down that path is to have a full-blown infringement opinion done looking at your entire portfolio within a certain area of technology,” NC State’s [W. Mark] Crowell told the Research Collaboration. “And if anybody here has ever paid the cost to have an infringement opinion done, you’re talking about a pretty scary proposition.” For all these reasons, universities rarely agree to sign binding agreements on background rights.³⁹⁵

Providing these background rights, even to license technology at commercially reasonable rates, can also complicate and/or limit academic researchers’ ability to pursue lines of inquiry, or the university’s ability to license the technology to another firm. This, in turn, can affect the ability of the university to attract future sponsored research, and can complicate incentives for start-up companies to participate in regional economic development plans involving the university. According to the Research Consortium, requests for universities to provide background rights first began with research consortia alliances such as the Semiconductor Research Corporation (SRC/SEMATECH), a government-industry manufacturing technology collaboration in the semiconductor industry, and the Electric Power Research Institute (EPRI). These agreements require the university to license back to the consortia any background rights deemed necessary on a nonexclusive basis. Today individual companies, particularly in the information technology arena, increasingly seek background rights for the research they sponsor.”³⁹⁶

In 2007, the British-based oil giant BP was granted BIP rights in connection with its \$500-million, ten-year research alliance with UC-Berkeley and two other public research institutions, known as the Energy Biosciences Institute (EBI).³⁹⁷ According to an internal UC-Berkeley

faculty committee examination of this BP-EBI alliance, the BIP terms were extensive and quite unusual, though they did reflect a positive effort to obtain advance informed consent by faculty and other personnel:

“The usual practice...has been to defer such negotiations about BIP to subsequent licensing negotiations. This contract, however, contains a general provision (App. 2, Sec. 8.12), which permits BP’s right to license the BIP related to a discovery developed in a specific funded project in the EBI. Any such BIP has to have been included in a list prepared by the Project Investigator in advance in the application for funding... In addition, all participants in an EBI project must agree to these BIP provisions as a condition of funding...The issue came up only in the contract negotiations, and both we and the administration would have preferred to treat BIP in the standard manner, relegating the issue to subsequent licensing negotiations. The resulting position reflects a compromise between UC and BP.”³⁹⁸

Part IV.
❖
General Principles:
Management of Financial Conflicts of Interest, COI, (22-34)

Definitions:

A conflict of interest is broadly defined as a situation in which an individual or corporate interest has a tendency to interfere with the proper exercise of judgment in another's behalf. Those who prefer to distinguish between individual and institutional COI often define the former as a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest (such as research conduct, teaching, or patient welfare) will be unduly influenced by a secondary interest (financial gain). Correspondingly, an institutional COI describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other governing activities of the institution. A growing body of empirical research has shown that financial COI are associated with decision-making bias, as well as research bias (see the main report for details). COI also introduce unreliability into the research process, undermine public trust, and erode respect for institutions of higher education. Disclosure of a COI, even full disclosure with informed consent, does not resolve these problems.

Opening Discussion:

Among the greatest contemporary threats to the freedom, autonomy, and integrity of academic work, and to the public's support of and confidence in that work are financial COI. As early as 1965, in "On Preventing Conflicts of Interest in Government-Sponsored Research at Universities," the AAUP and ACE pressed for "the formulation of standards to guide the individual university staff members in governing their conduct in relation to outside interests that

might raise questions of conflicts of interest.”³⁹⁹ Now the AAUP is returning to this pressing issue, within the context of heightened academic-industry engagement.

Starting in early 2000, many professional and academic groups took note of this rising commercial engagement and issued a series of consensus statements calling for stronger, more comprehensive financial COI policies at U.S. universities and academic medical centers. The AAUP agrees with the professional consensus reached by these groups—including the AAU, IOM, AAMC, and the Department of Health and Human Services/National Institutes of Health (DHHS/NIH), which released new COI rules in August 2011—that the purpose of these COI policies is to be preventative.⁴⁰⁰ As the DHHS/NIH explains, COI rules are “intended to be proactive rather than reactive to specific evidence of bias.”⁴⁰¹ Rather than trying to remedy possible bias or damage after it has occurred, or has been unearthed by the media, university COI rules are needed to reduce the risk of bias and the loss of public trust and credibility that may be associated with the existence of these financial conflicts. A growing body of empirical research, especially in the biomedical field, has found that financial COI are associated with research bias, and bias in professional decision-making (for a discussion of this literature see this Report Introduction).

In 2009, an IOM panel on COI in biomedicine observed that “a range of supporting organizations—public and private—can promote the adoption and implementation of conflict of interest policies and help create a culture of accountability that sustains professional norms and public confidence in professional judgments.”⁴⁰² It is in solidarity with this statement that the AAUP is now adding its voice to the chorus of groups calling for U.S. universities to strengthen and harmonize their COI policies. If U.S. universities do not act voluntarily to implement more rigorous, comprehensive, as well as more uniform COI policies and procedures, then pressure for external regulation from the federal government and others is likely to continue.

Disclosure is an important mechanism for addressing financial COI related to academic research, but simply disclosing such conflicts is not sufficient to instill confidence in the public, or to protect the integrity of academic scholarship. The AAUP is not inclined, nor does it have the authority, to impose hard and fast prohibitions on faculty engagement with outside sponsors. However, experience has clearly shown that, just as disclosure of financial conflicts is inadequate, so too are policies that rely heavily, or even exclusively, on case-by-case

management of individual faculty and institutional COI. (These terms—“individual faculty COI” and “institutional COI”—are defined under Principle 18 below.)

The AAUP wholeheartedly agrees with the AAU’s assessment (and those of other groups cited here) that university COI policies need to be comprehensive, and cover research “across all academic fields, not just biomedical ones.”⁴⁰³ This recommendation has already been endorsed by the AAU-AAMC (2008),⁴⁰⁴ and by a recent IOM panel (2009).⁴⁰⁵

The AAUP further agrees with the growing consensus that these policies must encompass both individual faculty as well as institutional COI. This recommendation, too, has been endorsed by the AAU (2001); AAMC (2002); AAU-AAMC 2008;⁴⁰⁶ Council on Government Relations, COGR (2003); the Department of Health and Human Services, DHHS (2004);⁴⁰⁷ the National Institutes of Health, Office of Inspector General;⁴⁰⁸ and the IOM (2009).⁴⁰⁹

Finally, the AAUP agrees with the AAU and others that university COI policies should “treat research consistently, regardless of the funding source—All research projects at an institution, whether federally funded, funded by a non-federal entity, or funded by the institution itself, should be managed by the same conflict of interest process...”⁴¹⁰ Again, this is consistent with recommendations issued by the AAU-AAMC (2008),⁴¹¹ and with new COI rules issued by the DHHS (2011), which require university faculty to report financial COI related to all of their “institutional responsibilities,” not only their DHHS-funded research.⁴¹²

The rationale for implementing such a comprehensive COI policy is clear: monitoring financial COI across the entire institution, regardless of funding source, ensures that all conflicts will be identified and handled similarly, instead of having effective procedures in place to handle some COI, while others go unidentified and potentially reap serious damage.

In 2001, the AAU’s Task Force on Research Accountability appropriately called on all universities to redouble their efforts with respect to implementing comprehensive COI policies:

“[A]lthough definitive data about the prevalence of conflicts of interest is lacking, academic-industry relationships are clearly increasing, and with them, the risk of conflicts of interest compromising the integrity of research conducted in academia continues to rise. Journal articles make clear that the stringency of financial conflict of interest polices varies substantially among institutions, as does the diligence of enforcement... [S]ince the risk to the integrity of the academic enterprise from

individual conflicts of interest is substantial, research universities should re-double their efforts to ensure objectivity in research.”⁴¹³

Ten years after this statement was issued we have far more empirical evidence concerning the prevalence of financial COI in biomedicine, and a growing body of empirical research linking financial COI to research bias and bias in professional decision-making (again for an overview of this research, see this report’s Introduction). While other areas of research have not received the same level of rigorous scrutiny, there is no reason to expect that biomedicine is unique (witness industry influence in areas ranging from tobacco research and economics analysis to agriculture). The operating assumption should be that such problems exist in all fields where there are relationships with business, thus requiring appropriate policies and safeguards.

Congressional and federal investigations have continued to expose how inadequate university management of financial conflicts is dangerously eroding public trust in the academic research enterprise.⁴¹⁴ Unfortunately, however, most U.S. universities have been slow to heed calls from a range of academic associations (including the AAU, AAMC, IOM and others)⁴¹⁵ to strengthen and harmonize their policies and procedures for handling financial COI. Independent surveys and analyses continue to show that COI policies and procedures at both universities and their academic medical schools remain highly variable and, overall, too weak:

- In 2001, for example, the AAMC called on universities to strengthen their financial COI policies governing research involving human subjects. A key AAMC recommendation issued in 2001 called for all medical schools to establish a strong “rebuttable presumption” against any investigators conducting research involving human participants when they have a related financial COI, except in highly exceptional circumstances. However, in 2003, an AAMC membership survey found that only 61 percent of medical schools had adopted this “rebuttable presumption” in their policies, and of those only a minority had defined what compelling circumstances would support such an exception.⁴¹⁶

- A 2006 analysis also reported on large variations in university COI disclosure policies. Only 48 percent of medical schools had policies that mentioned the disclosure of researchers’ financial COI to research participants. These policies also varied in what information was to be disclosed.⁴¹⁷

- In 2008, another survey of the AAMC membership found that, despite a 2002 joint recommendation from the AAMC and the AAU that all universities should implement *institutional COI policies*, only 38 percent of academic medical schools reported having such an institutional COI policy in place (another 37 percent reported they were still in the process of developing one).⁴¹⁸

- Meanwhile, in 2009, the Department of Health and Human Services' Office of the Inspector General (OIG) uncovered serious deficiencies in how universities are handling financial COI. After reviewing 184 separate financial conflict-of-interest reports submitted to the National Institutes of Health (NIH) in FY 2006 by 41 grantee institutions, the OIG concluded: "Vulnerabilities exist in grantee Institutions' identification, management, and oversight of financial conflicts of interest."⁴¹⁹ (See the introduction—in the section titled "A Brief History of Efforts to Address Financial Conflicts of Interest . . ."-- for a Box containing a brief summary of the OIG's main findings.)

- "Given the complex nature of researchers' conflicts and the vulnerabilities that exist regarding their identification and management," concluded the OIG, "[i]ncreased oversight is needed to ensure that (1) these conflicts are managed appropriately, (2) the research conducted using Federal funds is not biased by any conflicting financial interests of researchers, and (3) human subjects are not subjected to unnecessary risks."

On August 23, 2011, partly in response to the OIG findings as well as renewed Congressional pressure, the DHHS issued new COI rules, covering all NIH-funded research, designed to "expand and add transparency to Investigators' disclosure of Significant Financial Interests, enhance regulatory compliance and effective institutional oversight and management of Investigators' financial conflicts of interests, as well as increase the Department of Health and Human Services' (HHS) compliance oversight." These new rules, covering all recipients of DHHS and NIH research funding, include the following changes:

- New requirements for investigators to disclose to their university employers all significant financial interests related to their "institutional responsibilities," not only those related to a specific research project.
- A lowering of the monetary threshold required for COI disclosure (generally dropping from a de minimis of \$10,000 to \$5,000).

- More extensive university reporting to federal grant agencies, regarding the scope of their faculty investigators' financial COI, and the specific management plans that the university has implemented to address them.
- New requirements that universities make this information—regarding faculty COI and university management plans—accessible to the public.

However, as with the earlier 1995 DHHS-NIH rules on financial COI, it is important to note that the 2011 rules do not provide specific guidance on how U.S. universities should review, reduce, eliminate, and/or manage their financial COI internally. The 2011 DHHS-NIH rules merely provide a baseline from which universities must still develop their own detailed campus COI policies. Given significant variations in the stringency of these campus-based COI policies, and the rigor of their enforcement, this lack of federal guidance could present ongoing problems. As a 2009 IOM panel review noted: “extensive variations” in university COI policies and procedures “raise concerns that some institutions may not have sufficient data to make determinations about the extent and the nature of an individual’s financial relationships or to judge the severity of a conflict of interest... Absent outside pressures and oversight, variation in conflict of interest policies may encourage an unhealthy competition among institutions to adopt weak policies and shirk enforcement.”⁴²⁰

It is within this context that the AAUP is urging all universities and their faculty to review their COI policies and bring them into compliance with the recommendations offered here, nearly all of which are drawn from recommendations issued already by the AAU, AAMC, IOM, COGR, and most recently DHHS-NIH. The 2011 DHHS-NIH rules make this reexamination of university COI policies both timely, and necessary.

❖ Principle 22: Comprehensive COI Policies

Every university should have a comprehensive, written COI policy, covering both individual and institutional COI (the terms are defined under Part IV above and discussed in greater detail in the main report). Universities should be explicit in their guidelines about how financial COI will be reported, reviewed, managed, and/or eliminated. The guidelines should also spell out

how the university will enforce its COI policies. University policies should clearly delineate which financial conflicts of interest must be reported, which are prohibited, and what actions will be taken if faculty members do not comply with university COI disclosure and management policies. Actions may include: a faculty-led investigation leading to possible censure, federal-grant agency notification, a temporary hold on interactions with conflicted sponsors, or a temporary ban on receipt of outside research funding.

Principle (22a): A Basic Checklist for What These Comprehensive COI Policies Should Contain

Each campus's comprehensive, written COI policy should cover all of the following (adapted from the AAMC, 2001 and AAU, 2001):⁴²¹

- Clear procedures for gathering financial COI information from faculty, senior officials, and university departments. (For details on institutional COI reporting, see Principle 23, under Part V. below, titled “Inter-Office Reporting and Tracking of Institutional COI.”);
- COI disclosure forms should be standardized (preferably electronic) and easy to use; using an electronic disclosure form facilitates the operation of an integrated management system across various parts of the university.
- Financial COI reports should be required at least annually, with prompt updating whenever there is an interim, material change in significant financial interests;
- In making such reports, each covered individual should be required to be very thorough; the failure to report is unacceptable;
- Clear procedures for verifying the accuracy of reported COI information. (The 2009 federal “Physician Payment Sunshine Act”⁴²² and various state laws⁴²³ now mandate that pharmaceutical and other medical companies disclose their gifts and other financial payments to physicians, thus making verification of faculty self-reporting by the university employer both increasingly possible, and essential);⁴²⁴
- Clear explanation of how financial COI will be reviewed, reduced, eliminated, and/or managed, as appropriate;

- Faculty disclosure forms should include questions (connected with grant applications) about whether or not students are working on a research project to help identify situations that may compromise a student’s thesis or research project;
- Clear “time frame” for required disclosure. (According to the IOM, 2009, some policies ask about relationships that are pending, in negotiation, or expected in the next 12 months. Some organizations also require disclosure for longer periods: for example, the American Thoracic Society requires disclosure for the previous 3 years (ATS, 2008) and the Journal of the American Medical Association requires disclosure for the previous 5 years (Flanagin et al., 2006);
- Clear “de minimis” reporting rules: The AAUP strongly encourages universities to adopt the \$5,000 de minimis reporting requirement recommended here, and now also required by the DHHS-NIH COI rule of 2011;
- The policy should clearly indicate how, and to what extent, personal financial information will be handled and shared by the institution; how confidentiality will be maintained; and where, when, and in what form this information may be released to patients, colleagues, and/or the broader public. (Under the 2011 DHHS-NIH COI rule, universities must publicly disclose all “significant financial COI”—related to DHHS funded research—on a public website or respond to any public request within five days);
- Clear procedures for sharing financial COI information and conflict-management information, as needed, with relevant internal offices (including IRBs, sponsored research offices, and technology transfer offices); and with relevant affected parties (research volunteers, patients, conflict-of-interest management staff, department chairs/deans, patients, students, research colleagues), using appropriate safeguards to maintain the privacy of the information until it has been reviewed by the university’s standing COI Committee for internal management and public reporting.
- Details on how COI decisions will be adjudicated, implemented, and enforced by the university’s standing COI committee;
- Details on how the appeals process will work, and due process will be ensured;
- Policies for disclosure of reported information to academic journals and the public;
- Clear mechanisms to insure compliance with COI policies, and punish non-compliance.

Principle (22b): General Definition of a COI

The Institute of Medicine offers this concise, core definition of a COI:

A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.⁴²⁵

As noted in the Introduction, because financial COI are a function of a situation, not a function of whether someone is actually biased, they are either present or they are not. Thus, a financial COI should not be termed “potential,” a qualifier that one hears frequently and usually incorrectly because tends to suggest that the COI does not currently exist, and is only a future possibility, thereby seeming to diminish its risk and its significance.

Principle (22c): Definition of an “Individual COI”

The AAU’s Task Force on Research Accountability offers this helpful, expanded definition of an “individual COI” as it relates to the sciences:

The term individual financial conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.⁴²⁶

Principle (22d):

Definition of an “Institutional COI” (ICOI)

The AAMC and AAU offer this definition of an “institutional COI,” which covers both the institution itself, and senior officials:

“An institutional conflict of interest (institutional COI) describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution’s activities. The risks are particularly acute in the context of human subjects research, when the protection of human subjects and the integrity of the institution’s research may be threatened.”⁴²⁷

Principle (22e):

Why Are Institutional COI Important to Address?

An institutional COI may arise when a university is conducting research on campus that could affect the value of that institution’s own patents, or its equity positions or options in that same company. An institutional COI may also arise if a senior official, say a department chair or dean, has a major equity holding in a medical device company, which could bias that person’s decisions (about medical faculty appointments and promotions, assignment of office or laboratory space, or other administration matters) to favor that company’s interests. It may again arise when a hospital official who selects a company’s products for patient care has a personal financial interest in the manufacturer of those products. In situations such as these, secondary financial interests may bias the conduct of research, or distort administrative decisions that affect the university’s broader educational, research, and public health missions. Such institutional financial COI may erode public trust in the university; they may also erode collective faculty trust in both the fairness and impartiality of the institution’s internal decision-making systems. Because institutional conflicts of interest strike at the core of the university’s integrity, and the

public's confidence in that integrity, they are critically important to address.

As the AAMC and AAU wrote in a joint 2008 consensus report on financial COI: “Beyond compliance with policies and procedures, institutional officials must foster what has been described as a ‘culture of conscience’ in the research enterprise. Exercising their authority within the institution, officials should insist upon rigorous enforcement of conflict-of-interest policies. Leading by personal example, officers and administrators should demonstrate to the academic community and to the public that compliance with these policies, including full disclosure of financial conflicts of interest, is an imperative reflecting core institutional values.”⁴²⁸

Of course, the AAUP recognizes that some external relationships, which may give rise to an *institutional* COI, may also generate significant financial benefits for a university. For example, gifts to endow new professorships or fund the construction of a new laboratory may provide support for the core teaching and research missions of the university. As a 2009 IOM panel noted: “The question for institutions as well as individuals is whether a relationship with industry can be maintained in a way that achieves the desired benefits but avoids the risks of undue influence on decision making and the loss of public trust.”⁴²⁹ If strong COI policies are effectively implemented, the answer to this question is more likely to be Yes.

❖ Principle 23: Consistent COI Enforcement Across Campus

University COI policies must be adopted consistently across the whole institution, including at affiliated medical schools, hospitals, institutes, centers, etc., and they must apply to faculty, students, administrators, and academic professionals.

- This recommendation is drawn from both the AAU and AAMC (2008).⁴³⁰
- The goal of these COI policies should be to encourage the practice of objective science

and research integrity in an environment of openness and trust, guard against unintentional bias and error, and, of course, punish misbehavior whenever it is uncovered.

❖ Principle 24: Standing COI Committees

Every university should have one or two standing COI committees to oversee implementation of policies to address individual and institutional COI. At least one member should be recruited from outside the institution and approved by the faculty governing body. Members should be free of conflicts of interest related to their COI oversight functions. After faculty financial COI disclosure statements have been reviewed by an appropriate campus standing committee, they should be made available to the public, preferably on an easily accessible online database, as the AAUP recommends under Principle 27 below.

- This Principle is drawn from recommendations already issued by the Institute of Medicine (IOM, 2009)⁴³¹ and other professional and academic groups.

- The goal of these standing COI committee(s) should be to bring experience, professionalism, fairness, and consistency to COI oversight functions, across the whole university.⁴³²

- These committee(s) should strive to have members who reflect knowledge of the types of, and distribution of, conflict of interest cases that occur in different colleges within a campus.⁴³³

- As the IOM (2009) has recommended, final responsibility for oversight of *institutional conflicts of interest* should be lodged with an institution's governing body. However, when a senior administrator receives significant income from outside corporations doing business with his or her own institution (for example, a university president may earn a sizable share of his or her total income from compensation for serving on a corporate board), then a board of trustees dominated by business executives may itself present the risk of an appearance of conflict when evaluating whether the financial conflict of interest is serious. In such cases, the organization of a special standing faculty COI oversight committee to review administrators' consulting activities is a possible corrective.

- Finally, if the standing faculty COI oversight committee itself appears to have a related conflict-of-interest, then the faculty senate, or an equivalent faculty governing body, might seek review by an extramural committee consisting of faculty and administrators from other schools not in direct competition over the matter at issue.

Discussion:

A 2009 IOM panel wisely observed that managing institutional COI may, in many respects, be more challenging than managing individual COI. The panel wrote: “In the case of individual conflicts in large institutions such as universities, medical schools, and major teaching hospitals, opportunities for review usually exist at multiple levels of the institution and involve authorities who are relatively independent and do not stand to gain personally from the secondary interests in question.” In contrast, the IOM panel noted, an objective or impartial review “for institutional conflicts of interest may be difficult because the institutional officers themselves may stand to benefit indirectly from the conflict of interest and may be reluctant to question current or proposed relationships with companies that seem likely to improve the institution’s financial welfare...Because the potential financial gain from a secondary institution-level interest may not be personal for institutional officials, their decisions may be more easily rationalized as serving the institution rather than themselves—even when officials also stand to gain in personal reputation.”⁴³⁴

Because of these additional challenges in managing institutional COI, the AAUP recommends that universities and their faculty senates consider lodging final responsibility for oversight of institutional COI with a standing faculty COI committee capable of fairly and impartially reviewing administration level consulting activities, with one or more independent members—not affiliated with the institution—to foster greater public credibility and impartiality.

❖ Principle 25: Reporting Individual COI

Faculty members and academic professionals should be required to report to the standing campus COI committee all significant* outside financial interests relating directly or indirectly to their professional responsibilities (research,

teaching, committee work, and other activities), including the dollar amounts involved and the nature of the services compensated—regardless of whether they believe their financial interests might reasonably affect their current or anticipated university activities. All administrators should report similar financial interests to both their superiors and the standing COI committee. Presidents and chancellors should report to the standing committee.

**The AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is not controlled and/or managed by an independent entity, such as a mutual or pension fund. This is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services under its 2011 conflict of interest disclosure rules. (Source: Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” Federal Register, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)*

- This recommendation is adapted, slightly, from one already issued jointly by the AAU and AAMC in 2008.⁴³⁵ It is also in line with the new COI rules issued by DHHS-NIH (2011), which expand the definition of what financial relationships investigators must report to their university employers. The new rules state that all DHHS-NIH-grant recipients must report not just how their financial interests (in a company, or other entity) might affect a particular federal project or grant, but how they might affect all of their other “institutional responsibilities,” including research, consulting, teaching, and membership on university committees—a change designed, in the words of DHHS, to “provide institutions with a better understanding of the totality of an investigator’s interests.”⁴³⁶

- Under this DHHS-NIH rule, U.S. universities must now reach their own determination concerning which of these financial interests constitute a possible COI that could threaten the objectivity and integrity of DHHS-NIH-funded research, and how these conflicts will be reduced, eliminated, and/or managed accordingly. Finally, the new rules require the university to draw up a formal, written COI Management Plan for submission to the federal grant agency, which must also be made accessible to the public.

The AAUP recommends that the all following types of financial relationships should be

disclosed to the university for internal review by a standing COI committee and made public:

Recommended List of Financial Ties to Be Disclosed To the University

- ⇒ Research grants and contracts
- ⇒ Consulting agreements at or above \$5,000
- ⇒ Participation in “speakers bureaus”
- ⇒ Honoraria, valued at or above \$5,000
- ⇒ Intellectual property, including patents, royalties, licensing fees
- ⇒ Stock, options, warrants, and other ownership (excepting general mutual funds)
- ⇒ Positions with a company
- ⇒ Company governing boards
- ⇒ Technical advisory committees, scientific advisory boards, and marketing panels
- ⇒ Company employee or officer, full or part time
- ⇒ Fees for authorship* of publications prepared by others

*Reporting of fees for authorship are now specifically required under the 2011 DHHS-NIH rules for managing financial COI, due to the federal government’s growing concerns about the prevalence of industry-led ghostwriting of scholarly work.⁴³⁷

- ⇒ Fees to serve as an expert witness for a plaintiff or a defendant
- ⇒ Other significant payments from, or financial relationships with, Non-Profits (valued at or above \$5,000)—including professional societies, disease patient advocacy groups, research foundations, etc.—which may receive a significant amount of their funding from industry groups*

*The 2011 DHHS-NIH rules for managing financial COI also require reporting of non-profit income, because a growing number of these non-profit organizations now derive a sizable share of their funding from industry sources.⁴³⁸ According to one recent survey, many medical specialty societies and associations rely heavily on medical industry funding.⁴³⁹ The IOM (2009) noted that most professional societies and disease-focused or patient advocacy groups do not make public the details of their funding from industry, however their reliance on industry funding is well known. During one Congressional inquiry, the American Psychiatric Association (APA) reported that medical companies supplied about 28

percent of its annual income. An Associated Press story in 2009 reported that 40 percent of the annual budget of the National Fibromyalgia Association comes from industry groups.⁴⁴⁰ Many industry-trade groups (tobacco, oil, chemical) also fund non-profits front groups to distribute academic research grants on their behalf, making the source of this funding harder to detect.⁴⁴¹

Recommendations Adapted from IOM (2009)

❖ Principle 26: University-Vendor Relationships and COI

Universities should ensure that vendor evaluation, selection, and contracting for university products and services are consistent with their academic mission and do not jeopardize the best interests of students. Vendors should never be persuaded or coerced into making financial contributions to the university, either through direct university donations or the recruitment of other contributing donors, in exchange for winning university contract bids. All university bidding for contracts and services related to such areas as banking and student loans should be conducted through a fair, impartial, and competitive selection process. Many universities currently have ethics policies banning gifts from vendors; the policies should also clearly prohibit institutions from accepting direct remuneration, or kickbacks, from vendors doing business with the university or its students. Direct profiteering can undermine public trust in the university and compromise the best interests of the students the university has pledged to serve.

Student Loans for Higher Education

- This AAUP Principle draws partly on recommendations issued in 2007 by the American Association of Universities, AAU, in its “Statement of Guiding Principles Regarding Institutional Relationships with Student Loan Providers.”⁴⁴² The AAUP endorses the following AAU recommendations:

- Decisions by colleges and universities with respect to student lenders should be based on an assessment of student borrowers’ best interests.
- Institutional integrity and the appearance of integrity are essential in processes that identify and recommend student-loan providers.

- Colleges and universities should inform students and parents that they may select the lender of their choice, and should not penalize students and parents for selecting a lender not on a preferred lender list.
- Colleges and universities should disclose the criteria for recommending student lenders.
- Institutional personnel involved in or responsible for administration of student financial aid programs should not accept any personal benefit from a lender.
- Colleges and universities should take steps to ensure that a) lender representatives dealing with students and parents disclose their affiliation and not assert or imply that they are employees of the institution, and b) no lender representative, in the course of permissibly serving the institution, promotes a particular lender's loan product.

- Universities seeking to establish appropriate vendor relationships with student loan companies should also carefully consult the “Student Loan Code of Conduct”⁴⁴³ developed by New York Attorney General Andrew Cuomo in 2007; U.S. Department of Education regulations⁴⁴⁴ pertaining to federal student loans, issued in November 2007; and various new, state-level consumer protection laws for students and parents addressing financial aid assistance to pay for higher education.⁴⁴⁵

Credit Card and Other Banking Vendors On Campus

- Outside scrutiny of universities and colleges' financial relationships with banks and credit card companies has been growing in recent years. The Board of Governors of the Federal Reserve System now submits a report to Congress annually concerning agreements between credit card issuers and institutions of higher education, and certain affiliated organizations, such as alumni associations and foundations, that provide for the issuance of credit cards to college students.⁴⁴⁶ This information is also readily available to the public.⁴⁴⁷

Discussion:

An Overview of National Student Loan Scandal of 2007:

In 2007, investigations into the student loan business on university campuses conducted by the New America Foundation,⁴⁴⁸ New York State Attorney General Andrew Cuomo⁴⁴⁹ (which

subpoenaed hundreds of universities based in, or enrolling students from, New York), and various Congressional and government offices, produced a series of disclosures:

- Top financial aid administrators at leading U.S. universities across the country—whose job it is to advise cash-strapped students—had pervasive financial ties to the loan companies they were recommending to students, and were, in some cases, personally profiting off of their own students’ debt load. After it was exposed that financial aid directors had significant personal financial conflicts at the U. of Texas at Austin (stock holdings), Columbia University (stock holdings), U. of Southern California (stock holdings), and Johns Hopkins (\$65,000 in consulting fees and payments from lenders to pay for her graduate education) all of them lost their jobs.⁴⁵⁰

- In several cases university call centers were staffed by bank employees.⁴⁵¹

- Financial aid officials nationwide were found to have accepted cash, gifts, trips to exotic destinations, and sponsorships of things such as awards dinners and association conferences from lenders they recommended to their students. Some lenders made cash payments to the universities themselves. Some of these lenders were charging interest as much as four times as high as the rates on government-subsidized loans.⁴⁵²

- Many U.S. universities were found to have explicit revenue-sharing agreements with their “preferred lenders” (e.g. lenders whose names appeared on their “recommended lenders” list for students), which meant that they received a financial payment, or “kickback,” for every new student who subsequently took out a bank loan. “A preferred lender ought to mean that the lender is preferred by students for its low rates, not by schools for its kickbacks,” Cuomo told *The Times Higher Education*.⁴⁵³

- Before these inquiries were over, at least 35 universities had accepted Cuomo’s demand that they pay actual restitution to their students equal to the amount of money they took in as kickbacks. University of Penn was compelled to distribute \$1.6 million to students; NYU \$1.4 million.⁴⁵⁴

- Studies show that 90 percent of students choose the loan companies that their university Student Aid Offices recommend. In the last 12 years, national student loan debt has nearly doubled, with very high interest rates charged by these private lenders. Some private lenders charge as much as 19 percent interest.

Thanks in part to special arrangements with universities, private lenders have faced little competition on campus. Some schools have accepted payments from private lenders in exchange for pulling out of the federal direct loan program.⁴⁵⁵ One U.S. Department of Education investigation found that out of 55 colleges surveyed, 48 held more than 95 percent of their loan volume with a single lender and seven had at least 80 percent of their volume with a single lender. The Department expressed concern that this level of concentration might signal violations of federal law, such as having financial-aid websites that automatically direct students to a particular lender.⁴⁵⁶

In June and September of 2007, Senator Edward M. Kennedy (D.-Mass.) released two reports⁴⁵⁷ that provided further evidence that student loan program abuses were widespread, naming a large numbers of colleges that had accepted or even solicited inducements from lenders—often with the expectation or explicit agreement that the institution would grant the said lender preferential treatment. “Given the breadth of the evidence presented in this report it is clear that the problem is systemic and cannot be isolated to a few ‘problem’ lenders or schools,” the first report concluded.

“[M]any lenders in the FFEL [Federal Family Education Loan] program routinely engage in marketing practices that,” according to the report, “violate the letter and spirit of the inducement prohibition of the Higher Education Act,” which, the report noted, bars not only “a consummated quid pro quo deal, but the mere offer of such a deal.”⁴⁵⁸

Other investigations by the Government Accountability Office found that “... some student loan lenders were paying schools to promote their loans, and some schools were limiting students’ choice of lenders.”⁴⁵⁹ The GAO and the Inspector General of the U.S. Department of Education further found that the Department’s oversight of the federal student loan program had been inadequate.

Scrutiny of Other Types of Banking and Credit Card Vending Relationships On Campus:

In recent years, as public funding for higher education has declined, universities and colleges have sought to generate new sources of revenue by striking lucrative deals with corporations eager to market to student audiences. Some of these deals—including stadium naming rights, athletic and event sponsorships, soda vending deals—tend to be less objectionable. But others encourage students to fall prey to credit card and other banking

practices that could be potentially harmful, while their universities reap direct profits. These bank vendor relationships on campus now include credit card deals, and other types of arrangements in which colleges convert their campus ID cards into ATM/debit cards by outsourcing them to private banks.⁴⁶⁰ Under this arrangement, the banks produce the university ID cards, which students can use both to access checking/savings accounts and as a debit card. In exchange, these banking firms will produce and issue ID cards for free, and often pay a share of the money they earn off the students' purchases and debts back to the colleges, their alumni associations, or their athletics departments—enabling these universities to make direct profits off of their students.⁴⁶¹

In all of these deals, the host universities or colleges also provide financial firms with personally-identifiable information about their students. The companies then use this data—which can include permanent addresses, e-mail addresses, and local telephone numbers—to market credit cards and other financial services directly to students. Some schools also provide companies with face-to-face access to students, allowing salespeople to set up marketing tents in central campus locations. According to Higher Ed Watch, a project of the New America Foundation, such deals are often quite profitable: “An ID card deal between the University of Minnesota and TCF Financial has yielded an estimated \$40 million over 30 years for the school, while the bank’s deposits have increased by \$50 million.”⁴⁶² When Iowa lawmakers conducted an investigation in 2007, they found that “...credit card contracts generated millions of dollars a year for the institutions’ privately-run alumni organizations.” Their report found that Bank of America had marketing arrangements with about 700 U.S. campuses, mostly with alumni associations, athletics departments, and foundations, which typically collect 20 to 50 cents for every \$100 of credit card purchases.⁴⁶³

However, the benefits to students are far more difficult to discern. As a blog posting from Higher Ed Watch noted: “The deals that public universities are making with banks and other finance companies for credit cards and ID cards bear a striking similarity to the deals that were uncovered last year as part of the investigation into the ‘pay-for-play’ student loan scandal. Just as exclusive deals between lenders and colleges drew Congressional ire, policymakers need to take a closer look at schools’ revenue machinations and their implications for students.”⁴⁶⁴

In its October 2010 annual report to Congress,⁴⁶⁵ the Board of Governors of the Federal Reserve System reported receiving a total of 1,044 college credit card agreements between

universities and their affiliated alumni associations and foundations and seventeen credit card issuers. In 2009, these credit card issuers made total payments of \$83,462,712 to higher education institutions and their affiliated organizations. The total number of college credit card accounts opened, pursuant to these agreements, was 2,008,714.

Legislation in California, known as the Student Financial Responsibility Act (AB 262, Coto, Chapter 679, Statutes of 2007), requires the California State University and California Community Colleges, and requests the Regents of the University of California and governing bodies of private or independent colleges in the state, to adopt policies that regulate the marketing practices used on campuses by credit card companies. Each campus is directed to annually disclose all exclusive arrangements with banks or other entities that engage in on-campus credit card marketing activities. The law prohibits gifts to students who complete on-campus credit card applications for those lending entities. Additionally, the bill urges the Regents to revise the University of California Policy on the On-Campus Marketing of Credit Cards to Students.⁴⁶⁶

- Nellie Mae, one of the nation's largest student loan companies (fully owned by Sallie Mae), reports that 92 percent of graduate students have a credit card, with an average balance of \$8,612 in 2006 (15 percent had an average balance of more than \$15,000). Undergraduate students averaged about \$2,169 in credit card debt.⁴⁶⁷

❖ Principle 27: Inter-office Reporting and Tracking of Institutional COI (ICOI)

To keep track of institutional conflicts of interest (ICOI), every institutional COI committee should have a well-developed, campus-wide reporting system that requires the technology transfer office, the office of sponsored programs, the development office, the grants office, institutional review boards (IRBs), and reciprocal offices at affiliated medical institutions (in addition to its purchasing offices) to report, at least quarterly, to the standing ICOI committee on situations that might give rise to institutional conflicts.

- The purpose of this ICOI inter-office reporting system is to ensure that all university

decision-making processes and agents, charged with addressing institutional financial matters, are clearly and credibly separated from the institution's academic research activities.

- This AAUP recommendation has already been endorsed, in similar form, by the Institute of Medicine, IOM (2009)⁴⁶⁸ and by the Association of American Medical Colleges, AAMC/Association of American Universities, AAU (2008).⁴⁶⁹

- This campus-wide reporting system should encompass the following offices, which could give rise to the following possible ICOI situations:

- i) Technology transfer office (for licensing arrangements, patents, invention disclosures);
- ii) Office of sponsored programs, research administration, or corporate research relations (for sponsored research agreements and products that are the subject of research);
- iii) Development office (for gifts);
- iv) Grants office (for federal and state grants);
- v) Institutional review boards (IRBs) (for monitoring and approving human subjects research protocols);
- vi) Medical institution purchasing offices (for separation of financial interests from purchasing decisions)

Discussion:

Most universities have long-standing “firewall” arrangements governing the management of their endowment-related investment portfolios and gift funds, which separate the management of these funds from the campus's research and teaching enterprise. Such firewalls seek to ensure that the management of these funds remains in accordance with standard institutional investment policies, with no special restrictions or considerations, and with oversight by an appropriate external body or board-of-trustee committee that exercises no control over university programs and operations. However, many universities do not yet have firewall policies and procedures clearly in place to separate the university's academic and research operations from newer types of financial investments related to the university's technology transfer operations—these may involve options and other equity-type holdings, royalty income, milestone payments, legal actions to protect these financial interests, etc.⁴⁷⁰

At the highest levels of the institution, of course, all streams of finance oversight and research oversight do converge. However, it is critically important for the university to erect

clear firewalls so any institutional financial relationships with commercial research sponsors, and all technology transfer-related decisions connected with the university's own financial holdings, are separated, to the greatest extent possible, from the university primary academic and research operations. In 2001, Hamilton Moses and Joseph B. Martin put forward one suggestion that institutions create a separate entity to hold and manage individual and institutional equity interests in any companies that are supporting research on campus. This investment company would be overseen by a board with "wide representation," including representatives from outside the university.⁴⁷¹

Credible and meaningful separation is critical. However, the AAUP agrees with the AAMC, AAU, IOM and others that even when effective separation has been achieved, certain financial relationships with commercial research sponsors should be examined closely for the presence of any serious ICOI that could compromise the integrity of the institution and its research operations as a whole. In the case of human subject research, in particular, there should always be a strong presumption against permitting research to go forward under the auspices of a conflicted investigator, or a conflicted institution (see Principle 28 below for a more detailed discussion of this principle).

❖ Principle 28: Strategies for Reviewing, Evaluating, and Addressing Financial COI

Disclosure of a financial COI is not a sufficient management strategy. The best course of action, of course, is not to acquire financial COI in the first place. Strategies for addressing individual financial COI include: divesting troublesome assets, terminating consulting arrangements, resigning corporate board seats, and withdrawing from affected projects. Methods for addressing institutional financial COI include: the institution divesting its equity interest in companies doing campus research, placing conflicted equity holdings in independently managed funds with explicit firewalls to separate financial from academic decisions, recusing conflicted senior administrators from knowledge of, or authority over, affected research projects, and requiring outside committee review or oversight. Some university presidents decline to serve on corporate boards to avoid the appearance of COI. Because of

conflicting fiduciary responsibilities, campuses should prohibit senior administrators from receiving compensation for serving on corporate boards during their time in office.

The IOM (2009) developed the following two charts, which the AAUP endorses, for evaluating the “risks and benefits” associated with a reported financial COI; and for determining what steps to follow in identifying and responding to a financial COI situation.

BOX 3-2
Risks and Potential Benefits to Consider in Assessing the Severity of a Researcher’s Conflict of Interest

- Risks to human subjects: to what extent could the conflict of interest increase the risk (considering the role specified for the researcher with the conflict of interest in recruiting or treating research participants)?
 - Risks of bias in data collection, analysis, and reporting: to what extent could the researcher with the conflict of interest compromise the integrity of the data?
 - Risks to reputation: to what extent could the reputation of the researcher with the conflict of interest or the researcher’s institution be damaged, even if the institution establishes a plan to manage the conflict?
 - Expected benefits to medicine, science, and public health: how do the expected benefits of allowing the research to proceed compare with the risks?

SOURCE: Adapted from AAMC-AAU, 2008.

BOX 3-1
Model of Steps Used to Identify and Respond to a Conflict of Interest

Step 1 Obtain the disclosure of information about financial and other relationships that could constitute a conflict of interest.

No relationships reported: stop. Relationships disclosed: go to Step 2.

Step 2 Evaluate the disclosures—in light of the individual's responsibilities or specific activities (e.g., research, teaching, and patient care)—to determine whether a conflict of interest exists. If necessary, collect additional information to assess the likelihood of undue influence and the seriousness of possible harms.

No conflict exists: stop. Conflict exists: go to Step 3.

Step 3 Determine whether the relationship is one prohibited under institutional or other policies or whether the risks of the relationship are so serious that the individual should either eliminate it or forgo participation in the activity put at risk by the relationship.

Conflict elimination necessary: go to Step 5.
Elimination not necessary: go to Step 4.

Step 4 If management is appropriate, devise and implement a plan to manage the conflict. Go to Step 5.

Step 5 Monitor conflict elimination or management plan and assess adherence.

Plan followed. Plan not followed: go to Step 6.

Step 6 Determine the nature of the noncompliance and the appropriate response (e.g., education, penalty, or revision of the plan) and implement the response.

Strategies for eliminating, reducing, and/or managing financial COI could include any of the following:

In the case of a *faculty member with financial COI*, these remedial strategies might include:

- Divestiture of troublesome assets;
- Terminating consulting arrangements, or seats on company boards;
- Withdrawing the conflicted researcher from an affected project;
- Disclosure of significant financial assets in any published report, or public presentations,

related to the affected research;

- Use of a formal external Data Safety Monitoring Board (DSMB) or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;

In the case of an *institutional COI*, involving the university (the institution) or any senior officials (representing the institution), remedial strategies might include:

- Divesting the institution of an equity interest in a company performing research on campus;
- Increasing the segregation between decision-making regarding the financial interest and any research or campus activities;
- Placing conflicted equity holdings in an independently managed fund, with explicit firewalls to strictly separate financial from academic decisions;
- Isolation or recusal of a conflicted senior official from knowledge of, or decision-making authority over an affected research project;
- Decline to perform research in which the institution has a financial stake (beyond the funding of the research itself);
- Disqualification of a senior officer from activities associated with the COI;
- Recusal from decision-making that might potentially be affected by the COI;
- Transfer of professional responsibilities (and/or decision-making authority within a proscribed area) to someone who is conflict free;
- Require independent review, or oversight, by an outside committee;
- Formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator.⁴⁷²

It is important to keep in mind that research misconduct—such as intentionally counterfeiting or distorting data—is a separate issue, and universities and the federal government have established separate regulations and procedures to investigate misconduct charges and to punish proven misconduct.

❖ Principle 29:
**Development of a Formal,
Written COI Management Plan**

If a university’s standing COI committee finds compelling circumstances for allowing a research project, or other professional activity, to continue in the presence of a significant financial COI—without the elimination of the conflict—the committee should document the circumstances and write a formal management plan for each case. The plan should detail how the university will manage the financial COI and eliminate or reduce risks to its constituents (students, faculty, patients), its pertinent missions (research integrity, informed consent, and recruitment of research volunteers), and its reputation and public trust. This recommendation is consistent with the Department of Health and Human Services (DHHS)-National Institutes of Health (NIH) rules implemented in 2011 to address financial conflicts, requiring all universities that receive DHHS grants to prepare and enforce such management plans.

- The DHHS-NIH (2011) COI rule requires all universities to prepare a written Management Plan whenever an DHHS grant recipient has a significant financial conflict of interest related to his or her research that is not eliminated. Under the PHS rules, these management plans must be provided to the federal grant-making agency “prior to the Institution’s expenditure of any funds under a PHS-funded research project.” They must also be made readily accessible to the public, either on a public website or by responding to any public request “within five business days.”⁴⁷³

- **The AAUP believes these management plans—addressing both individual and institutional COI—should meaningfully and effectively address all of the following:**

- | |
|---|
| <ol style="list-style-type: none">1. the nature of the conflict;2. possible perceived risks to human subject research and/or clinical-care decisions, involving research volunteers and/or patients;3. possible issues affecting the interests of students; |
|---|

4. perceived risks to the integrity of the research (e.g., recruitment of research volunteers, informed consent, study design, protocol changes, study oversight, data analysis, statistical analysis, final reporting); and
5. any perceived risks to the reputation of the institution.

❖ Principle 30: Oversight and Enforcement of COI Rules

All university COI policies should have effective oversight procedures and sanctions for noncompliance. They are essential to ensure compliance with university rules and public trust in the university's ability to regulate itself.

Adequate COI policy enforcement is missing on many campuses:

- A 2009 IOM panel addressing COI in biomedicine reported finding no peer-reviewed studies on the monitoring of institutional COI policies, or on the enforcement of COI disclosure requirements.⁴⁷⁴
- Investigations by Sen. Charles Grassley (R-IA) in 2008 and 2009 exposed numerous high profile cases where senior university faculty members failed to report millions of dollars in outside commercial income from pharmaceutical firms.⁴⁷⁵
- One 2002 report by the Council on Government Relations, an association of research universities, found significant inadequacies with respect to enforcement: “While virtually all research universities and organizations have written policies governing individual financial conflicts of interest in research-related areas, most institutions are still developing formal and informal education programs to assure that the policies are well understood and that compliance by affected faculty and researchers is fully in place.”⁴⁷⁶
- More recently, in 2008, the American Medical Student Association (AMSA) evaluated academic medical school policies and found a similar absence of oversight and enforcement mechanisms: Of the 58 schools that initially responded to the AMSA survey and supplied written policies for review, 55 percent were characterized by trained external reviewers as having oversight policies, 45 percent were characterized as having enforcement policies, and only 34 percent were characterized as having both.⁴⁷⁷

**❖ Principle 31:
COI Transparency
(Public Disclosure of Financial Interests & COI Management Plans)**

University COI policies should require faculty, administrators, students, postdoctoral fellows, and academic professionals to disclose to all journal editors all personal financial interests that may be directly, or indirectly, related to the publications they are submitting for consideration. The same requirements should apply to oral research presentations, presented in conferences, courts, and legislative chambers. After the university’s standing COI committee reviews faculty conflict of interest disclosure statements, they should be posted to a publicly accessible website. This is important to address growing demands from Congress, state governments, journal editors, the media, and public interest groups for increased reporting and transparency of faculty COI. It is also consistent with DHHS-NIH (2011) rules, which require universities to disclose all significant* financial COI (as per the DHHS-NIH definition) related to a faculty member’s DHHS-funded research on a public website or provide the information upon public request within five days. Disclosure of financial COI should also extend to affected patients and human research volunteers. (For details, see Principle 31 below.)

**The AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is not controlled and/or managed by an independent entity, such as a mutual or pension fund. This is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services under its 2011 conflict of interest disclosure rules. (Source: Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” Federal Register, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)*

** The DHHS rule defines a “significant” financial conflict of interest as follows: “Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research... Significant financial interest means:*

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the

value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education." [Emphasis added] (Source: Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," Federal Register, Vol. 76, No. 165, August 25, 2011, quotes on pp. 53283-53284.)

In summary, the AAUP recommends stronger COI disclosure policies covering the following four areas:

i) Disclosure to Academic Journals:

This principle is consistent with the standards on author disclosure of financial interests adopted by the International Committee of Medical Journal Editors and the World Association of Medical Editors (WAME),⁴⁷⁸ which all universities and their academic medical centers should endorse in their own policies.

ii) Disclosure in Oral Presentations:

This principle is consistent with the journal recommendation above, since oral presentations (including public lectures, Grand Rounds at medical schools, Congressional testimony) represent other common forums where faculty transmit their expertise, and thus financial COI disclosure should be required.

iii) Disclosure of Faculty Financial COI, and Corresponding University Management Plans, On a Public Website:

This recommendation goes further than those issued by other professional groups. However, it is fully compatible with the DHHS-NIH COI rules (2011), which require disclosure of all significant financial COI, related to DHHS-NIH funded research, on a public website or release of that information within five days of any public request, as well as the development of a detailed COI Management Plan.⁴⁷⁹ If such disclosure is warranted in the case of DHHS-NIH funded research, why should it not be extended to all faculty research? In the view of the AAUP, it is time for universities to make this information broadly available as a routine practice to promote transparency and enhance public accountability.

iv) Disclosure of Financial COI to Patients & Research Subjects:

(For details, see Principle 31 below.)

Part V.
❖
**Targeted Principles:
Managing COI in the Context of Clinical Care
and Human Subject Research**

Opening Discussion:

With the welfare of patients and research subjects always of utmost concern, academic institutions should regard financial conflicts of interest in the areas of clinical care, pre-clinical research⁴⁸⁰, and human subject research as requiring close scrutiny, regulation and oversight.⁴⁸¹ The integrity of science—as well as the moral imperative of medicine “to do no harm”—require vigilant attention to financial COI in these three areas.

This principle was codified in the Charter on Medical Professionalism, issued by the ABIM,⁴⁸² Adopted by more than 100 professional groups worldwide, the Charter lays out 10 essential professional medical responsibilities, one of which is maintaining patient trust by managing conflicts of interest. The IOM⁴⁸³, AAU and the AAMC (2008)⁴⁸⁴ have all issued similar recommendations endorsing the need for heightened vigilance regarding financial COI in the areas of direct patient care and human subject research.

The AAUP agrees with this assessment. As a recent 2010 AAMC report on clinical care observed: “[T]he entire medical profession shares the responsibility for upholding the values of medical professionalism. The medical profession is the public face of medicine, and the degree to which all of its components accept the responsibility for addressing potential conflicts that may result from its relationships with industry is directly related to the maintenance of public trust in the integrity of medical decision making.”⁴⁸⁵

Human subject research is obviously an acutely sensitive area. As Harvard professor Eric Campbell, an IOM panel member, explained in his Congressional testimony, in 2009, regarding COI regulation in medicine: “It is critical for public trust that research institutions protect the integrity of the medical research that is the foundation of clinical practice and education. Bias in the design and conduct of clinical trials may expose research participants to risks without the prospect that the trials will generate valid, generalizable knowledge. Moreover, such bias—and also bias in the reporting of research—may result in compromised findings being submitted to

the Food and Drug Administration for approval of drugs or devices. Further, it may also expose much larger numbers of patients to ineffective or unsafe clinical care.”⁴⁸⁶

Here are the AAUP’s recommendations in these critical areas of clinical research and patient care:

❖ **Principle 32:** **Individual and Institutional COI and Human Subject Research**

A “rebuttable presumption” against permitting the research should govern decisions about whether conflicted researchers or conflicted institutions should be allowed to pursue a particular human subject research protocol or project, unless a compelling case can be made to justify an exception. To maximize patient safety and preserve public trust in the integrity of the research enterprise, there should always be a strong presumption against permitting financial COI related to experimental studies involving human subjects.

- This AAUP recommendation has already been endorsed, in similar form, by the IOM (2009),⁴⁸⁷ AAMC (2001, 2002), and the AAMC-AAU (2008),⁴⁸⁸ all of which favor a strong “rebuttable presumption” against the presence of financial conflicts of interest, whether individual or institutional, in human subject research.
- Here is how the IOM explains the origin and meaning of this term rebuttable presumption: “The ‘rebuttable presumption’ concept is taken from the law and refers to assumptions that are taken to be true unless they are explicitly and successfully challenged in a particular case... A compelling circumstance would exist, for example, if a researcher with a conflict of interest has unique expertise or skill with implanting and adjusting a complex new medical device and this expertise is needed to carry out an early-stage clinical trial safely and competently. Generally, some kind of management plan would then be devised.”⁴⁸⁹
- For a detailed discussion of the institutional financial and fiduciary interests that affect human subject research, please see this reference from the AAMC and AAU (2008).⁴⁹⁰

Discussion:

In keeping with recommendations issued by the AAMC, AAU, and IOM, the AAUP understands that in some exceptional cases it may be necessary to allow a university investigator, who has a financial conflicts of interest, to participate in human subject research, if the testing and development of a potential new drug, therapy, or procedure would be unable to proceed without that faculty member's participation (as in the case of a surgeon, who may be the only skilled expert capable of testing a new medical technique). However, in the view of the AAUP, such waivers (from the normal prohibition against financial COI in human subject research) should be granted rarely, and any waiver should be made public, together with a copy of the university's complete COI Management Plan. As a 2009 IOM panel observed: "In most cases of a conflict of interest [related to human subject research], no compelling argument that the investigator's participation is essential can be made. Even if the investigator's participation is essential, the elimination of the conflict of interest (e.g., through the sale of stock) is the preferred step. If an exception is granted, it should be made public."⁴⁹¹

**❖ Principle 33:
Institutional Review Boards (IRBs)
and COI Management**

An institutional review board (IRB) should review all proposed human clinical trial protocols, paying careful consideration to all related financial COI, before research is allowed to proceed. First, institutions should have clear policies, compliant with applicable federal regulations, to address reporting and management of financial COI associated with IRB members themselves. Policies should require conflicted IRB members to recuse themselves from deliberations related to studies with which they have a potential conflict. Second, the policies should require the institution's standing COI committee to prepare summary information about all institutional and individual financial conflicts of interest related to the research protocol under review. The summary should accompany the protocol when it is presented to the IRB. The IRB should take the COI information into account when determining whether, and under what circumstances, to approve a protocol. Neither the IRB nor the standing COI committee should be able to reduce the

stringency of the other’s management requirements. The double-protection system is consistent with the two sets of federal regulations governing clinical research and provides appropriate additional safeguards for research involving patient volunteers. Finally, if a research protocol is allowed to proceed, university policies should require the IRB to disclose any institutional and investigator financial COI as well as the university’s management plans for addressing them to (i) all patient volunteers in “informed consent” documents and (ii) all investigators and units involved with the research protocol.

- This AAUP Principle is drawn directly from recommendations already endorsed by the Association of American Medical Colleges (AAMC)-Association of American Universities (AAU) (2008),⁴⁹² and the AAU (2001).⁴⁹³

- This Principle is designed to address well-documented problems with sitting IRB members at universities having extensive financial conflicts of interest themselves,⁴⁹⁴ as well as widespread evidence that IRB members often do not have full knowledge of the institutional and investigator financial conflicts of interest related to the research protocols under their review, due to inadequate communication of this information between the IRB and the university’s standing COI committees.⁴⁹⁵ To address these issues, the AAU (2001) recommends more effective integration and communication of information between IRBs and the university’s standing COI committees.⁴⁹⁶

- Disclosure of financial COI to patients and human subject volunteers is critical to safeguard public confidence in the medical research system. Numerous media exposes and public investigations, including one reported in 2012 on 60 Minutes regarding research conducted at Duke University, have focused public attention on both university and investigator financial interests that were not disclosed to patient volunteers. One study (by Weinfurt et al. 2006) found considerable variation in university policies in this area: This study reported that only 48 percent of medical schools had policies that mentioned the disclosure of researchers’ financial conflicts of interest to research participants. The policies also varied in what information was to be disclosed.⁴⁹⁷

- Because of the strong presumption against conducting human subject research in the presence of both institutional and individual COI (discussed above), this situation should be rare, however clear policies on disclosure are nonetheless urgently needed and important.

**❖ Principle 34:
COI, Medical Purchasing, and Clinical Care**

Academic medical centers should establish and implement COI policies that require all personnel with financial interests in any manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, to disclose such interests and to recuse themselves from involvement in related purchasing decisions. To the extent an individual’s expertise is necessary in evaluating a product or service, the individual’s financial ties must be disclosed to those responsible for purchasing decisions.

- This AAUP Principle is drawn directly from recommendations issued by the Association of American Medical Colleges (AAMC) in 2008⁴⁹⁸ and 2010,⁴⁹⁹ for addressing management of financial COI in the context of clinical care.

**❖ Principle 35:
COI Transparency in the Context of Medical Care**

University policies should require all physicians, dentists, nurses, and other health professionals as well as investigators to disclose their financial COI to both patients and the broader public.

- This AAUP Principle is drawn from one that was issued by the Association of American Medical Colleges, AAMC in 2010,⁵⁰⁰ addressing the importance of financial COI disclosure to all patients. The AAUP agrees with the AAMC that disclosure is “one method, though not the exclusive method, of managing actual and perceived conflicts of interest in clinical care.”

- This AAMC guidance does not specify any preferred method for delivering this information to patients. However the AAUP believes this information should properly be posted on a public website, together with other information the academic medical center may wish to provide concerning the value of these outside relationships, and the institution’s formal Management Plans for mitigating any potential bias stemming from such relationships.

Part VI.
❖
Targeted Principles:
Strategic Corporate Alliances SCAs, (36-47)

Discussion:

What is an SCA?

A Strategic Corporate Alliance (SCA) is a formal, comprehensive, university-managed research collaboration with an outside company sponsor (or several company sponsors) centered around a major, multi-year financial commitment involving research, programmatic interactions, “first rights to license” intellectual property, and other services.*

*This definition is adapted from one drawn up and used by Cornell University’s administration.⁵⁰¹

An SCA is distinct from an Industrial Research Consortium, in which it is customary for a group of some ten or more companies to pay yearly membership fees to jointly support a broad research goal and/or technology development objective that all the corporate subscribers have a common interest in supporting. Research results developed within the Industrial Research Consortium are usually shared among the sponsoring members under *non-exclusive licensing* terms. Research results in an SCA, by contrast, are commonly licensed to the sponsor on an *exclusive* basis.

The structure of the SCA is also quite distinct from the far more common industry-sponsored research agreements traditionally forged on campus. Most traditional industry-sponsored research grants tend to come in smaller dollar amounts (ranging from several-thousand to several-hundreds-of-thousands of dollars); they also tend to be episodic and usually grow out of an individual faculty member’s direct relationships with outside companies. An SCA, by contrast, is established on a far larger scale, runs for several years, and is negotiated through a central university development office in tandem with a group of faculty, an entire academic department, or many different departments in unison.

Unlike most traditional industry-sponsored grants, the SCAs also frequently requires the university to set up new, internal SCA governing structures to manage and oversee the industry

alliance over a period of several years. SCAs are often negotiated to last three-to-five years in the \$1 million-to-\$25 million range, or they may run ten years or longer in the \$50 million-to-\$250 million range. The largest individual SCA, thus far, is a 2007 alliance worth \$500 million over ten years that BP signed with three public research institutions: U.C. Berkeley, the University of Illinois at Urbana-Champaign, and Lawrence Berkeley National Laboratory.

SCAs are not new. Some campuses, like MIT, have been administering SCAs since the 1950s; MIT reports receiving roughly 45 percent of its total corporate research support in this form.⁵⁰² However, the vast majority of US universities have far less experience with SCAs, although this type of academic-industry alliance is growing, and many universities are now actively pursuing them—within the pharmaceutical, agriculture, and energy sectors, in particular.

In the pharmaceutical sector, companies and universities are also experimenting with new types of SCA-type collaborations, where academic researchers are becoming more commercially engaged not only in early-stage drug discovery, but in “translational” commercial drug development—an area which was traditionally only performed in industry not academia. As the *Financial Times* reported in 2008:

“Colleges and universities have become the next generation research and development labs for drug makers at a time when they are battling increased generic competition for top-selling medicines, and a dearth of drugs in the pipeline... Pharmaceutical companies have a long history of partnering with universities for drugs research and technology, but these new entrepreneurial arrangements represent a departure from the traditional model. In previous industry-academic partnerships, pharmaceutical companies engaged university researchers for a certain line of research that benefited their projects, and that research was carried out exclusively by the university scientist. New ventures, however, tend to involve teams of university and industry scientists working together on wide-ranging experiments to advance new drug discovery and stimulate basic research.”⁵⁰³

Examples of SCAs in the Pharmaceutical and Energy Sectors

- In August 2006, Chevron signed a five-year, \$25 million alliance with University of California at Davis to develop low-cost biofuels for transportation.
- In April 2007, ConocoPhillips signed an eight-year, \$22.5 million research collaboration with Iowa State University to study and develop biofuels.
- In March 2007, the University of Colorado at Boulder launched an alliance with 27 large firms (including Archer Daniels Midland Co., Chevron Corp., ConocoPhillips, Dow Chemical Co., E.I. du Pont de Nemours and Co., and Royal Dutch Shell Group) to finance the Colorado Center for Biorefining and Biofuels (C2B2), a consortium to develop biofuels that has brought in \$6 million over three years.* (*This collaboration appears to be a hybrid deal; part Industrial Research Consortium and part SCA.)

In 2007, BP, the U.K.-based oil giant, signed a 10-year, \$500 million SCA agreement, known as the Energy Biosciences Institute, with three public institutions: University of California-Berkeley, University of Illinois-Urbana-Champaign, and Lawrence Berkeley National Laboratory. The EBI is primarily targeting next-generation biofuels research, as well as some oil discovery work.

- In July 2008, Harvard signed a five-year, \$25 million alliance with GlaxoSmithKline to support stem-cell research, particularly in the areas of heart disease and cancer. According to news reports, joint projects will take place either on campus, or in Glaxo's labs. Glaxo will get the rights to any patents generated in its labs, including those generated by university scientists, and first rights to a non-exclusive license for any discoveries made on campus. A Harvard spokesman also said the research consortium "will be overseen by a steering committee made up of equal numbers of Harvard and GSK personnel."⁵⁰⁴

- In 2008, *Business Week* reported on two additional SCA agreements Harvard has with Merck: One alliance is targeting treatments for the bone disease osteoporosis; the other, negotiated with the Dana-Farber Cancer Institute, a Harvard affiliate, targets cancer therapies. According to *Business Week*, "This is nothing like past partnerships between industry and academia, in which

drugmakers helped fund discoveries at the university but relied on their own teams to come up with commercial products. In this case, Merck expects its Harvard allies to stay involved throughout the drug development process.” Dr. Ronald DePinho, a professor of medicine at Harvard, told the magazine that Harvard recently hired about 40 scientists from large pharmaceutical companies so they can coach the academics on drug development. “We’re creating a larger discovery enterprise,” he explained.⁵⁰⁵

- In 2008, the University of California-San Francisco and Pfizer signed a novel, broad-ranging research alliance that will provide up to \$9.5 million over three years. According to the *San Francisco Chronicle*, the agreement is “part of Pfizer’s attempt to break the traditional mold of pharmaceutical development and embrace the nimble work style of biotechnology companies that build on cutting-edge research.”⁵⁰⁶

- Pfizer also operates a three-year, \$14 million SCA collaboration to study diabetes, involving four research universities: the University of California-Santa Barbara, Caltech, the Massachusetts Institute of Technology, and the University of Massachusetts.⁵⁰⁷

What Distinguishes a “Broad SCA” from a “Narrow SCA”?

In **Broad SCA** agreements, it is customary for the university, in each new grant cycle, to issue a formal “request for faculty research proposals” (RFP) on behalf of the outside corporate sponsor(s). After faculty research proposals have been received, the university (often in collaboration with the sponsor) oversees a research evaluation-and-selection process to choose which faculty projects are eligible for SCA funding.

In **Narrow SCA** agreements, by contrast, all the faculty members eligible to receive SCA funding and their projects have been named and identified in advance, so this university-led RFP

and research-selection process is not required. This feature of a Narrow SCA limits some, but not all, of the institutional conflict of interest concerns raised by Broad SCAs.

**This discussion is drawn from a detailed analysis of SCAs conducted by Cornell University's faculty senate,⁵⁰⁸ which is referenced frequently in this report.*

“Academic freedom entails the responsibility to undertake and present research with openness and integrity, and conditions have to be maintained in which faculty can fulfill this responsibility.”

--Cornell University Faculty Statement of

Principles & Best Practices

Concerning Strategic Corporate Alliances, Fall 2005

Why Do SCAs Raise Distinctive Academic and Oversight Challenges?

Strategic Corporate Alliances raise a number of distinctive academic governance, academic freedom, and research integrity concerns. In part, this stems from the size, scope, and structure of the SCA. In part, it stems from the fact that nearly all SCAs present distinctive *institutional conflict-of-interest* concerns and challenges, which frequently arouse increased campus as well as public scrutiny and must, therefore, be addressed with greater levels of care and attention.

This brief overview of some of the challenges posed by SCAs is drawn from faculty senate reviews of SCAs at both Cornell and UC-Berkeley,⁵⁰⁹ a commissioned external review of the UC-Berkeley-Novartis SCA by independent researchers at Michigan State University,⁵¹⁰ legislative hearings in the California state senate addressing the UC-Berkeley-Novartis deal,⁵¹¹ and a detailed analysis of the terms and conditions spelled out in 10 SCA legal contracts negotiated between US universities and energy-related firms during the period 2002-2011, published by the Center for American Progress.⁵¹²

This 2010 analysis of 10 SCA agreements in the energy sector (see Box below for overview details) found that a majority of these SCAs grant the industrial sponsor joint control over the alliance's central steering committee, and its final research-selection committee. Eight

of the 10 agreements permitted the corporate sponsor or sponsors to fully control both the evaluation and selection of faculty research proposals in each new grant cycle.⁵¹³ Moreover, none of the SCA contracts required the use of independent academic peer review for reviewing and awarding research grants. Two institutions stated that, in practice, they are in fact using peer review procedures, however these procedures are not secured in their legal contracts. Also, at one of those institutions, the contract states that independent peer review will be used only at the discretion of the industry sponsors. At the other institution, the report's author found that the overwhelming majority of faculty members appointed to sit on the SCA's research-selection committee have either personal financial interests related to biofuels research, or were themselves beneficiaries of the SCA's sponsored researched grants, raising serious questions about the committee's ability to fairly and impartially evaluate other faculty members' research proposals.⁵¹⁴

As a consequence of these shared academic-industry governing structures, SCAs may present special challenges to the university's shared academic governance traditions: What role should shared faculty governance bodies play in the original design and approval of a newly proposed SCA? What role in subsequent oversight? This joint governing structure may also challenge longstanding traditions of independent expert "peer review," and the assumption that all faculty appointments and research should be evaluated on the basis of high quality scholarship and science, not based upon the corporate sponsor's commercial or strategic business objectives. In the case of the U.C. Berkeley-Novartis/Syngenta alliance, an independent review by researchers at Michigan State University concluded that the SCA may have affected one faculty member's tenure review, due to a breakdown of collective faculty confidence in the impartiality of the academic process (this case, involving U.C. Berkeley professor Ignacio Chapela, was discussed earlier in the Introduction).⁵¹⁵

SCAs may also encroach on collective faculty control over academic hiring (if for example new funding for full-time faculty (FTE) appointments are included as part of the SCA, or if corporate employees are offered adjunct faculty positions). When U.C. Berkeley negotiated major SCA deals with Novartis (renamed Syngenta) and later with BP, in both instances the faculty senate grew concerned about perceived attempts to bypass established faculty governance procedures with regards to academic hiring and resource allocation.⁵¹⁶ SCAs may also impact on institutional resource use and allocations (such as lab space, equipment, and graduate students).

In addition, SCAs may present a greater risk of distorting faculty research agendas. Faculty working at institutions with large SCAs may be more inclined to steer their research toward topics and approaches that will be attractive to the SCA sponsor's commercial interests in order to build positive relationships with the sponsor and its employees, to bring funding into their own labs, and/or to ensure the sponsor remains satisfied with the partnership and continues to renew its funding. Some institutions may also end up diverting additional internal funds to the project in order to produce results more quickly, and please the corporate partner.

SCA's may also bias reported research outcomes. As noted in the Introduction, a large body of empirical research has shown that when research is funded by industry sponsors it is far more likely to report outcomes that favor the sponsor's products and interests, compared with non-profit or government-funded research. When a faculty senate committee charged with evaluating SCAs at Cornell University issued its final consensus report, it summarized some of these challenges as follows: "[The SCA] may result in a re-focusing of laboratory space, faculty effort and graduate student research within the department, as well as the need to limit communications between participating and non-participating faculty and graduate students to protect proprietary knowledge, and a stronger-than-usual preference for obtaining positive results in order to secure future funding (as compared, for example, with NIH funding)."⁵¹⁷

Due to these and other pressures, SCAs may also foster, or exacerbate, internal tensions and divisions within the larger university community. Tensions may surface between faculty who operate largely "inside" versus "outside" the SCA due to intellectual property barriers, heightened secrecy, and other issues. The SCA may also exacerbate perceived inequalities between faculty whose research is attractive to commercial sponsors, and faculty whose research is not—despite its possibly high merits in terms of academic value or public good benefits. Genuine intellectual divisions and debates may also arise regarding the university's public purpose and mission, its institutional priorities, and its ability to sustain balanced support for all academic disciplines.⁵¹⁸

Finally, because the SCA often impacts on many researchers, labs, and academic departments at once—and usually requires centralized university governing structures—it tends to formalize and "institutionalize" the university's relationship with one outside corporation. This, in turn, ties the university, as an institution, as well as its public reputation, far more closely with that of the SCA sponsor, raising a host of complicated institutional COI challenges. This

potential for heightened institutional COI has been noted by various analysts, including faculty senate bodies, government legislators, public interest groups, and academic investigators.⁵¹⁹

As discussed in the Introduction, the existence of such an institutional conflicts of interest does not imply any malicious intent or wrongdoing on the part of the university, or the corporate sponsor. In the words of a joint AAU-AAMC report: “An institutional conflict of interest (institutional COI) describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the institution’s core ‘primary interests’ in research, education, clinical care...” In other words, this institutional conflict is situational.

After the 1998-2003 U.C. Berkeley-Novartis SCA concluded, an external review by researchers at Michigan State University highlighted the need to address the growing problem of institutional conflicts: “This case study suggests that the boundaries of current COI policy and codes of conduct are unrealistically narrow in several respects...Given the growing role of the institution in the management of [intellectual property] and economic development, institutional COI policies (or conflicts of mission) need heightened scrutiny.”⁵²⁰ Cornell’s faculty senate committee reached a similar conclusion: In the case of an SCA, “the essential quality of academic independence from the sponsor is more difficult to maintain at an institutional, as well as individual, level...Therefore more formal decisional processes and oversight mechanisms are appropriate as continual self-checking and self-correcting mechanisms.”⁵²¹

The Cornell committee continued: “Academic freedom brings with it the responsibility of disinterested integrity in the conduct of research and the publication of results...Although this responsibility attends all research, sponsored or not, the comprehensiveness and scale of an SCA and the pervasive influence of the corporate partner may make it particularly difficult to maintain the conditions in which faculty are able, and motivated, to fulfill their responsibility.” For these reasons, noted the committee, “more formal decisional processes and oversight mechanisms are appropriate as continual self-checking and self-correcting mechanisms.”⁵²²

Few reliable data or rigorous assessments of SCAs exist. One 2010 analysis⁵²³ of ten SCA agreements in the energy sector found significant variation in their legal contract terms, and few academic protections overall. The study’s major findings are presented in the box, presented in the Introduction on page 33; the study’s methodology is discussed in this endnote.⁵²⁴

The Cornell faculty statement, referenced above, represents one of the few, detailed assessments of SCAs that the AAUP was able to identify. The senate committee that researched and wrote this statement included members from a wide cross section of academic disciplines.⁵²⁵ There were points of disagreement,⁵²⁶ to be sure, however, the committee’s final consensus statement provides a thoughtful, well-developed set of “Principles & Best Practices” to guide the future development of “Strategic Corporate Alliances” on that campus. The AAUP drew upon these recommendations heavily when drafting its own recommendations below.

Due to proprietary considerations and other negotiating challenges, it appears most SCAs are not currently being disclosed to the full faculty until well after they have been largely approved and finalized. Many SCA contracts, at both private and state-funded universities, are never made public at all. Even many state institutions now contend these industry research agreements are “corporate proprietary information,” when public requests are filed under state open record act laws. One researcher reported making 35 requests for university-industry collaboration agreements, including 24 that were filed as formal “public record act” (PRA) requests under applicable state laws. However, state universities failed to fulfill, or outright ignored, more than half of her 24 public record act requests. Often the universities released the documents only after extremely long delays.⁵²⁷ That is why the AAUP urges all faculty senates to develop standards, principles, and procedures to guide the formation of new SCAs on their own campuses, and require these contracts to be public documents, so wherever these alliances originate, they will conform to standards developed by the faculty and protect the university’s core academic values, including its commitment to openness and integrity.

**❖ Principle 36:
Shared Governance and
Strategic Corporate Alliances (SCAs)**

Faculty senates or other comparable governing bodies should be fully involved in the planning, negotiation, approval, execution, and ongoing oversight of new SCAs formed on campus. The faculty’s academic senate or main governing body should appoint a confidential committee to review a first draft of a memorandum of understanding (MOU) pertaining to newly proposed SCAs. All parties’ direct and indirect financial obligations should be made clear from the outset. Before an agreement is finalized on a broad SCA,

a full faculty senate or equivalent governing body should review it. Formal approval of broad SCAs should await both stages in this process. All approved SCA agreements should be made available to all faculty and academic professionals as well as the public. If the SCA designates specific funding for new full-time faculty appointments (FTEs), all normal university and departmental procedures for academic searches and hiring—as well as advancement and promotion decisions—must be followed to honor and protect academic self-governance. Temporary employees should not exclusively staff, administer, or supervise SCAs. Normal grievance procedures, under collective bargaining agreements where they exist, should govern complaints regarding interference with academic freedom or other faculty or academic rights that may arise under SCAs. In the absence of procedures, grievances and complaints should be reported to the SCA faculty oversight committee (see Principle 42 below for more details on this faculty oversight body) or to relevant college or university grievance committees for independent investigation. Standard safeguards regarding procedural fairness and due process must be respected and followed.

- Because large-scale, multiyear, SCA agreements with outside companies tend to have a broader impact on the whole university, due to their size, structure, and potential to influence public perceptions, they warrant far greater faculty involvement in their initial design and subsequent oversight. This faculty oversight also engenders greater campus support and public trust through enhanced transparency. Once again, that level of support and trust cannot be secured unless SCA agreements are made public (as the AAUP recommends under Principle 43 below). No SCA grant should ever be accepted if it is conditioned, explicitly or implicitly, on the sponsor's opportunity to influence the selection of any new faculty hires. To ensure that all permanent faculty are secure, universities should seek to have mechanisms unambiguously in place to cover new SCA faculty salaries from university funds after the SCA contract ends, or in case of premature termination of the grant.

- The AAUP recognizes this principle is not likely to be rapidly applied in schools of medicine (SOMs), where there is tenure of position but not tenure of salary. SOM faculty are often required to generate 100 percent of their salaries from clinical revenue, or research grants, or both. Nonetheless, the creation of such a special group of faculty at the medical schools, who lack true job security and financial autonomy, also warrants serious reflection due to its far-reaching implications, not only for campus standards of fairness, but also for the ability of

faculty to resist pressures to compromise their academic freedom and professional ethics.

- This Principle draws on longstanding AAUP principles, as articulated in the “Statement on Government of Colleges and Universities”²⁸ (1966–67)—endorsed by the American Council on Education (ACE) and the Association of Governing Boards of Universities and Colleges (AGB)—and in the AAUP “Statement on Corporate Funding of Academic Research” (2004). This latter document reads in part as follows: “Consistent with the principles of sound academic governance, the faculty should have a major role not only in formulating the institution’s policy with respect to research undertaken in collaboration with industry, but also in developing the institution’s plan for assessing the effectiveness of the policy.”²⁹

❖ Principle 37: SCA Governance and Majority Academic Control

The best practice in any academic-industrial alliance agreement—consistent with the principles of academic freedom, university autonomy, and faculty self-governance—is to build clear boundaries separating corporate funders from the university’s academic work. However, the current conditions of increasingly close university-industry relations make erecting strict walls unrealistic on some campuses. Instead, at a minimum, universities should retain majority academic control and voting power over internal governing bodies charged with directing or administering SCAs in collaboration with outside corporate sponsors. The SCA’s main governing body should also include members who are not direct stakeholders of the SCA and are based in academic disciplines and units that do not stand to benefit from the SCA in any way. A joint university-industry SCA governing body appropriately may have a role in awarding funding, but it should have no role in exclusively academic functions, such as faculty hiring, curriculum design, course content, and academic personnel evaluation.

- This recommendation reflects core AAUP principles integral to a series of AAUP documents and policy statements, beginning with the historic definition of the faculty’s role in the 1915 “Declaration of Principles on Academic Freedom and Tenure” and following through to “The Role of the Faculty in Budgetary and Salary Matters” (1972, 1990), “On the Relationship of Faculty Governance to Academic Freedom” (1994) and “Statement on Corporate Funding of

Academic Research” (2004).

- It also draws upon Cornell University’s “Faculty Statement of Principles & Best Practices Concerning Strategic Corporate Alliances,” (2005), which reads in part as follows: “Day-To-Day Management of the SCA Should Be Predominantly By Cornell Faculty, Not Corporate Representatives. One fundamental touchstone can never be lost: This is academic research, not corporate research. If there is a Director of the alliance...that Director needs to be a Cornell faculty member. If all management is to be done by the JSC as a committee of the whole, then Cornell representation has to predominate. The corporate sponsor appropriately has a voice in management decisions, but may not have a representative with Co-Director status.”²⁵³⁰

**❖ Principle 38:
Academic Control Over SCA Research Selection
(For Broad SCAs)**

In the case of broad SCAs, university representatives should retain majority representation and voting power on SCA committees charged with evaluating and selecting research proposals or making final research awards. These committees should also employ an independent peer review process (discussed under Principle 39 below).

- This recommendation draws upon Cornell University’s “Faculty Statement of Principles & Best Practices Concerning Strategic Corporate Alliances,” (2005). This statement reads in part as follows: “Selection of Faculty Proposals for Funding Should Not Be Dictated by Corporate Representatives. The distribution of alliance funds to Cornell faculty, staff and students should be primarily in the hands of Cornell, not the sponsor. In keeping with the purposes of the alliance...representatives of the corporate sponsor may participate in the selection of proposals to be funded, but this process should be led by Cornell faculty.”²⁵³¹

**❖ Principle 39:
Peer Review
(For Broad SCAs)**

Using a standard peer-review process, independent academic experts should evaluate and award funding whenever SCAs issue a request for proposals (RFPs) in a new grant cycle. Any expert involved in the peer-review and grant-award process should be free of personal financial COI related to the area of research being reviewed to insure that research selection is scientifically driven, impartial, and fair. Appointees to committees charged with research selection should be prohibited from awarding commercial research funding to themselves, their departments, or their labs.

Discussion:

Peer review has long been considered the most widely accepted standard for evaluating the quality and worthiness of scientific and academic research. When faculty research proposals are evaluated by independent experts using an impartial peer-review process it helps to insure that corporate-research funding is awarded on the basis of both scientific and academic merit, not merely on the basis of one firm's short-term business needs or the narrow strategic goals of one industrial sector.

When a Cornell University faculty senate committee issued consensus recommendations in 2005 for how best to structure large-scale, multi-year SCAs, it emphasized the centrality of independent peer review.⁵³²

Anyone involved in this peer review and SCA grant-awarding processes should be free of personal financial COI, and not be in a position to derive any financial benefit from the agreement or its corporate donors/partners. These are standard procedures at National Institutes of Health, NIH, and other government funding agencies. (As noted already in the overview discussion of SCAs, above, this type of COI surfaced as a significant problem at the BP-funded Energy Biosciences Institute (EBI), administered by U.C. Berkeley, where a majority of the faculty appointed to sit on the EBI's principal research-selection committee were also recipients of BP-EBI research funding.⁵³³ To address this problem, all prospective faculty proposals submitted for possible funding should be evaluated by non-participating faculty who are competent to assess their academic and technical merit.

The AAUP recognizes that peer review, itself, can be an imperfect process. It can, for example, reinforce biases against unconventional research. Also, some conflicts of interest are ideological, or motivated by personal advancement or competitiveness concerns, rather than

explicitly financial. Additionally, heavy institutional involvement in collaborations with industry or government can create a climate in which peer review committees are inclined to overlook problems. As David Michaels points out, the nature of peer review is also widely misunderstood: “Even rigorous peer review by honest scientists does not guarantee a study’s accuracy or quality. Peer review is just one component of a larger quality control process that never ends.”⁵³⁴ Nonetheless, it remains the case that well administered peer review procedures can help to guard against many of the risks outlined in this report.

**❖ Principle 40:
Transparency Regarding the SCA Research Application Process
(This applies to Broad SCAs)**

SCA agreements must clearly and transparently detail the methods and criteria for research selection and must explain how academic researchers may apply for SCA grant funding.

Discussion:

In the case of most Broad SCAs, the host university is clearly responsible for administering and overseeing the research-selection process on behalf of the university-industry alliance as a whole. Due to this grant-application oversight function, it is essential that every SCA spell out transparently in writing, in advance, how faculty may apply for SCA funding and what the methods and criteria for research selection will be. Otherwise, if such procedures are not clearly delineated, in advance, the university could fall prey to accusations that it is putting the commercial and business interests of its corporate sponsors ahead of its commitment to high quality, disinterested, academic research—and such accusations would be difficult to refute.

**❖ Principle 41:
Protection of Publication Rights and Knowledge Sharing
in SCA Agreements***

All the provisions of Principle 3, above, should apply to strategic corporate

alliances as well.

*This Principle is consistent with General Principle 3

Discussion:

Insulating faculty and students from the pressures of self-censorship is very difficult, especially when the SCA sponsor has pledged large amounts of funding over multiple years. As the 2005 Cornell faculty senate committee's review of SCAs observed, "[such] difficulties are multiplied when the faculty member has been working side by side with employees of the corporate partner, who understandably share their employer's interests."⁵³⁵ However, the inclusion of the above listed provisions at least puts faculty, the sponsor, and sponsor employees on notice that publication decisions lie solely in the realm of academic judgment and should be guided by academic and scholarly norms, not by commercial interests.

**❖ Principle 42:
SCA Confidentiality Restrictions**

To protect the university's distinctively "open" academic research environment, restrictions on sharing corporate confidential information and other confidentiality restrictions should be minimized to the maximum extent possible in SCA agreements.

- To achieve this goal sponsors should be discouraged from sharing confidential corporate trade secrets with the academic partners, except when absolutely necessary and, then, only disclosing to the smallest number of academic investigators possible, with strict supervision from the university's legal office, to prevent corruption of the larger "open" academic research environment.

Discussion:

Regarding confidentiality and non-disclosure agreements, the University-Industry Research Collaboration Initiative (a project directed by the Business Higher Education Forum) observed in its final 2001 report: "The ability of faculty researchers to discuss their work with colleagues and

to publish their results is a cornerstone of the academic enterprise and supports the creation of new scientific knowledge. Nothing should be done to put this at risk. At the same time, companies have a legitimate need—and fiduciary responsibility to their shareholders—to protect the value of their investments. Companies recognize that universities are not the best places to try to keep secrets. The challenges and consequences of maintaining confidentiality are particularly acute in the case of students, and universities differ in their ability to manage this process.”⁵³⁶ Of course the most straightforward way to solve this problem is not to do trade-secret related work at universities.

Karen Hersey, then senior counsel for intellectual property at MIT, informed the Research Collaboration that she “is leery of allowing individual faculty members to sign nondisclosure agreements. She prefers the institution to sign, so that the faculty would not have to put personal assets at risk. ‘Researchers should not be encouraged to sign unless they have been made very aware of the risks they are assuming, and unless they understand what it is they are signing,’ she said. ‘These are legal documents and enforceable against the individual. They can also be misused by industry to muzzle individual investigators.’”⁵³⁷ That said, it is far preferable that institutions not sign them either.

❖ Principle 43: SCA Anti-Competitor Agreements

Anti-competitor or noncompete agreements compromise the university’s academic autonomy, its ability to collaborate with other outside firms, and its commitment to knowledge sharing and broad public service. Restrictions in SCA agreements on faculty, academic professionals, postdoctoral fellows, and students interacting with and/or sharing information and research with private-sector competitors of SCA sponsors, or receiving separate research support from outside firms, should be avoided and/or minimized to the greatest extent possible.

- In an SCA agreement, it is reasonable for the university to recognize and seek to protect corporate proprietary and/or confidential information provided by the sponsor, however the scope of this claimed protected material should be clearly defined in advance in writing, and the

transfer of commercial trade secrets and proprietary data from the company should be as limited as possible.

- Any trade secret and anti-compete clauses associated with an SCA agreement should be minimized, and also be subject to careful review and approval by an independent faculty committee (made up of faculty who stand to gain no benefit from the deal) to make sure they are not overly broad and will not unduly interfere with campus-wide research and the university's essential academic mission.

- The AAUP endorses the Cornell Faculty Senate statement on this issue, which reads in part as follows:

Restrictions on Relationships Between Faculty or Students and 'Competitors' of the Corporate Partner Should Be Minimized. Agreeing to restrict faculty or student relationships with 'competitors' of the corporate partner both shrinks the sphere of potential alternative research support and inhibits the public dissemination of knowledge that is a central part of the university's traditional mission. Therefore, such promises should be made only sparingly, and should be very narrowly drawn.⁵³⁸

- Legally justified claims to protect trade secrets or similar proprietary data from competitors can be recognized, but the group of 'competitors' and the scope of the claimed protected material should be clearly identified and defined in advance (at the time the SCA is entered into).

- The Cornell report appropriately warns:

"[I]t is important that commitments in an SCA to 'facilitate' access by the corporate partner to Cornell faculty and students not become the effective equivalent of discouraging such access to the partner's competitors. A properly conceptualized SCA is a collaboration supporting academic research of interest to the corporate sponsor – it is not a joint venture in which a Cornell department/program becomes a remote research facility 'belonging' to the sponsor."⁵³⁹

Formulating an agreement that avoids confidential and trade secret information remains a key way to avoid that result.

**❖ Principle 44:
Exclusive Licensing and SCA Agreements**

All the provisions of Principle 12, above, should apply to strategic corporate alliances as well.

**❖ Principle 45:
Limits on Broader Academic Disruption By SCAs**

Given the size and scope of many SCAs, a vigorous effort must be made to ensure that diverse areas of research (which pursue avenues of inquiry outside the purview of, not in conformity with, or even in opposition to the SCA's research agenda) are not crowded out, and continue to enjoy institutional support, resources, and sufficient financing. SCAs should be approved only if faculty and students within all academic units will, as a practical as well as a theoretical matter, retain the freedom to pursue their chosen research topics. All SCA agreements should strive to limit to the greatest extent possible negative financial, intellectual, or professional impacts on other academic units, colleges, and the university as a whole, as well as on faculty, academic professionals, postdoctoral fellows, and students engaged in research and activities outside the purview of the collaborative SCA arrangement. University policies should clearly affirm that no faculty member, postdoctoral fellow, academic professional, or student will ever be coerced into participating in a sponsored project; all participation will be entirely voluntary.

• This Principle draws from a set of recommendations issued in 2005 by a Cornell faculty senate committee reviewing SCAs, which reads, in part, as follows:

“[C]onstriction of research freedom by the pressure of donor preferences is not unique to SCAs. Unless a gift is unrestricted, sponsored research (public and private) always forces the researcher to choose a project of interest to the sponsor. However, the potential magnitude and comprehensiveness of SCAs substantially enhances the threat. Therefore, the key question is whether the SCA occupies so much of the department's/program's potential research capacity that it crowds out non-conforming research agendas.”⁵⁴⁰

- This statement also draws on an earlier AAUP “Statement on Conflicts of Interest” (1990), which reads in part as follows:

“Faculties should make certain that the pursuit of such joint [research] ventures [whether public or private] does not become an end in itself and so introduce distortions into traditional university understandings and arrangements. Private and public agencies have a direct interest in only a few fields of research and in only certain questions within those fields. Accordingly, external interests should not be allowed to shift the balance of academic priorities in a university without thorough debate about the consequences and without the considered judgment of appropriate faculty bodies. So, too, care must be taken to avoid contravening a commitment to fairness by widening disparities—in teaching loads, student supervision, or budgetary allocation—between departments engage in such outside activity and those not less central to the nature of a university, which have, or can have, no such engagement.”⁵⁴¹

- To address these “research crowding” concerns, the AAUP endorses the following 2005 Cornell faculty senate committee recommendations:

“An SCA should be approved only if faculty within the department/program will, as a practical as well as theoretical matter, retain a sphere of freedom to pursue research topics of their own choosing – either within the SCA or by seeking alternative support for such projects. Factors relevant to this assessment include:

- (a) the proportion of department/program faculty expected to receive all or most of their funding through the SCA;
- (b) the magnitude of any unrestricted funds available within and outside the SCA;
- (c) the proportion of department/program physical, administrative, support, and other resources devoted to SCA projects;
- (d) the narrowness or breadth of the type of projects fundable through the SCA;
- (e) departmental/ program commitments to funding diversity of research beyond the SCA;
- (f) whether the success of the SCA has been identified as one of the strategic goals of the department, thereby putting undue pressure on faculty to take part in it;
- (g) likely effect of the SCA on projects/programs traditionally conducted in the public interest.”⁵⁴²

- Finally, in developing SCA agreements, institutions may want to consider tithing, or other fundraising initiatives, to generate income that will support academic work not supported by the collaborative agreement.

**❖ Principle 46:
Early Termination of SCA Sponsor Funding**

With any large-scale SCA, sponsors may threaten termination of funding or limits on funding, or imply the threat, to pressure researchers in an effort to shape the research agenda or to express displeasure with the way the academic research is trending. To reduce this risk, all SCA legal contracts should include provisions to prohibit sudden, early termination of the agreement. If the negotiating process leads to inclusion of an early-termination option, it must prohibit the sponsor from arbitrarily or suddenly terminating the agreement or lowering pledged funding prior to the expected term, without at least three months advance notification. Salaries and research costs associated with the project must be continued for that period.

**❖ Principle 47:
Independent, Majority-Faculty Oversight of the SCA,
and Post-Agreement Evaluation**

An independent, majority faculty oversight committee consisting of faculty with no direct involvement in the SCA should be established at the start of a new SCA agreement to monitor and at least annually review the SCA and its compliance with university policies and guidelines. A post-agreement evaluation plan should also be included in the formal SCA contract agreement so the campus can reflect on, and learn, best practices regarding the optimal organization for campus-based academic-industrial alliances. External evaluation may be appropriate for broad SCAs. Evaluation reports should be public documents.

- The primary purpose of these independent faculty review committees should be to assess how the SCA is upholding the university's core educational, academic research, and knowledge sharing missions (as articulated in the standards and principles contained in this AAUP statement and other written campus-based policies).

- This committee should also receive and carefully review any grievances by faculty, postdoctoral fellows, students, academic professionals, and outside public interest groups;
- The committee should regularly review and assess financial conflicts of interest (working with the university’s standing COI committees); commercial competition concerns; intellectual property issues; as well as the overall impact of the SCA on faculty, students, and other campus researchers (both inside and outside the collaboration).
- With each review, this faculty committee should propose concrete recommendations for how to reduce and/or eliminate any negative impacts identified.
- Each independent review should be made available to all members of the university community and the public, and should be distributed to all the faculty, research staff, and students working on projects funded by the SCA.
- Finally, after the alliance has terminated, this same faculty committee should perform a final, post-agreement evaluation, summarizing the overall accomplishments of the SCA and any concerns that arose. The results of this final post-agreement evaluation should also be posted on a public website, and distributed to all faculty.
- Credible oversight and transparency will help to ensure that the SCA operates in a manner consistent with the university’s academic mission, while also fostering both public- and campus-wide trust.
- This Principle draws on longstanding AAUP principles, as articulated in the “Statement on Government of Colleges and Universities”⁵⁴³ (1966–67), endorsed by the American Council on Education (ACE) and the Association of Governing Boards of Universities and Colleges (AGB), and the AAUP “Statement on Corporate Funding of Academic Research” (2004). This latter document reads in part as follows: “Consistent with the principles of sound academic governance, the faculty should have a major role not only in formulating the institution’s policy with respect to research undertaken in collaboration with industry, but also in developing the institution’s plan for assessing the effectiveness of the policy.” The statement goes on to state: “The faculty should call for, and participate in, the periodic review of the impact of industrially sponsored research on the education of students, and on the recruitment and evaluation of researchers (whether or not they hold regular faculty appointments) and postdoctoral fellows.”⁵⁴⁴
- It also draws on Cornell University’s “Faculty Statement of Principles & Best Practices Concerning Strategic Corporate Alliances,” (2005), Section E, which states that the faculty,

through its representatives, should have a central role in the approval and the evaluation and oversight of SCAs, with annual external evaluations and broader evaluations as well.⁵⁴⁵

**❖ Principle 48:
Public Disclosure of SCA Research Contracts
and Funding Transparency**

No SCA or other industry-, government-, or nonprofit-sponsored contract should restrict faculty, students, postdoctoral fellows, or academic professionals from freely disclosing their funding source. A signed copy of all final legal research contracts formalizing the SCA agreement should be made freely available to the public—with discrete redactions only to protect valid commercial trade secrets, but not for other reasons.

- Public disclosure is the best way to eliminate any possible suspicion that the SCA sponsor may be unduly influencing the university or its researchers. Full transparency also enhances accountability, helping to ensure that both the SCA sponsor and the university investigators uphold their contractual obligations.
- It is highly unusual for private companies to disclose any corporate proprietary trade secrets in a university-sponsored-research contract, so redactions should not be necessary.
- Due to the university's substantial public funding and public-interest obligations, intellectual property terms should also be considered a matter of public record.

❖
Part VII.

**Targeted Principles:
Clinical Medicine, Clinical Research,
and Industry-Sponsorship (49-56)**

**Why Are Targeted Recommendations for Clinical Medicine
and Clinical Research Needed?**

As the Introduction explains, there has been a high level of concern about financial conflicts of interest and undue industry influence within the field of biomedicine. Numerous professional academic and medical groups (including the Association of American Universities, AAU, 2001; Association of American Medical Colleges, AAMC, 2001, 2002, 2006, 2008, 2010; the Federation of American Societies for Experimental Biology, FASEB, 2006,⁵⁴⁶ 2008⁵⁴⁷) have issued principles and guidelines designed to reign in industry influence and financial conflicts of interest, in both clinical medicine⁵⁴⁸ and clinical research.

In 2002, the American Board of Internal Medicine and more than 100 world-wide medical groups endorsed a new “Charter on Medical Professionalism,”⁵⁴⁹ a comprehensive statement that emphasized both a “Commitment to Scientific Knowledge” and a “Commitment to Maintaining Trust by Managing Conflicts of Interest.” The Charter reads in part as follows:

- “Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence and physician experience.”
- “Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially

when the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.”

In 2006, the AAMC proclaimed it was issuing new, more precise *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*, because current levels of “inconsistency in research standards can affront human research ethics, undermine academic integrity, distort public policy and medical practice, and impair public health.”⁵⁵⁰

Here below, the AAUP has culled from the best of these professional guidelines, and added contributions of its own, to provide a comprehensive set of recommendations to safeguard academic medicine, research integrity, and the interests of patients.

❖ Principle 49: Access to Complete Clinical Trial Data and the Performance of Independent Academic Analysis

All the provisions of Principle 5, above, should apply to clinical trial data as well.

- This AAUP Principle is in keeping with recommendations already issued by the AAMC (2001),⁵⁵¹ FASEB (2006),⁵⁵² the International Committee of Medical Journal Editors, ICMJE (2001),⁵⁵³ and the World Association of Medical Editors, WAME.⁵⁵⁴

Discussion:

Today, it has become common for pharmaceutical companies to assert “proprietary control” over the complete clinical data associated with a particular drug trial (which is often generated from multiple testing sites simultaneously), as well as the corresponding statistical codes required to interpret that data.⁵⁵⁵ Often these companies assert that this data may only be analyzed in-house by company statisticians, and guarded on company computers. One academic physician has dubbed these industry-controlled drug trials “ghost research,” because they effectively permit the sponsor to control both the analysis and final interpretation of all study results, making academic authorship essentially meaningless.

The prevalence of this industry practice is not known, and difficult to quantify. However, reported incidents of industry control over drug trials have been growing.⁵⁵⁶ The clearest evidence of a serious problem came in 2001, when 13 editors of prominent medical journals published an editorial in the *New England Journal of Medicine* expressed their alarm over excessive drug industry influence over study design, data access, and final interpretive analysis. At this time, the editors announced that the International Committee of Medical Journal Editors (ICMJE) would soon be issuing new standards for all journal submissions designed enhance research integrity. The editors wrote:

“A submitted manuscript is the intellectual property of its authors, not the study sponsor. We will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication. We encourage investigators to use the revised ICMJE requirements on publication ethics to guide the negotiation of research contracts. Those [sponsored research] contracts should give the researchers a substantial say in trial design, access to the raw data, responsibility for data analysis and interpretation, and the right to publish — the hallmarks of scholarly independence and, ultimately, academic freedom.”⁵⁵⁷

The ICMJE’s new requirements ask authors to provide full disclosure of the sponsor’s role in the research, and provide assurances that the investigators are independent of the sponsor, are fully accountable for the design and conduct of the trial, have independent access to all trial data, and control all editorial and publication decisions.⁵⁵⁸ However, compliance, of course, is voluntary.

In 2001, the AAMC also issued conflict of interest recommendations targeting these dual problems of data access and data analysis. Like the journal editors, the AAMC specifically cited the need to protect data access and independent analysis of data in legal contracts signed with industry:

“The [conflict of interest] policy should affirm an investigator’s accountability for the integrity of any publication that bears his or her name. The policy should also affirm the right of a principal investigator to receive, analyze, and interpret all data generated in the research, and to publish the results, independent of the outcome of the research. Institutions should not enter, nor permit a covered individual to enter, research agreements that permit a sponsor or other financially interested company to require

more than a reasonable period of pre-publication review, or that interfere with an investigator's access to the data or ability to analyze the data independently."⁵⁵⁹

❖ Principle 50: Registry of Academic-Based Clinical Trials in A National Registry

Universities and affiliated academic medical centers should adopt clear, uniform, written policies to require all clinical trials conducted by their academic investigators to be entered into ClinicalTrials.gov (<http://www.clinicaltrials.gov/>)—the national clinical trial registry maintained by the US National Library of Medicine (NLM) and the National Institutes of Health (NIH)—at, or before, the onset of patient enrollment. The practice will help ward against manipulation of study results, suppression of negative findings, and improper altering of clinical trial protocols after the research has begun.

- The purpose of this AAUP recommendation is to discourage sponsors and researchers from altering clinical trial protocols after the research has begun, when the aim is to manipulate study results and/or suppress negative research findings. This does not, for example, prevent researchers from altering protocol designs when there are valid medical or other reasons for doing so.

- The International Committee of Medical Journal Editors, ICMJE (2005),⁵⁶⁰ the US Congress, FDA (2007),⁵⁶¹ AAMC (2006),⁵⁶² and the IOM have all either endorsed, or mandated, use of publicly accessible online clinical trial registries—such as the www.ClinicalTrials.gov registry⁵⁶³—to protect the integrity of evidence-based medicine (see the discussion below for details).

- It is time for universities and academic medical centers to step up to the plate, and incorporate such registry filings into their own sponsored-research practices and policies.

- The US NLM and the NIH established ClinicalTrials.gov as publicly accessible online registry in 2000 to address the problem that sponsors of drug trials often fail to publicly disclose studies with negative research results, and/or distort final research results when reported in the medical literature. The ClinicalTrials.gov registry requires summary information concerning the

trial's original design, the stage of the clinical trial (i.e. Phase I-IV), criteria for participation, overall outcomes of the study, summary of adverse events experienced by participants, etc.⁵⁶⁴

- However, according to two studies published in 2009, fewer than half of published clinical trials are adequately registered on national registries, suggesting that greater university oversight and faculty compliance is needed.⁵⁶⁵ These studies confirm that selective publication of clinical trial results remains a serious problem. Even among clinical trials that were registered, fewer than half were published in peer-reviewed journals. Still, without a national registry, knowledge of these human clinical trials (as well as critical data on original study design, protocol and endpoint changes, and research suppression would be untraceable.

Discussion:

The purpose of this recommendation is to curb undue industry-sponsor influence over the conduct and reporting of clinical research trials. According to a 2009 IOM panel on COI in biomedicine:

“The registration of clinical trials and the provision of key details about the trial protocol and the data analysis plan ensure that basic methods for the conduct and analysis of the findings of a study as well as the primary clinical end points to be assessed and reported are specified before the trial begins and before data are analyzed. The substitution of ad hoc or secondary end points for primary end points and other important departures from the protocol can thus be detected in reports of the findings of a trial. Clinical trials registries also allow others to determine whether the results from a trial have not been presented or reported at all. Researchers carrying out critical literature reviews can then contact the investigators to try to obtain unpublished results.”⁵⁶⁶

Registry of clinical trials is important not only to safeguard the scientific and evidentiary foundations of medicine, but also to uphold the ethical underpinnings of medicine. As Robert Steinbrook wrote in a 2005 commentary in the *New England Journal of Medicine* concerning industry suppression and distortion of clinical trial results:

“A basic tenet of research ethics is that the data from clinical trials should be fully analyzed and published. If the knowledge gained from trials is not shared, subjects have been exposed to risk needlessly. Moreover, participants in future studies

may be harmed because earlier results were not available. These principles are reflected in federal regulations regarding the protection of human subjects, which define research as ‘a systematic investigation designed to develop or contribute to generalizable knowledge.’⁵⁶⁷

❖ **Principle 51:** **Safeguarding the Integrity and Appropriate Conduct of Clinical Trials**

All clinical trials affiliated with academic institutions should be required to use independent data safety monitoring boards (DSMBs) and/or publication and analysis committees to protect the integrity and appropriate conduct of academic-based clinical trial research.

• This AAUP Principle is consistent with a 2006 recommendation, issued by the Association of Academic of Medical Centers (AAMC) in its “*Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*,”⁵⁶⁸ which asserts that any “multisite clinical trial, at the outset, should establish a publication and analysis committee [hereinafter P&A committee].” This recommendation continues as follows:

“It is essential that the P&A committee be independent of the sponsor’s control, have access to the full data set, understand and implement the prespecified analysis plan, and have the resources and skills both to interpret that analysis and perform additional analysis if required. In order to prevent any appearance of undue influence by the sponsor, the P&A committee should contain a majority of participating, non-sponsor-employed investigators, with appropriate skills in analysis and interpretation of clinical trials. The P&A committee and the steering committee may have the same membership.”⁵⁶⁹

• This recommendation is also consistent with a Food and Drug Administration (FDA) guidance (2001), stating that it is desirable for all Data Safety Monitoring Boards overseeing a clinical trial to have statistical reports prepared by statisticians who are independent of the trial sponsors and clinical investigators.⁵⁷⁰

• Finally, the *Journal of the American Medical Association* (2008) has also pressed for

greater assurances that data has been independently analyzed, by insisting that for all industry-funded clinical trials “in which the data analysis is conducted only by statisticians employed by a company sponsoring the research,” the *Journal* will require that a statistical analysis also be conducted by an independent statistician at an academic institution, such as a medical school, academic medical center, or government research institute, that has oversight over the person conducting the analysis and that is independent of the commercial sponsor.⁵⁷¹

❖ Principle 52: Patient Notification

Neither industry-, government-, nor nonprofit-sponsored research agreements should restrict faculty or academic professionals from notifying patients about health risks and/or lack of treatment efficacy when such information surfaces and patients’ health may be adversely affected.

- Whenever research is performed in connection with a university, an academic medical center, or any of their affiliated teaching hospitals, patients’ rights must be protected and treated as sacrosanct.

- This AAUP Principle stems from recommendations contained in an October 2001 investigative report⁵⁷² commissioned by the Canadian Association of University Teachers (CAUT) concerning a high-profile academic freedom case involving Dr. Nancy Olivieri, a Canadian physician-researcher based at the University of Toronto. Legal provisions in Dr. Olivieri’s corporate-sponsored-research contract sought to prevent her from communicating health risks to the study’s patient volunteers.

- The AAUP endorses the following specific recommendations drawn from The Olivieri Report (2001):

- “[Academic contracts signed with an industry sponsor] should expressly provide that the clinical investigators shall not be prevented by the sponsor (or anyone) from informing participants in the study, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community, of risks to participants that the investigators identify during the research. The same provisions should apply to any risks of a treatment identified following the conclusion of

a trial in the event there are patients being administered the treatment in a non-trial setting.”⁵⁷³

- “Certain circumscribed confidentiality restrictions may be appropriate, for example, those pertaining to information on the chemical structure, or synthesis of a drug, or its method of encapsulation. However, restrictions on disclosure of risks to patients are not appropriate, subject only to the condition that the investigator believes there is a reasonable basis for identification of the risk. Under the term “risk” we include inefficacy of the treatment, as well as direct safety concerns.”⁵⁷⁴

❖ Principle 53: Undue Commercial Marketing Influence and Control at Academic Medical Centers

Educational programs, academic events, and presentations by faculty, students, postdoctoral fellows, and academic professionals must be free of industry marketing influence and control. Both academics and administrators should be prohibited from participating in industry-led “speakers bureaus” financed by the pharmaceutical or other industry groups. Institutions should also develop funding systems for clinical practice guidelines and high-quality accredited continuing medical education (CME) programs free of industry influence.

This recommendation may be broken down into three parts, discussed in further detail below.

- a) Speakers Bureaus
- b) Clinical Practice Guidelines
- c) Continuing Medical Education

Discussion:

The influence of industry marketers has grown rife in three core areas where academic medical faculty play a central role: a) Speakers Bureaus; b) Clinical Practice Guidelines; and c) Continuing Medical Education. Prominent medical associations have already put forward strong corrective recommendations in these three areas, as discussed below. They have done so, first, because undue industry influence over educational programs and faculty presentations

undermines the intellectual integrity of medical research, and erodes public trust in the academic enterprise, and, second, because this type of corporate marketing influence is in many cases illegal.

According to the Institute of Medicine (2009), the U.S. Department of Justice as well as state attorneys general have filed charges against a number of pharmaceutical and medical device companies for illegal practices related to the awarding of educational grants as an inducement to use the company's products (which can be illegal under the Medicare law), as well as industry initiatives to bias the content of educational programs, writings, and presentations, particularly as part of their corporate campaigns to promote the off-label use of drugs (i.e., for purposes not approved by the FDA), which is also illegal.⁵⁷⁵

The IOM referenced several prominent cases, including a \$430 million payment in 2004 by Warner-Lambert to settle U.S. Department of Justice charges that the company promoted off-label uses of the drug Neurontin in violation of the Food, Drug, and Cosmetic Act:

According to DOJ, this illegal and fraudulent promotion scheme corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk.” Tactics included “[paying] doctors to attend so-called ‘consultants meetings’ in which physicians received a fee for attending expensive dinners or conferences during which presentations about off-label uses of Neurontin were made; . . . [and sponsoring] purportedly ‘independent medical education’ events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants...”⁵⁷⁶

The Office of the Inspector General (OIG) at the U.S. Department of Health and Human Services has also identified the provision of educational grants as an activity that places a company at higher risk for violating federal anti-kickback rules and certain FDA regulations.⁵⁷⁷ These compliance guidelines advise manufacturers to separate their [educational] grantmaking activities from their sales and marketing activities to “help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate.”

Principle (53a): Industry-Led Speakers Bureaus

The AAUP recommends that faculty be restricted from participating in industry-led “speakers bureaus,” or other long-term industry-led speaking engagements, whether financed by the pharmaceutical industry or other industry groups.

- It is entirely appropriate for faculty to speak to industry groups and deliver presentations related to their own research and areas of expertise, however when an industry group employs a faculty member to support their own marketing goals by explicitly cultivating speakers (through “speakers bureaus” and other long-term arrangements) who are expected to deliver positive messages regarding their products, this relationship no longer honors academic independence or professional integrity and should be prohibited.

- This AAUP Principle is supported by consensus recommendations put forth by a number of prominent medical groups. Both the Institute of Medicine (2009)⁵⁷⁸ and the Association of American Medical Colleges (2008)⁵⁷⁹ have issued recommendations that strongly discourage faculty from participation industry-led “speakers bureaus.” In 2006, a group of prominent physicians at the Institute on Medicine as a Profession (IMAP) and other academic centers issued a set of detailed recommendations stating that medical faculty should be “prohibited” from involvement in “speakers bureaus.”⁵⁸⁰

- Some leading academic medical institutions (The University of Massachusetts, the Mayo Clinic, Johns Hopkins, Stanford School of Medicine, and the University of Pittsburg Medical Center) have also already instituted policy restrictions, or outright prohibitions, on faculty participation in “speakers’ bureaus”; these should be emulated.⁵⁸¹

Discussion:

Studies suggest academic participation in industry-led “speakers bureaus” is surprisingly high: A 2007 study of 459 medical school department chairs found that 21 percent of clinical chairs had ongoing corporate speaking relationships, often referred to as “speakers bureaus.”⁵⁸² This suggests that pharmaceutical firms may target higher-level faculty—often referred to in the industry as “key opinion leaders.” This apparent industry preference for recruiting senior faculty

raises institutional conflict of interest concerns for the university, and other concerns as well. According to the IOM (2009), “One concern is that ongoing company payments for presentations (and travel to attractive locations) create a risk of undue influence. A second concern that is frequently tied to the speakers bureau label is that the company exerts substantial control over the content of a presentation. Industry influence in these arrangements may be direct (e.g., when a talk and slides are largely or entirely prepared by someone else or when speakers are instructed to provide the company-prepared responses to questions and avoid the favorable mention of competing products). Influence may also be less direct (e.g., when a company-trained and company-paid physician modifies talks to fit the objectives of the company).”⁵⁸³

Principle (53b): Clinical Practice Guidelines

The AAUP endorses the following recommendations on Clinical Practice Guidelines issued by Institute of Medicine in 2009. These recommendations read as follows:

- Groups that develop clinical practice guidelines should generally exclude as panel members individuals with conflicts of interest and should not accept direct funding for clinical practice guideline development from medical product companies or company foundations.
- Groups should publicly disclose with each guideline their conflict of interest policies and procedures and the sources and amounts of indirect or direct funding received for development of the guideline.
- In the exceptional situation in which avoidance of panel members with conflicts of interest is impossible because of the critical need for their expertise, then groups should:
 - a.) publicly document that they made a good-faith effort to find experts without conflicts of interest by issuing a public call for members and other recruitment measures;
 - b.) appoint a chair without a conflict of interest;
 - c.) limit members with conflicting interests to a distinct minority of the panel;
 - d.) exclude individuals who have a fiduciary or promotional relationship with a company that makes a product that may be affected by the guidelines;
 - e.) exclude panel members with conflicts from deliberating, drafting, or voting on specific

recommendations; and

f.) publicly disclose the relevant conflicts of interest of panel members.⁵⁸⁴

Discussion: The IOM panel's 2009 conflict of interest report offers the following explanation for its recommendation:

“Given the important role that clinical practice guidelines play in many aspects of health care, it is important that these guidelines be free of industry influence and be viewed by clinicians, policy makers, patients, and others as objective and trustworthy... On the basis of its judgment and experience (including experience with conflicting guidelines and guidelines not based on formal reviews of the evidence), the committee believes that the risk of undue industry influence on clinical practice guidelines is significant, and that risk justifies that strong steps be taken to strengthen conflict of interest policies governing the development of guidelines.”⁵⁸⁵

Studies have found the process for developing Clinical Practice Guidelines, used to guide the practice of medicine, is rife with financial COI. One 2002 study by Choudhry et al. found that authors of practice guidelines had widespread financial relationships with the pharmaceutical industry, but of the 44 practice guidelines reviewed, only two included disclosures of the authors' financial relationships. A follow-up survey of 100 authors involved with the development of 37 of these guidelines found that 87 percent of the authors had some financial relationship or interaction with industry, and that 59 percent had relationships with companies whose products were considered in the actual guideline.⁵⁸⁶

According to the IOM, several important case studies have also uncovered pervasive financial COI related to specific clinical guideline development programs. For example, in one case from 2006, “14 of 16 members of a group that worked on the development of guidelines for the treatment of anemia in patients with chronic kidney disease received consultant fees, speaking fees, research funds, or some combination thereof from at least one company that could be affected by the guidelines.⁵⁸⁷ The principal funder of the guidelines was a company that would be affected by the guidelines, and the chair and co-chair of the work group had financial relationships with that company.⁵⁸⁸ The development group recommended that the dosage of a drug made by the company be raised, which could have

substantially increased costs to the Medicare program. By coincidence, the guidelines were announced at the same time that research showing adverse patient outcomes associated with the approach recommended by the guidelines was published. The lead investigator of the research allegedly informed the guideline development work group that the study in question had been terminated early, according to the IOM, and he advised that they wait for the results before issuing the new guidelines. The group, however, chose not to wait.”⁵⁸⁹

In another case, Amgen, the manufacturer of epoetin, a drug that increases hemoglobin levels, was the founding and primary sponsor of the Kidney and Dialysis Outcomes Quality Initiative carried out by the National Kidney Foundation.⁵⁹⁰ This project issued practice guidelines recommending an increase in the target hemoglobin level for patients with chronic kidney disease, which would entail the use of higher doses of epoetin and increased sales of the sponsor’s product.

Principle (53c): Continuing Medical Education, (CME)

The AAUP endorses the following recommendation issued by the IOM, in 2009, which calls for “a broad-based consensus process to develop a new system for funding high-quality accredited continuing medical education that is free of industry influence.”⁵⁹¹

- The AAUP encourages all U.S. universities, academic medical centers, and their faculty to develop new policies that preclude faculty from participating in Continuing Medical Education (CME) programs paid for and influenced by industry. Universities and their medical faculty bear significant responsibility for content and quality of this nation’s CME programs, which all medical school graduates are required to take, throughout their careers, to keep their medical licenses and their medical knowledge up to date.

- In the past, the fees paid by attendees covered the majority of the costs associated with the operation of these CME programs. Today, according to the Accreditation Council for Continuing Medical Education, roughly half of all funding for accredited continuing education programs comes from commercial sources.⁵⁹² (Although these programs are frequently administered by professional societies, academic medical schools also sponsor CME programs,

and academic faculty members are extensively involved in all CME content development and instruction.)

- According to Congressional testimony by Eric Campbell, a member of the 2009 IOM panel that issued the above recommendation on CME: “The members of the IOM generally agreed that accredited continuing medical education has become far too reliant on industry funding and that such support tends to promote a narrow focus on medical products and a neglect of broader education on alternative strategies for preventing and managing health conditions and other important issues...”⁵⁹³

Discussion:

Some institutions have already successfully limited their reliance on industry funding to pay for Continuing Medical Education (CME) programs. In 2008, for example, Stanford University School of Medicine announced that it would no longer accept direct industry funding for specific accredited CME courses either on or off campus, nor would it accept payments from third parties that have received commercial support.⁵⁹⁴ Industry support is, however, permitted, provided it is not designated to a specific subject, course, or program and is provided through a central university office for continuing medical education.

According to the IOM, Memorial Sloan-Kettering Cancer Center went still further: In 2007, it “announced a 6-month trial period during which it would no longer accept industry funding for its continuing medical education programs (industry provided about 25 percent of total funding for continuing medical education at that institution). To reduce costs, off-site programs were moved on-site, free lunches were eliminated, advertising was cut, and fewer external speakers were used. Although the fees for external participants were raised by 10 to 20 percent, program attendance stayed the same. The ban on industry funding is now permanent.”⁵⁹⁵ The rationale for a permanent ban is clear: you cannot take the money without taking on the bias along with it.

❖ Principle 54:
**Appropriate Use of Facilities and Classrooms at Universities
and Academic Medical Centers**

Universities, academic medical schools, and affiliated teaching hospitals should have clear and consistent policies and practices barring pharmaceutical, medical device, and biotechnology companies from distributing free meals, gifts, or drug samples on campus and at affiliated academic medical centers, except under the control of central administration offices for use by patients who lack access to medications. As a general principle, academic facilities and classrooms should not be used as for commercial marketing and promotion purposes, unless advance written permission from academic institutional authorities has been explicitly granted, with academic supervision required. (Commercial marketing of services would, for example, be appropriate at a job fair.) Campus policies should also prohibit marketing representatives from making unauthorized site visits. Finally, faculty, physicians, trainees, and students should be prohibited from directly accepting travel funds from industry, other than for legitimate reimbursement of contractual academic services. Direct industry travel funding for marketing junkets, trips to luxury resorts, and expensive dinners should be prohibited.

- This AAUP principle is consistent with recommendations issued already by prominent medical groups, including the Institute of Medicine (2009)⁵⁹⁶, AAMC (2008),⁵⁹⁷ Institute on Medicine as a Profession (IMAP) and the American Board of Internal Medicine (ABIM) Foundation (2006).⁵⁹⁸

- Many physicians sincerely believe industry payments and free gifts do not affect their clinical behavior, however a large body of empirical social science and neurobiological research,⁵⁹⁹ reviewed in the Introduction to this report, indicates that individuals often cannot accurately assess their own bias. Studies show that gifts, even ones of small value, create reciprocal expectations and behaviors.

- According to a 2000 review of this research, published in the *Journal of the American Medical Association*,⁶⁰⁰ some of the negative effects associated with industry/physician marketing and financial relationships include:

- Reduced generic prescribing (leading to higher drug expenditures)

- Increased overall prescription rates
- Quick uptake of the newest, most expensive drugs including those of only marginal benefit over existing options with established safety records
- Formulary request for drugs with few if any advantages over existing drugs
- Residents and physicians alike admit that without gifts and meals, their interaction with the industry would decline.

The AAUP endorses the following specific recommendations (with some modifications)* issued by the AAMC in 2008.⁶⁰¹ These cover four areas:

- (a) Industry Distribution of Free Gifts, Meals, and Drug Samples
- (b) Marketing by Pharmaceutical Companies
- (c) Marketing by Device Manufacturers
- (d) Industry-Funded Professional Travel

*Since the AAUP believes all universities, medical schools, and their affiliated teaching hospitals should have consistent policies, we endorse this language *with the additional proviso that these written policies should be adopted across the whole institution.*

Principle (54a): Industry Distribution of Free Gifts, Meals, and Drug Samples

Industry Gifts to Individuals

Recommendation:

- Academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on-site or off-site. Such standards should encompass gifts from equipment and service providers as well as pharmaceutical and device providers.

Food

Recommendations:

- With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies that industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers.
- Policies should make clear that the same standard of behavior should be met off-site.

Pharmaceutical Samples

Recommendations:

- The distribution of medications in academic medical centers, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.
- If central management is not thought to be feasible, or would interfere with patient access to optimal therapeutics, the academic medical center should carefully consider whether or not there are alternative ways to manage pharmaceutical sample distribution that do not carry the risks to professionalism with which current practices are associated.⁶⁰²

Discussion:

Both the AAMC (2008) and the IOM (2009) have called stringent restrictions on corporate marketing of free meals, gifts, and drug samples at academic medical centers, because of extensive research (discussed in the Introduction to this report) showing that these gifts, often subconsciously, bias physician's medical decisions. On-site commercial marketing has grown pervasive at many academic medical schools and their affiliated teaching hospitals, where pharmaceutical, medical device, and biotechnology companies now routinely distribute "gifts," in the form of marketing pens, pads, mugs, free meals, and drug samples to both physicians and trainees.

The IOM panel on COI in biomedicine appropriately noted, in its 2009 report, that such restrictions are not intended, and should in no way discourage, "appropriate and productive research collaborations between industry and academic researchers. In addition to promoting

scientific progress and the development of useful products, academic-industry collaborations can provide educational benefits to medical students, graduate students, and postdoctoral fellows who are engaged in legitimate collaborative research projects with industry partners under appropriate supervision.”⁶⁰³ However, the AAUP wholeheartedly agrees with the IOM, AAMC, IMAP, ABIM, and others, who have weighed in on this issue, that such pervasive industry marketing and gift giving must cease to ensure that both the practice of medicine and teaching are free of (often subconscious) industry influence and bias.

Principle (54b): Marketing by Pharmaceutical Representatives

The AAUP endorses the following recommendations issued by the AAMC (2008):⁶⁰⁴

Site Access by Pharmaceutical Representatives

Recommendations:

- To protect patients, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians should be restricted to nonpatient care areas and nonpublic areas and should take place only by appointment or invitation of the physician.
- Involvement of students and trainees in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.
- Academic medical centers should develop mechanisms whereby industry representatives who wish to provide educational information on their products may do so by invitation in faculty-supervised structured group settings that provide the opportunity for interaction and critical evaluation. Highly trained industry representatives with M.D., Ph.D., or Pharm.D. degrees would be best suited for transmitting such scientific information in these settings.

Principle (54c): Marketing by Medical Device Companies

The AAUP endorses the following language from the AAMC:⁶⁰⁵

Site Access by Device Manufacturer Representatives

Recommendations:

- Access by device manufacturer representatives to patient care areas should be permitted by academic medical centers only when the representatives are appropriately credentialed by the center and should take place only by appointment or invitation of the physician.
- Representatives should not be allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patient, and then only to provide in-service training or assistance on devices and equipment.
- Student interaction with representatives should occur only for educational purposes under faculty supervision.

Principle (54d): Industry-Funded Travel Expenses

The AAUP endorses the following recommendations issued by the AAMC (2008):⁶⁰⁶

Industry-Funded Professional Travel

Recommendation:

- Academic medical centers should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services as described above.

**❖ Principle 55:
Marketing Projects That Masquerade as “Clinical Research”**

Faculty, students, postdoctoral fellows, and academic professionals based at academic-affiliated institutions must not participate in marketing projects that masquerade as scientifically driven clinical trial research. When pharmaceutical firms fund these thinly disguised marketing studies, they are often referred to as “seeding trials,” because they are designed primarily to expose doctors and patients to newer, brand name drugs.

- University and academic medical center policies should explicitly prohibit faculty, and any other of its academic researchers, from accepting industry-sponsored clinical research trials that have little or no objective scientific value, or academic merit, except to facilitate the marketing goals of the industry sponsor. Such a study could take the form of an industry-funded “seeding trial,”⁶⁰⁷ where the sponsor’s principle motivation is to change the prescribing habits of participating physicians, or expose the physician to a new medical intervention, not to gather scientifically valid information.⁶⁰⁸ Or could also take the form of a clinical trial protocol that is riddled with study design biases that are intended to enhance the likelihood of research outcomes that will favor the sponsor’s product.

- Prominent academic medical journal editors and others, including former U.S. Food and Drug Administration commissioner David Aaron Kessler, have written critically of such industry marketing efforts and urged academic institutions to refuse this type of pseudo research.⁶⁰⁹

**❖ Principle 56:
Predetermined Research Results**

Faculty and other academic investigators should be prohibited from soliciting research funding from outside sponsors with the implied suggestion or promise of predetermined research results.

- Promising a prospective sponsor positive research results, before a study has begun, is both unethical and scientifically unsound. It should be explicitly prohibited in a university’s

written codes of conduct, and whenever identified and proven to have occurred such practices should be vigorously punished.

Discussion:

Ethical research, especially research that involves human subjects, requires doubt about the outcome; this is known as equipoise. It is unethical to use human beings for commercially motivated trials whose findings are predetermined or manipulated to come to predetermined conclusions. Following litigation, several cases have come to light—at Harvard (medicine)⁶¹⁰ and UCLA (tobacco),⁶¹¹ for example—where university professors pitched research studies to potential corporate sponsors by explicitly suggesting that predetermined research outcomes would favor the corporate sponsors’ products and/or commercial interests. Such practices should be strictly forbidden, with appropriate review procedures, sanctions, and punishment specified for non-compliance.

ENDNOTES

¹ American Association of University Professors (AAUP), *Policy Documents and Reports*, 10th ed. (Washington, DC: AAUP; Baltimore: Johns Hopkins University Press, 2006), 297.

² *Ibid.*, 130.

³ *Ibid.*, 185.

⁴ *Ibid.*, 184.

⁵ *Ibid.*, 139.

⁶ *Ibid.*, 143.

⁷ *Ibid.*, AAUP, p. 296.

⁸ The University-Industry Demonstration Project (UIDP) describes itself as an organization of universities and companies “committed to increasing the number and breadth of university-industry collaborative partnerships in the US.” The UIDP states that it is a project of the National Academies, carried out in association with the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine (IOM), although its recommendations are far less comprehensive and strong than the 2009 IOM recommendations related to conflicts of interest in health research, cited frequently in this AAUP report. In addition to issuing several university-industry guidelines, including “Guiding Principles for University-Industry Endeavors” and “Contract Accords for University Industry Sponsored Agreements,” UIDP has put out a software program, called TurboNegotiator, which it says can be used to streamline industry-academy contract negotiations and “reach consensus regarding critical business elements in these agreements, such as intellectual property, indemnification and publication rights.” The UIDP’s Contract Accords pamphlet admirably lays out the fundamental purposes of university research, and it contains good advice about how to work collaboratively with industry. However, in the AAUP’s view, it does not offer guidelines sufficient to protect the distinctive campus “open research environments” it endorses. In what follows, we note agreements and disagreements the AAUP has with the work UIDP has done. *Conflicts of Interest*: The “Contract Accords” statement lists among its principles that “conflicts of interest, real and potential, should be reduced, eliminated, or managed in accordance with university policy and disclosed to the sponsor” (8), but it fails to address our primary concern: conflicts of interest that arise directly from the relationship with the sponsor, which must be disclosed, not only to the sponsor, but to other outside parties as well, including members of the scientific community, journal editors, and the broader public. *Publication*: The “Contract Accords” properly declares that “[publication] delays shouldn’t be allowed to jeopardize academic progress of students” (11). It also points out that “publication of research results in a timely and appropriate manner can be beneficial to opening markets and expanding product options” (12). It further notes, “Research conducted by tax-exempt organizations must be performed in the public interest and is expected to lead to information that is published and available to the interested public” (11). It thus concludes that “universities need to be free to publish, present, or otherwise disclose results in a timely manner following review by sponsors,” properly suggesting that “the time of publication delay must be specified and specific.” However, glaringly absent from the Contract Accords document are any suggested limits to the publication delays that can be negotiated, or any acknowledgement that this “review by sponsors” should be authorized only to protect commercial trade secrets, not to alter or edit reported academic research findings.

⁹ Association of American Universities (AAU), Task Force on Research and Accountability, *Report on Individual and Institutional Financial Conflict of Interest*, October 2001.

¹⁰ Academic freedom does not embody a principle comparable to the one the US Supreme Court articulated in *Buckley v. Valeo* (1976), in which it ruled that spending money to influence elections is a form of constitutionally protected speech. The ability of universities to set standards for academic research and for the approval of outside funding would be decisively compromised if higher education adopted the notion that the simple availability of outside funding necessarily carries with it the right to spend it in the institution’s name. If the power of industry money were to become absolute in academic research, it would also carry the risk that given areas of research could be overwhelmed by resources that competing research agendas and hypotheses could not match. Academic freedom and research integrity would suffer as a result.

¹¹ “An Issue of Academic Freedom in Refusing Outside Funding for Faculty Research,” *Academe*, September–October 1992, 49.

¹² AAUP, “Academic Freedom and Rejection of Research Funds from Tobacco Corporations,” a section of the *2002–03 Committee A Report*, available online at <http://www.aaup.org/AAUP/comm/rep/A/2002-03Comm-A-report.htm>. This 2003 wording is slightly revised from “An Issue of Academic Freedom in Refusing Outside Funding for Faculty Research,” 49.

¹³ AAUP, “Academic Freedom and Rejection of Research Funds from Tobacco Corporations.”

¹⁴ See the website of the World Health Organization (WHO), Framework Convention on Tobacco Control’ (<http://www.who.int/fctc/en>), for a 2010 history of the framework’s adoption, the text of the framework itself, and a list of the nations that have signed. The quote about “vested interests” is taken from Article 5.3 of the framework, available at http://who.int/fctc/protocol/guidelines/adopted/article_5_3/en/index.html.

¹⁵ National Institutes of Health, National Institute on Drug Abuse, “Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants,” available at <http://www2.drugabuse.gov/about/organization/nacda/points-to-consider.html>.

¹⁶ The full final ruling from the US District Court for the District of Columbia in this case, *US Department of Justice v. Philip Morris USA Inc. et al.*, dated September 8, 2006, is available online at <http://www.justice.gov/civil/cases/tobacco2/amended%20opinion.pdf>.

¹⁷ National Institutes of Health, National Institute on Drug Abuse, “Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants.”

¹⁸ *Ibid.*

¹⁹ For one example, see George F. DeMartino, *The Economist’s Oath: On the Need for and Content of Professional Economic Ethics* (New York: Oxford University Press, 2011). DeMartino argues: “Over the long sweep of its history, the American economics profession has been far more ambitious about achieving influence than it has been attentive to the harm that it might do or the ethical questions that might arise were it to achieve the influence it sought” (227). He also observes that “absent careful thinking by the profession, it is not clear that well-meaning economists will recognize when the circumstances in which they find themselves represent a conflict of interest or know what to do about it when they do recognize apparent or real conflicts . . . Conflicts of interest can bleed into outright corruption” (135).

²⁰ “Universities are increasingly subsidizing grants from their own funds (see [paragraph] ‘Footing the US research bill’). Between 1969 and 2009, the proportion of research funding supported by institutional money rose from 10% to 20%, according to the US National Science Foundation. Public universities and all but the wealthiest private ones are increasingly taking that money from tuition fees.” Eugenie Samuel Reich, “Thrift in Store for US Research,” *Nature* 476 (25 August 2011): 385, available at <http://www.nature.com/news/2011/110824/full/476385a.html>.

²¹ See the two-year study of academic-industry partnerships *Working Together, Creating Knowledge: The University-Industry Research Collaboration Initiative* (Washington, DC: Business–Higher Education Forum, 2001), 11, available at <http://www.acenet.edu/bookstore/pdf/working-together.pdf>.

²² N. Rosenberg and R. R. Nelson, “American Universities and Technical Advance in Industry,” *Research Policy* 23 (1994): 323–48; R. Mazzoleni and R. Nelson, “The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate,” *Research Policy* 27 (1998): 274–84; D. C. Mowery and N. Rosenberg, “The U.S. National Innovation System,” in *National Innovation Systems: A Comparative Analysis*, ed. R. R. Nelson (New York: Oxford University Press, 1993); D. C. Mowery and T. Simcoe, “The Origins and Evolution of the Internet,” in *Technological Innovation and National Economic Performance*, ed. D. Victor, B. Steil, and R. R. Nelson (Princeton, NJ: Princeton University Press, 2012).

²³ In 2006, to cite but one example of nondisclosure of financial interests, a scandal erupted in the pages of the *Wall Street Journal* over a *Journal of the American Medical Association* publication that investigated the pros and cons of antidepressant withdrawal during pregnancy. The paper failed to disclose that the investigators had sixty financial relationships to pharmaceutical companies, and most authors were paid consultants to the makers of antidepressants. “Financial Ties to Industry Cloud Major Depression Study, At Issue: Whether It’s Safe for Pregnant Women to Stay on Medication—JAMA Asks Authors to Explain,” *Wall Street Journal*, July 11, 2006.

²⁴ Center for Science in the Public Interest, “Animal Ag Report Encounters Industry Interference,” *Integrity in Science Watch*, May 5, 2008, available online at <http://www.cspinet.org/integrity/watch/200805051.html#3>. Rick Weiss, “Report Targets Costs of Factory Farming,” *Washington Post*, April 30, 2008. The report is Pew Commission on Industrial Farm Animal Production, *Putting Meat on the Table: Industrial Farm Production in America* (Baltimore: Pew Charitable Trusts and Johns Hopkins Bloomberg School of Public Health, 2008), available at <http://www.ncifap.org/bin/e/j/PCIFAPFin.pdf>.

²⁵ Joseph S. Ross, Kevin P. Hill, D. S. Egilman, and H. M. Krumholz, “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib,” *Journal of the American Medical Association* 299.15 (2008): 1800–1812. See also US Senate Committee on Finance (Sen. Charles E. Grassley, ranking member), *Ghostwriting in Medical Literature*, Minority Staff Report, 111th Congress, June 24, 2010; and J. R. Lacasse and J. Leo, “Ghostwriting at Elite Academic Medical Centers in the United States,” *PLoS Medicine* 7.2 (2010): e1000230, available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000230>.

²⁶ Dan Berrett, “Not Just Florida State,” *Inside Higher Ed.com*, June 28, 2011; Kris Hundley, “Billionaire’s Role in Hiring Decisions at Florida State University Raises Questions,” *St. Petersburg Times*, May 10, 2011.

²⁷ For example, the tobacco industry created several organizations, including the Council for Tobacco Research and the Center for Indoor Air Research. These were presented to the public as independent scientific organizations governed by principles of peer review when, in fact, they were covertly managed by cigarette company executives and lawyers to serve political, legal, and public relations purposes. This “myth of independent science” was a key element of a federal court ruling finding that the companies had constituted an illegal “racketeering enterprise” for the purpose of defrauding the American public under the Racketeer Corrupt Influenced Organizations (RICO) Act. The full RICO ruling, a seventeen-hundred-page document by District Court Judge Gladys Kessler, is available at <http://www.justice.gov/civil/cases/tobacco2/amended%20opinion.pdf>.

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- ²⁸ Matthew Keenan, "CEOs Pushing Ayn Rand Studies Use Money to Overcome Resistance," *Bloomberg.net*, April 11, 2008, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=as6BR0QV4KE8>.
- ²⁹ Anne Marie Chaker, "Companies Design, Fund Curricula at Universities," *Wall Street Journal*, September 11, 2006.
- ³⁰ Institute of Medicine (IOM), *Conflict of Interest in Medical Research, Education, and Practice*, ed. Bernard Lo and Marilyn J. Field (Washington, DC: National Academies Press, 2009) [Hereafter IOM report (2009)], 189–215, chap. 7: "Conflicts of Interest and Development of Clinical Practice Guidelines."
- ³¹ M. Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (London: Random House, 2005); D. Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton, NJ: Princeton University Press, 2000); D. S. Greenberg, *Science for Sale: The Perils, Rewards, and Delusions of Campus Capitalism* (Chicago: University of Chicago Press, 2007); J. Kassirer, *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health* (New York: Oxford University Press, 2004); S. Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Lanham, MD: Rowman and Littlefield, 2003); D. Michaels, *Doubt Is Their Product* (New York: Oxford University Press, 2008); T. O. McGarity and W. E. Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* (Cambridge, MA: Harvard University Press, 2008); J. Washburn, *University Inc.: The Corporate Corruption of Higher Education* (New York: Basic Books, 2005).
- ³² Bronwyn H. Hall, "University-Industry Research Partnerships in the United States." An earlier version of this essay was presented at the Sixth International Conference on Technology Policy and Innovation, Kansai, Japan, August 2002, and is available at http://elsa.berkeley.edu/~bhhall/papers/BHH04_Kansai.pdf. See Table 1.
- ³³ There is some variation here between the amounts received by private and public institutions. According to the National Science Foundation, "In FY 2008, the federal government provided 72% of the R&D funds spent by private institutions, compared with 55% for public institutions. Conversely, public institutions received approximately 9% of their \$35.3 billion in R&D expenditures from state and local governments, compared with 2% of private institutions' \$16.6 billion." National Science Board, "Academic Research and Development," chap. 5 of *Science and Engineering Indicators* (Arlington, VA: National Science Foundation, 2010), available at <http://www.nsf.gov/statistics/seind10/c5/c5h.htm>.
- ³⁴ *Ibid.*: "Industrial support accounts for the smallest share of academic R&D funding (6%), and support of academia has never been a major component of industry-funded R&D. After a three-year decline between 2001 and 2004, industry funding of academic R&D increased for the fourth year in a row, to \$2.9 billion in FY 2008. (See appendix table 4-5 for time-series data on industry-reported R&D funding.)"
- ³⁵ National Center for Science and Engineering Statistics, "Detailed Statistical Tables NSF 11-313," in *Academic Research and Development Expenditures: Fiscal Year 2009* (Arlington, VA: National Science Foundation, 2011), available at <http://www.nsf.gov/statistics/nsf11313/>.
- ³⁶ Quoted in IOM report (2009), 101. J. L. Read and P. M. Campbell, "Health Care Innovation: A Progress Report," *Health Affairs* 7.3 (1988): 174–85; J. L. Read and K. B. Lee Jr., "Health Care Innovation: Progress Report and Focus on Biotechnology," *Health Affairs* 13.3 (1994): 215–25.
- ³⁷ Quoted in IOM report (2009), 101. H. Moses, E. R. Dorsey, D. H. Matheson, and S. O. Thier, "Financial Anatomy of Biomedical Research," *Journal of the American Medical Association* 294.11 (2005): 1333–42; L. A. Hampson, J. E. Bekelman, and C. Gross, "Empirical Data on Conflicts of Interest," in *The Oxford Textbook of Clinical Research Ethics*, ed. E. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, and D. Wendler (New York: Oxford University Press, 2008).
- ³⁸ National Science Board, "Academic Research and Development."
- ³⁹ E. G. Campbell, J. S. Weissman, S. Ehringhaus, S. R. Rao, B. Moy, S. Feibelmann, and Susan Dorr Goold, "Institutional Academic-Industry Relationships," *Journal of the American Medical Association* 298.15 (2007): 1779–86.
- ⁴⁰ Campbell Zinner, "Participation of Academic Scientists in Relationships with Industry," *Health Affairs* 28.6 (November–December 2009): 1820. Among those in clinical departments, the percentage decreased from 36% to 23%; in nonclinical departments the percentage decreased from 21% to 9%.
- ⁴¹ David Mowery, Richard Nelson, B. N. Sampat, and A. A. Ziedonis, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer before and after the Bayh-Dole Act* (Stanford, CA: Stanford Business Books, 2004).
- ⁴² Gerald Epstein Jessica Carrick-Hagenbarth, "Financial Economists, Financial Interests and Dark Corners of the Meltdown: It's Time to Set Ethical Standards for the Economics Profession," Working Paper Series, No. 239 (Amherst, MA: Political Economy Research Institute, November 2010), available at http://www.peri.umass.edu/fileadmin/pdf/working_papers/working_papers_201-250/WP239_revised.pdf.
- ⁴³ Patent and Trademark Amendments of 1980 (P.L. 96-517), known as the Bayh-Dole Act.
- ⁴⁴ Economic Recovery Tax Act of 1981 (1981 ERTA, §221(d)); Tax Reform Act of 1986 (1986 TRA, §231(a)). The Economic Recovery Tax Act of 1981 (P.L. 97-34) provides a 25% tax credit for 65% of private investments in universities for basic research. This tax credit substantially reduces the cost of industrial R&D; IOM report (2009), 36.
- ⁴⁵ The widespread perception in the 1980s that US technological leadership was slipping led policymakers to conclude that existing US antitrust laws and penalties were too restrictive and were possibly impeding the ability of US companies to compete in global markets. The passage of the National Cooperative Research Act (NCRA) in 1984 encouraged US firms to collaborate on generic, precompetitive research. To gain protection from antitrust litigation, NCRA required firms

engaging in research joint ventures to register them with the US Department of Justice. By the end of 1996 more than 665 research joint ventures had been registered. In 1993, Congress again relaxed restrictions—this time on cooperative production activities—by passing the National Cooperative Research and Production Act, which enables participants to work together to apply technologies developed by their research joint ventures. SEMATECH has perhaps been the most significant private R&D consortium formed since the US Congress passed the National Cooperative Research Act of 1984. See A. L. Link, “Research Joint Ventures: Patterns from Federal Register Filings,” *Review of Industrial Organization* 11.5 (October 1996): 617–28.

⁴⁶ This section draws from written comments from Gerald Barnett, Ph.D., Director, Research Technology Enterprise Initiative, to the American Association of University Professors (AAUP), April 30, 2012: “Under Bayh-Dole’s primary standard patent rights clause, the university contractor is to designate personnel responsible for the administration of patent matters (37 CFR 401.14(a)(f)(2)). The primary duties of those personnel under the standard patent rights clause are very limited: receive reports of invention, send those reports on to the federal sponsors, and notify the federal sponsors if the university obtains title to a federally supported invention and elects to retain that title. These and other duties are essentially paperwork notifications” (Title 37, “Patents, Trademarks, and Copyrights,” Chapter IV, Part 401, Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements,” Government Printing Office, available at <http://www.gpo.gov/fdsys/pkg/CFR-2002-title37-vol1/content-detail.html>)

⁴⁷ The complete US Supreme Court decision in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems* (2011) is available at <http://www.supremecourt.gov/opinions/10pdf/09-1159.pdf>.

⁴⁸ Kathi Wescott, “Faculty Ownership of Research Affirmed,” *Academe*, September–October 2011, available at <http://www.aaup.org/AAUP/pubsres/academe/2011/SO/nb/patentlaw.htm>.

⁴⁹ See Matt Jones, “Supreme Court Rules for Roche, Clarifies Bayh-Dole,” *GenomeWeb Daily News* (June 6, 2011): “The most likely effect of the ruling will be that universities will begin making sure that their employees sign assignment agreements that make it clear if they expect to own the rights to the patents their employees generate, Steve Chang, an attorney with the IP firm Banner and Witcoff, told *GenomeWeb Daily News* Monday.”

⁵⁰ “1915 Declaration of Principles on Academic Freedom and Academic Tenure,” in AAUP, *Policy Documents and Reports*, 295.

⁵¹ Wesley M. Cohen and John P. Walsh, “Real Impediments to Academic Biomedical Research,” in *Innovation Policy and the Economy*, vol. 8 (2008): 1–30, available at <http://www.nber.org/~marschke/mice/Papers/cohenwalsh.pdf>.

⁵² All original statistics on university and hospital patenting and licensing come from Licensing Activity Surveys coordinated by the Association of University Technology Managers’ (AUTM). However these figures were extracted from: Cohen and Walsh, “Real Impediments to Academic Biomedical Research”; and also from A. D. So, B. N. Sampat, A. K. Rai, R. Cook-Deegan, J. H. Reichman, et al., “Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience,” *PLoS Biology* 6.10 (2008).

⁵³ AUTM, *Licensing Activity Survey Full Report, FY 2007*, ed. R. Tieckelmann, R. Kordal, S. Flanigan, T. Glavicic-Théberge, and D. Bostrom.

⁵⁴ So et al., “Is Bayh-Dole Good for Developing Countries?” e53, 2079. Original sources: Association of University Technology Managers (2007) AUTM U.S. licensing activity survey: FY2006 survey summary, Data Appendix, available at http://www.autm.net/AM/Template.cfm?Section=Licensing_Surveys_AUTM&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=6&ContentID=2409 Mowery DC, Nelson RR, Sampat BN, Ziedonis AA (2001) The growth of patenting and licensing by U.S. universities: An assessment of the effects of the Bayh-Dole Act of 1980. *Res Pol* 30: 99-119.

⁵⁵ H. Bulut, G. Moschini, “U.S. Universities’ Net Returns from Patenting and Licensing: A Quantile Regression Analysis,” Center for Agricultural and Rural Development at Iowa State University Working Paper 06-WP 432 (2006), available at <http://www.card.iastate.edu/publications/dbs/pdffiles/06wp432.pdf>

⁵⁶ L. Nelsen, “The Rise of Intellectual Property Protection in the American University,” *Science* 279 (1998): 1460–61.

⁵⁷ Mowery et al., *Ivory Tower and Industrial Innovation*, 241.

⁵⁸ J. Colyvas, M. Crow, A. Gelijns, R. Mazzoleni, R. R. Nelson, et al., “How Do University Inventions Get into Practice?,” *Management Science* 48 (2002): 61–72.

⁵⁹ Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, “Links and Impacts: The Influence of Public Research on Industrial R&D,” 1–23; and Ajay Agrawal and Rebecca Henderson, “Putting Patents in Context: Exploring Knowledge Transfer from MIT,” 44–60, both in *Management Science* 48.1 (January 2002).

⁶⁰ *Ibid.*

⁶¹ Alfonso Gambardella, *Science and Innovation* (Cambridge: Cambridge University Press, 1995).

⁶² The landmark 1980 *Diamond v. Chakrabarty* US Supreme Court decision, for example, and the 1985 *ex parte Hibbard et al.* opinion made it possible to patent live artificially engineered organisms, including plants and animals. For a deeper discussion of this expansion of patent eligibility, see Dan L. Burk and Mark A. Lemley, *The Patent Crisis and How the Courts Can Solve It* (Chicago: University of Chicago Press, 2009). Regarding medical process patents, see Aaron Kesselheim and Michelle Mello, “Medical-Process Patents: Monopolizing the Delivery of Health Care,” *New England Journal of Medicine*, 355.19 (November 9, 2006): 2036-2041.

⁶³ Hall, "University-Industry Research Partnerships in the United States." See also Hank Chesbrough, "Is the Central R&D Lab Obsolete?," *Technology Review*, April 24, 2001, available at <http://www.technologyreview.com/business/12357/>

⁶⁴ Hall, "University-Industry Research Partnerships in the United States."

⁶⁵ National Science Board, "Academic Research and Development."

⁶⁶ Ibid.: "The share of support provided by institutional (university) funds increased steadily between 1972 (12%) and 1991 (19%) but since then has remained fairly stable at roughly one-fifth of total funding. After a 3-year decline between 2001 and 2004 (low of \$2.1 billion), industry funding of academic R&D increased for the fourth year in a row, to \$2.9 billion in 2008."

⁶⁷ *Working Together, Creating Knowledge*, 3.

⁶⁸ National Research Council (NRC), *Government-Industry Partnerships for the Development of New Technologies* (Washington, DC: National Academies Press, 2003).

⁶⁹ Denis O. Gray, Mark Lindblad, and Joseph Rudolph, "Industry-University Research Centers: A Multivariate Analysis of Member Retention," *Journal of Technology Transfer* 26.3 (2001): 247-54. The authors write: "According to research by Cohen and his colleagues (1994), industry-university research centers in the U.S. had research expenditures of \$2.53 billion, accounting for roughly 15 percent of university research funding. Add to this support for traditional cooperative activities like consulting and contract research and industry-sponsored and industry-leveraged government research probably accounts for 20 percent to 25 percent of university R&D" (247).

⁷⁰ Phone interview with Jilda D. Garton, associate vice provost for research at Georgia Institute of Technology, and Jennifer Washburn, October 18, 2007, published in J. Washburn, *Big Oil Goes to College* (Washington, DC: Center for American Progress, October 2010), 46, available at http://www.americanprogress.org/issues/2010/10/big_oil.html

⁷¹ NRC, *Government-Industry Partnerships for the Development of New Technologies*. See also: Greg Linden, David Mowery, and Rosemarie Ziedonis, "National Technology Policy in Global Markets," in *Innovation Policy in the Knowledge-Based Economy*, ed. Albert Link and Maryann Feldman (Boston: Kluwer Academic, 2001), 312; and Leon Rosenberg, "Partnerships in the Biotechnology Enterprise," in National Research Council, *Capitalizing on New Needs and New Opportunities: Government-Industry Partnerships in Biotechnology and Information Technologies* (Washington, DC: National Academy of Sciences, 2001).

⁷² Phone interview with Doug Hooker, division director for Renewable Energy Projects Division, Department of Energy (DOE) Golden Field Office, and Jennifer Washburn, January 22, 2008, published in Washburn, *Big Oil Goes to College*. According to the DOE's website, "The mission of the Golden Field Office is to support DOE's Office of Energy Efficiency and Renewable Energy through R&D partnerships, outreach to stakeholders nationwide to further the use of energy efficiency and renewable energy technologies, and laboratory contract administration" (www.eere.energy.gov/golden/About_The_Office.aspx).

⁷³ Hall, "University-Industry Research Partnerships in the United States." An earlier version was presented at the Sixth International Conference on Technology Policy and Innovation, Kansai, Japan, August 2002 (6).

⁷⁴ Eric G. Campbell and David Blumenthal, "Industrialization of Academic Science and Threats to Scientific Integrity," chap. 71, 780-86, see Table 71.1, "Conceptualization of AIRs" (781), in *The Oxford Textbook of Clinical Ethics*, ed. Ezekiel J. Emanuel, Christine Grady, et al. (Oxford: Oxford University Press, 2008).

⁷⁵ Adapted from *ibid.*, 781.

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⁷⁹ See, e.g., Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," Fall 2005, final document, available at

http://www.theuniversityfaculty.cornell.edu/forums/forums_main.html, 9; Lawrence Busch, Richard Allison, Craig Harris, et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California* (East Lansing: Michigan State University, Institute for Food and Agricultural Standards, July 13, 2004): 13, 152, available at http://berkeley.edu/news/media/releases/2004/07/external_novartis_review.pdf; and UC-Berkeley Academic Senate, Task Force on University-Industry Partnerships, "Principles and Guidelines for Large-Scale Collaborations between the University and Industry, Government, and Foundations," final, n.d., 12-13, available at http://academic-senate.berkeley.edu/sites/default/files/recommendations-reports/tf_uip_report-final1.pdf.

⁸⁰ Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*.

⁸¹ Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," 9.

⁸² Washburn, *Big Oil Goes to College*.

⁸³ Quoted in *Working Together, Creating Knowledge*, 22. See also Industrial Research Institute, *A Report on Enhancing Industry-University Cooperative Research Agreements* (Washington, DC, 1995), 1.

⁸⁴ *Working Together, Creating Knowledge*, 22.

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- ⁸⁶ D. Blumenthal, E. G. Campbell, N. Causino, and K. S. Louis, "Participation of Life-Science Faculty in Research Relationships with Industry," *New England Journal of Medicine* 335.23 (1996a):1734–39.
- ⁸⁷ IOM report (2009), 102.
- ⁸⁸ *Working Together, Creating Knowledge*, 23.
- ⁸⁹ Zinner, "Participation of Academic Scientists in Relationships with Industry," 1818.
- ⁹⁰ Research by Diana Hicks and Kimberly Hamilton (CHI Research Inc., Haddon Heights, NJ) found that, between 1981 and 1992, 3.3 of every one thousand papers published by university-industry collaborations were among the one thousand most cited in other scientific publications over the next four years. By contrast, 2.2 of every one thousand multiuniversity papers, and only 1.7 of every one thousand single-university papers, landed among the top-cited publications. Diana Hicks and Kimberly Hamilton, "Does University-Industry Collaboration Adversely Affect University Research?," *Issues in Science and Technology* (Summer 1999), 74-75.
- ⁹¹ Zinner, "Participation of Academic Scientists in Relationships with Industry," 1818; Blumenthal et al., "Participation of Life-Science Faculty in Research Relationships with Industry."
- ⁹² Pierre Azoulay, Ryan Michigan, and Bhaven N. Sampat, "The Anatomy of Medical School Patenting," *New England Journal of Medicine* 20.357 (2007): 2049–56.
- ⁹³ *Working Together, Creating Knowledge*, 27–28. Studies by Diane Rahm and Robert Morgan at Washington University in St. Louis did find a small association between greater faculty involvement with industry and more applied research. However, statistics from the National Science Foundation show that the amount of basic research performed in academia has remained relatively stable since 1980. Diana Hicks and Kimberly Hamilton of CHI Research also categorized research according to the journal in which it appeared and found that the percentage of basic research being performed in universities was unchanged from 1981 to 1995. Richard Florida, "The Role of the University: Leveraging Talent, Not Technology," *Issues in Science and Technology* (Summer 1999), available at <http://www.issues.org/15.4/florida.htm>; Hicks and Hamilton, "Does University-Industry Collaboration Adversely Affect University Research?"
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²⁰⁵ The full final ruling from the US District Court for the District of Columbia in the case, *US Department of Justice v. Philip Morris USA Inc. et al.*, dated September 8, 2006, is available online at <http://www.justice.gov/civil/cases/tobacco2/amended%20opinion.pdf>.

²⁰⁶ Allan M. Brandt, "Inventing Conflicts of Interest," *American Journal of Public Health* (January 2012): 63–71, esp. 63–64; Brandt, *The Cigarette Century*, 165–207; Glantz et al. *The Cigarette Papers*, 32–46; Michaels, *Doubt Is Their Product*, 3–11; and Proctor, *The Golden Holocaust*, 257–88. A passage from the US District Court judge's 2006 ruling in the Racketeer Influenced Corrupt Organizations (RICO) case against the tobacco companies suggests what the fruits of this meeting were: "Finally, a word must be said about the role of lawyers in this fifty-year history of deceiving smokers, potential smokers, and the American public about the hazards of smoking and second hand smoke, and the addictiveness of nicotine. At every stage, lawyers played an absolutely central role in the creation and perpetuation of the Enterprise and the implementation of its fraudulent schemes. They devised and coordinated both national and international strategy; they directed scientists as to what research they should and should not undertake; they vetted scientific research papers and reports as well as public relations materials to ensure that the interests of the Enterprise would be protected; they identified 'friendly' scientific witnesses, subsidized them with grants from the Center for Tobacco Research and the Center for Indoor Air Research, paid them enormous fees, and often hid the relationship between those witnesses and the industry; and they devised and carried out document destruction policies and took shelter behind baseless assertions of the attorney client privilege." *US Department of Justice v. Philip Morris USA Inc. et al.*, September 8, 2006, 4, available online at <http://www.justice.gov/civil/cases/tobacco2/amended%20opinion.pdf>.

²⁰⁷ Michaels, *Doubt Is Their Product*, 11.

²⁰⁸ Ibid., 4. Michaels details the use of the “tobacco strategy” on behalf of multiple products and contaminants. For a time, the PR firm Hill and Knowlton benefited from providing its services to other companies marketing toxic products. As Michaels documents, the PR firm used the tobacco strategy to defend asbestos (18), vinyl chloride (36–37), and lead (42). Eventually Hill and Knowlton would be superseded: “As the product defense work has gotten more and more specialized, the makeup of the business has changed: generic public relations operations like Hill and Knowlton have been eclipsed by product defense firms, specialty boutiques run by scientists” (46).

²⁰⁹ The Legacy Tobacco Documents Library archive is available at <http://legacy.library.ucsf.edu>. It became fully text searchable as a digital archive only in 2007, which enabled Robert N. Proctor, a historian based at Stanford, to compile and publish representative lists of thousands of faculty (including historians, scientists, statisticians, and others) who had testified for Big Tobacco, or served as industry consultants without testifying. In his book *The Golden Holocaust*, Proctor also offers a case study of the risks to research integrity, public understanding, and public health that resulted as an **outgrowth** of these pervasive financial relationships between the Medical College of Virginia (MCV, later renamed Virginia Commonwealth University [VCU]) and a rogue industry. Commenting on the MCV/VCU’s seventy-year entanglement with the tobacco industry, Proctor wrote: “It would be a mistake to characterize this interpenetration of tobacco and academia as merely a ‘conflict of interest;’ the relationship has been far more symbiotic. We are really talking about a confluence of interests, and sometimes even a virtual identity of interests” (R. Proctor, *The Golden Holocaust*, 190). For Proctor’s list of academic statisticians who have testified for tobacco companies, see 439–41; for his list of historians who have testified as witnesses on behalf of tobacco companies, see 460–63; for his list of historians who served as tobacco industry consultants without testifying, see 464.

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²¹¹ This is adapted from the IOM report (2009), 46; and “Understanding Financial Conflicts of Interest,” *New England Journal of Medicine* 329 (1993): 573.

²¹² Association of American Medical Colleges and Association of American Universities (AAMC-AAU), *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research—Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research* (Washington, DC: AAMC, February 2008), 36, available at https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107. The IOM report (2009), offers this definition: “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” (218).

²¹³ IOM report (2009), 61.

²¹⁴ Association of American Medical Colleges (AAMC), *Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research* (Washington, DC: AAMC, 2001), quotes appear on 3, available at <http://www.aamc.org/research/coi/firstreport.pdf>.

²¹⁵ The PLoS Medicine Editors, “Does Conflict of Interest Disclosure Worsen Bias?,” *PLoS Medicine*, 9(4) April 24, 2012, e1001210. This editorial is responding in part to: Cosgrove L, Krimsky S, “A Comparison of DSM- IV and DSM-5 Panel Members’ Financial Associations with Industry: A Pernicious Problem Persists,” *PLoS Medicine* 9(3), March 13, 2012, e1001190.

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²¹⁷ Association of American Medical Colleges (AAMC), *In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making: Report of the Task Force on Financial Conflicts of Interest in Clinical Care* (Washington, DC: AAMC, June 2010), 6–7.

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- ²²⁴ A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?," *Journal of the American Medical Association* 283 (2000): 373–80.
- ²²⁵ Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit, *The Scientific Basis of Influence and Reciprocity: A Symposium* (Washington, DC: Association of American Medical Colleges, 2007), available at www.aamc.org/reciprocity. See also J. Dana and G. Loewenstein, "A Social Science Perspective on Gifts to Physicians from Industry," *Journal of the American Medical Association* 290.2 (2003): 252–55.
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- ²³¹ AAUP, "Statement on Conflicts of Interest" (June 1990), in AAUP, *Policy Documents and Reports*, 185.
- ²³² USPHS, "Objectivity in Research."
- ²³³ See IOM report (2009), table 1-1: "Timeline of Selected Events Relevant to the Evolution of Conflict of Interest Principles, Policies, and Practices," 36–38. In 1994, the National Science Foundation (NSF) issued a new Investigator Financial Disclosure Policy "to help ensure the appropriate management of actual or potential conflicts" (effective 1995). In 1998, the Food and Drug Administration (FDA) followed suit, publishing regulations (63 FR 5233) requiring disclosure by clinical investigators of certain financial relationships. As the Association of American Universities notes, FDA regulations are largely directed at drug companies, not universities: "they require companies filing a New Drug Application to certify that no financial arrangements with an investigator have been made where study outcomes could affect compensation, and to disclose to the FDA any pertinent investigator financial arrangements and the steps taken to minimize the potential for bias." AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 3.
- ²³⁴ S. Van McCrary, Cheryl B. Anderson, Jelena Jakovljevic, et al., "A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research," *New England Journal of Medicine* 343 (30 November 2000): 1621; Mildred K. Cho, Ryo Shohare, Anna Schissel, and Drummond Rennie, "Policies on Faculty Conflicts of Interest at U.S. Universities," *Journal of the American Medical Association* 284.17 (1 November 2000): 2203–08; Bernard Lo, Leslie E. Wolf, and Abiona Berkeley, "Conflict-of-Interest Policies for Investigators in Clinical Trials," *New England Journal of Medicine* 343 (November 30, 2000): 1616.
- ²³⁵ IOM report (2009), 217. See also R. Steinbrook, "The Gelsinger Case," in *The Oxford Textbook of Clinical Research Ethics*, ed. E. J. Emanuel, C. Grady, R. A. Crouch, R. Lie, F. Miller, and D. Wendler (New York: Oxford University Press, 2008); and S. G. Stolberg, "The Biotech Death of Jesse Gelsinger," *New York Times Magazine*, November 28, 1999, 136–40, 149–50.
- ²³⁶ National Institutes of Health (NIH), Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Centers for Disease Control (CDC), "Human Subject Protection and Financial Conflicts of Interest Conference," Washington, DC, agenda and speakers list available at <http://www.hhs.gov/ohrp/archive/coi/agenda.htm>; Donna Shalala, "Protecting Research Subjects: What Must Be Done," *New England Journal of Medicine* 343.11 (September 14, 2000): 808–10; DHHS Office of Inspector General, "Protecting Human Research Subjects: Status of Recommendations," Department of Health and Human Services, OEI-01-97-00197, 22, 3; General Accounting Office (GAO), "Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest," November 2001, GAO-02-89: In this 2001 report to Congress, the GAO called upon the US Department of Health and Human Services to promulgate new regulations or to issue guidance to address institutional conflicts of interest, noting that equity ownership or other investment in a

research sponsor “may color [an institution’s] review, approval, or monitoring of research conducted under its auspices or its allocation of equipment, facilities, and staff for research.”

²³⁷ DHHS, “Financial Relationships in Clinical Research: Draft Interim Guidance,” January 10, 2001, available at <http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.html>.

²³⁸ See Washburn, *University Inc.*, 134, which references Letters of Comment to the Office of Human Research Protections from major university consortiums, including the Association of American Medical Colleges, the Association of American Universities, the Council on Government Relations, and the National Association of State Universities and Land Grant Colleges, all demanding that the 2001 HHS proposed guidelines be withdrawn.

²³⁹ Davidoff et al., “Sponsorship, Authorship, and Accountability”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.”

²⁴⁰ Davidoff et al., “Sponsorship, Authorship, and Accountability.”

²⁴¹ Starting in 2005, the Senate Committee on Finance (Committee) initiated an inquiry into educational grants for continuing medical education (CME) programs. This inquiry began after reports that drug companies were using the grants to promote off-label uses of their drugs, i.e., uses that had not been approved by the Food and Drug Administration. The findings of that inquiry were released in a committee staff report in April 2007. See Committee Staff Report to the Chairman and Ranking Member, “Use of Educational Grants by Pharmaceutical Manufacturers,” S. Prt. 110–21, April 2007, available at <http://finance.senate.gov/newsroom/chairman/release/?id=af4af834-3fab-4293-be6d-ca7f1246484f>. In 2008, Grassley also started to investigate university researchers’ financial conflicts of interest; Charles Grassley, “Payment to Physicians,” *Congressional Record—Senate*, 2008, S5030, available at http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2008_record&page=S5030&position=all.

²⁴² Charles Grassley, “Grassley Works to Disclose Financial Ties between Drug Companies and Doctors,” press release, January 22, 2009, available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=18901; Charles Grassley, “Grassley Seeks Information about Medical School Policies for Disclosure of Financial Ties,” June 29, 2009, available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=21465.

²⁴³ IOM, 2009, 74.

²⁴⁴ Gardiner Harris, “Top Psychiatrist Didn’t Report Drug Makers’ Pay,” *New York Times*, October 3, 2008, available at <http://www.nytimes.com/2008/10/04/health/policy/04drug.html?fta=y&pagewanted=all>.

²⁴⁵ S. Shelton, “Emory Will Punish Psychiatrist Nemeroff: Chairmanship Taken Away, Outside Income to Be Vetted,” *Atlanta Journal-Constitution*, December 23, 2008, available at <http://www.ajc.com/services/content/printedition/2008/12/23/nemeroff.html>.

²⁴⁶ Jocelyn Kaiser, “Conflicts Investigation Turns to Stanford,” *Science*, June 24, 2008.

²⁴⁷ Paul Thacker, “The Ugly Underbelly of Medical Research,” Project on Government Oversight, blog post with internal NIH—Stanford University e-mail correspondence, January 13, 2011, available at <http://pogoblog.typepad.com/pogo/nih-emails-mifepristone-20080515.html>.

²⁴⁸ Banerjee, Devin, “Conflict forces professor to quit grant post; Under Senate investigation, Schatzberg temporarily resigns,” *Stanford Daily*, September 22, 2008, available at: <http://www.stanforddaily.com/2008/09/22/conflict-forces-professor-to-quit-grant-post/>.

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²⁴⁹ G. Harris and B. Carey, “Researchers Fail to Reveal Full Drug Pay,” *New York Times*, June 8, 2008.

²⁵⁰ Ed Silverman, “Harvard Docs Disciplined for Conflicts of Interest,” *Pharmalot.com*, July 2, 2011, available at <http://www.pharmalot.com/2011/07/harvard-docs-disciplined-for-conflicts-of-interest/>.

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²⁵² Liz Kowalczyk, “Senator Broadens Inquiry into Psychiatrist; Suggests MGH Doctor Was Biased in Research,” *Boston Globe*, March 21, 2009; Gardiner Harris, “Drug Maker Told Studies Would Aid It, Papers Say,” *New York Times*, March 19, 2009.

²⁵³ Office of the Inspector General (OIG), National Institutes of Health, *Conflicts of Interest in Extramural Research*, (Washington, DC: US Department of Health and Human Services, 2008), available at <http://oig.hhs.gov/oei/reports/oei-03-06-00460.pdf>.

²⁵⁴ Physician Payments Sunshine Act (S.301). For details see “Pew Prescription Project Fact Sheet: The Physician Payment Sunshine Act, 2009,” available at http://www.prescriptionproject.org/tools/sunshine_docs/files/0001.pdf.

²⁵⁵ According to the IOM report (2009), “District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia require pharmaceutical manufacturers to report their financial relationships with physicians; and a number of other states are considering such requirements (Wallack, 2008; Lopes, 2009; MedPAC, 2009). Minnesota and Massachusetts make the information public. Vermont requires the state’s attorney general to make an annual public report based on the information that the pharmaceutical manufacturers have disclosed” (71). On the industry side, according to the IOM report (2009), “Eli Lilly announced that it would create a publicly accessible registry of its payments to physicians beginning in 2009 (Lilly, 2008). Pfizer has released information about its grants and educational awards to

medical, scientific, and patient organizations and has announced that it is eliminating grants to commercial providers of continuing medical education (Pfizer, 2008)” (180–81).

²⁵⁶ Quote from IOM report (2009), 88.

²⁵⁷ See discussion in IOM report (2009), 110. This 2003 AAMC survey is S. Ehringhaus and D. Korn, *U.S. Medical School Policies on Individual Financial Conflicts of Interest: Results of an AAMC Survey* (Washington, DC: Association of American Medical Colleges, 2004), available at <http://www.aamc.org/research/coi/coiresults2003.pdf>.

²⁵⁸ IOM report (2009), 68. K. P. Weinfurt, M. A. Dinan, J. S. Allsbrook, J. Y. Friedman, M. A. Hall, K. A. Schulman, and J. Sugarman, “Policies of Academic Medical Centers for Disclosing Financial Conflicts of Interest to Potential Research Participants,” *Academic Medicine* 81.2 (2006b):113–18.

²⁵⁹ Discussed in IOM report (2009), 221–22. The survey cited here is S. Ehringhaus, J. S. Weissman, J. L. Sears, S. D. Goold, S. Feibelmann, and E. G. Campbell, “Responses of Medical Schools to Institutional Conflicts of Interest,” *Journal of the American Medical Association* 299.6 (2008): 665–71. This study concludes as follows: “Despite strong national recommendations from 2 prominent higher education organizations, adoption of ICOI [Institutional Conflict of Interest] policies by US medical schools is far from complete. . . . wider adoption of ICOI policies covering these interests is imperative in light of the compelling interests of research integrity, protection of human subjects, and preservation of public trust.”

²⁶⁰ Department of Health and Human Services (DHHS), Office of the Inspector General (OIG), “How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health,” OEI–03–07–00700, November 2009, 12, , available at <http://oig.hhs.gov/oei/reports/oei-03-07-00700.pdf>.

²⁶¹ DHHS, OIG, “How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health.”

²⁶² IOM report (2009): “One analysis of cases in which researchers disclosed their financial relationships found that university conflict of interest committees determined that 26 percent of the cases reviewed involved conflicts of interest that needed management [Boyd, E. A., S. Lipton, and L. A. Bero, “Implementation of Financial Disclosure Policies to Manage Conflicts of Interest,” *Health Affairs* 23, 2 (2004): 206–214]. The three most commonly applied management strategies were requiring disclosure in publications and presentations (40 percent of the managed cases), appointing an oversight committee to protect the interests of students involved in the project (21 percent of the managed cases), and eliminating the relationship during the period of the project (22 percent of managed cases). The least common management approach was eliminating the conflict of interest or prohibiting the research” (84).

²⁶³ DHHS, OIG, “How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health”: “The most common type of conflict among researchers was equity ownership (including stocks and stock options) in companies in which the researchers’ financial interests could significantly affect the grant research. One-hundred eleven researchers owned equity in companies ranging from publicly traded companies to small, privately held companies. Of these 111 researchers, 44 (39 percent) were founding members of the companies” (8).

²⁶⁴ *Ibid.*, iii, 19.

²⁶⁵ General Accounting Office (GAO), “University Research: Most Federal Agencies Need to Better Protect against Financial Conflicts of Interest,” November 2003, GAO-04-31, available at <http://www.gao.gov/new.items/d0431.pdf>.

²⁶⁶ Francis S. Collins and Sally J. Rockey, “Managing Financial Conflict of Interest in Biomedical Research,” *Journal of the American Medical Association*, published online May 24, 2010, available at http://www.nih.gov/about/director/articles/jama_052410.pdf.

²⁶⁷ Davidoff et al., “Sponsorship, Authorship, and Accountability”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.”

²⁶⁸ Schulman et al., “Provisions in Clinical-Trial Agreements.”

²⁶⁹ *Ibid.*

²⁷⁰ Jeffrey M. Drazen, “Institutions, Contracts, and Academic Freedom,” editorial, *New England Journal of Medicine* 347.17 (October 24, 2002), 1362–1363.

²⁷¹ Michelle M. Mello, Brian R. Clarridge, and David M. Studdert, “Academic Medical Centers’ Standards for Clinical-Trial Agreements with Industry,” *New England Journal of Medicine* 352 (2005): 2202–10.

²⁷² T. A. Brennan, D. J. Rothman, L. Blank, et al., “Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers,” *Journal of the American Medical Association* 295 (2006): 429–33; D. J. Rothman and S. Chimonas, “New Developments in Managing Physician-Industry Relationships,” *Journal of the American Medical Association* 300 (2008): 1067–69.

²⁷³ Association of American Medical Colleges (AAMC), *Industry Funding of Medical Education: Report of an AAMC Task Force* (Washington, DC: AAMC, June 2008), available at https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232

²⁷⁴ IOM report (2009).

²⁷⁵ Susan Chimonas, Lisa Patterson, Victoria H. Raveis, and David J. Rothman, “Managing Conflicts of Interest in Clinical Care: A National Survey of Policies at U.S. Medical Schools,” *Academic Medicine* 86.3 (March 2011): 293–299.

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- ²⁷⁶ Robert Berdahl (UC-Berkeley), *Proceedings of "A Dialog on University Stewardship: New Responsibilities and Opportunities, Government-University-Industry Research Roundtable"* (Washington, DC: National Academy Press, 1999), 24.
- ²⁷⁷ For a discussion of this skirting of faculty governance and review, see the discussion of a major strategic alliance agreement signed by UC-Berkeley and BP in Washburn, *Big Oil Goes to College*, e.g., 85–94, esp. 91. On November 9, 2007, UC-Berkeley (Regents of University of California) signed a \$500 million strategic alliance agreement with BP Technology Ventures Inc. to launch the Energy Biosciences Institute (also in partnership with Lawrence Berkeley National Laboratory and the University of Illinois at Urbana-Champaign). A copy of the final EBI agreement is available at http://www.energybiosciencesinstitute.org/images/stories/pressroom/FINAL_EXECUTED_11-14.pdf.
- ²⁷⁸ Donald L. Lemish, "Establishing a University Foundation," American Association of State Colleges and Universities, 1989.
- ²⁷⁹ "Access to University Foundation Records," Student Press Law Center, SPLC TIP SHEET, 2010. See also "Crumbling Foundations: Records of University Fundraising Entities May Be Open under State Sunshine Laws," Student Press Law Center, *Legal Analysis* 26.2 (Spring 2005): 34. Both available from: www.splc.org.
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- ²⁸² Sean Hill, Student Press Law Center, "Iowa District Court Orders ISU Foundation to Release Documents; Decision Is in Line with Iowa Supreme Court's February Ruling That Foundation Is Public," June 22, 2005; Liz Allen, "ISU Foundation Audit Includes Walden's Pay," *Ames (Iowa) Tribune*, March 6, 2001.
- ²⁸³ Fred Grimm, "Catanese Affair Suggests a New FAU Nickname," *Miami Herald*, September 30, 2003.
- ²⁸⁴ AAUP, "Statement on Corporate Funding of Academic Research," 2004. This report was prepared by a subcommittee of the Association's Committee A on Academic Freedom and Tenure. It was approved by Committee A and adopted by the Association's Council in November 2004. Its first two recommendations are "1. Consistent with principles of sound academic governance, the faculty should have a major role not only in formulating the institution's policy with respect to research undertaken in collaboration with industry, but also in developing the institution's plan for assessing the effectiveness of the policy. The policy and the plan should be distributed regularly to all faculty, who should inform students and staff members associated with them of their contents" (6). See "Statement on Government of Colleges and Universities," 1966, in AAUP, *Policy Documents and Reports*, 135–40: "2. The faculty should work to ensure that the university's plan for monitoring the institution's conflict-of-interest policy is consistent with the principles of academic freedom. There should be emphasis on ensuring that the source and purpose of all corporate-funded research contracts can be publicly disclosed. Such contracts should explicitly provide for the open communication of research results, not subject to the sponsor's permission for publication."
- ²⁸⁵ AAUP, "Statement on Conflicts of Interest" (June 1990), in AAUP, *Policy Documents and Reports*, 185.
- ²⁸⁶ AAUP, *Freedom in the Classroom* (2007), prepared by a subcommittee of the Association's Committee A on Academic Freedom and Tenure, approved in June 2007, available at <http://www.aaup.org/AAUP/comm/rep/A/class.htm>.
- ²⁸⁷ In 2011, it came to light that two leading German universities, Humboldt University and the Technical University of Berlin, signed an agreement with Deutsche Bank to sponsor a joint institute for applied mathematical research, known as the Quantitative Products Laboratory. Under the terms of the 2007 contract—worth \$17 million over four years—Deutsche Bank was given a say in the hiring of both of the two endowed professorships, one at each university. Deutsche Bank was also granted the right to have bank employees designated as adjunct professors, who were allowed to grade student work. Under the contract, appropriate *topics for research and research strategy were decided by a steering committee made up of two academics and two bank employees, with the managing director, a bank employee, casting the deciding vote in the event of a tie*. Finally, Deutsche Bank was granted permission to review all academic work sixty days before it was published, and could *withhold permission for publication for as long as two years*. The agreement further specified that the laboratory would be located "in close proximity to the Deutsche Bank" headquarters in Berlin. Finally, the whole agreement was to be secret. The contract only became public after Peter Grottian, a political scientist and emeritus professor at Humboldt, became a shareholder and obtained a copy, resulting in huge headlines in the German news media. "You cannot avoid the impression that science is for sale," Michael Hartmer, director of the German Association of University Professors, told *Der Spiegel*. Donald D. Guttenplan, "Cash Tempts the Ivory Tower's Guardians," *New York Times*, July 17, 2011.
- ²⁸⁸ "University Programs Supported by the Charles G. Koch Charitable Foundation," August 2011, available at <http://www.kochfamilyfoundations.org/pdfs/Koch%20Family%20Foundations-ListofFundedProgramAugust2011.pdf>.
- ²⁸⁹ Berrett, "Not Just Florida State"; Hundley, "Billionaire's Role in Hiring Decisions at Florida State University Raises Questions."
- ²⁹⁰ Chaker, "Companies Design, Fund Curricula at Universities."
- ²⁹¹ Keenan, "CEOs Pushing Ayn Rand Studies Use Money to Overcome Resistance."
- ²⁹² DHHS, NIH, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources," 72093. Under the heading "Prompt Publication," this NIH guidance reads in part as follows: "Agreements to acquire materials for use in NIH-funded research are expected to address the timely

dissemination of research results. Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results. A delay of thirty to sixty days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable.”

²⁹³ IOM report (2009), available at <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>.

²⁹⁴ S. Ehringhaus and D. Korn, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials* (Washington, DC: AAMC, January 2006), printed in D. Korn and S. Ehringhaus, “Principles for Strengthening the Integrity of Clinical Research,” *PLoS Clinical Trials* 1.1 (April 21, 2006): e1, available at <http://clinicaltrials.ploshubs.org/article/info:doi/10.1371/journal.pctr.0010001>. See Principle 16: “Ghost or guest authorship is unacceptable. Authorship implies independent, substantial, and fully disclosed participation in the study and in the preparation of the manuscript.”

²⁹⁵ Association of American Medical Colleges (AAMC), *Industry Funding of Medical Education: Report of an AAMC Task Force* (Washington, DC: AAMC, June 2008), available at https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232

In this report the AAMC recommends that “[a]cademic medical centers should prohibit physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise” (22). It also notes that properly acknowledged collaborations with industry personnel or medical writers is not ghostwriting.

²⁹⁶ Davidoff et al., “Sponsorship, Authorship, and Accountability”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication,” available at <http://www.icmje.org/icmje.pdf>. For World Association of Medical Editors (WAME) sources, see “Publication Ethics Policies for Medical Journals,” available at <http://www.wame.org/resources/publication-ethics-policies-for-medical-journals#conflicts>. See also WAME, “Policy Statements: Ghost Writing Initiated by Commercial Companies,” available at <http://www.wame.org/resources/policies#fundres>.

²⁹⁷ Lacasse and Leo, “Ghostwriting at Elite Academic Medical Centers in the United States.”

²⁹⁸ IOM (2009), 153.

²⁹⁹ B. Moffatt and C. Elliott, “Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles,” *Perspectives in Biology and Medicine* 50 (2007): 18–31.

³⁰⁰ D. Healy and D. Cattell, “Interface between Authorship, Industry and Science in the Domain of Therapeutics,” *British Journal of Psychiatry* 183 (2003): 22–27.

³⁰¹ E. Lopatto, J. Feeley, and M. Fisk, “Eli Lilly ‘Ghostwrote’ Articles to Market Zyprexa, Files Show,” *Bloomberg.com*, June 12, 2009, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aVvfe.v1k VY>.

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³⁰³ N. Singer, “Medical Papers by Ghostwriters Pushed Therapy,” *New York Times*, August 5, 2009.

³⁰⁴ Ross et al., “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib.”

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³⁰⁶ M. Petersen, “Madison Ave. Has Growing Role in the Business of Drug Research,” *New York Times*, November 22, 2002.

³⁰⁷ D. Healy, *Let Them Eat Prozac* (New York: New York University Press, 2004).

³⁰⁸ Howard Brody, *Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry* (Lanham, MD: Rowman and Littlefield, 2007).

³⁰⁹ C. Elliott, “Pharma Goes to the Laundry: Public Relations and the Business of Medical Education,” *Hastings Center Report* 34 (2004): 18–23.

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³¹⁴ US Senate Committee on Finance (Sen. Charles E. Grassley, ranking member), *Ghostwriting in Medical Literature*, Minority Staff Report, 111th Congress, June 24, 2010.

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³¹⁷ Ehringhaus and Korn, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*. See Principle 10, "Publication and Analysis Committee," which reads in part: "It is essential that the P&A committee be independent of the sponsor's control, have access to the full data set, understand and implement the prespecified analysis plan, and have the resources and skills both to interpret that analysis and perform additional analysis if required."

³¹⁸ Davidoff et al., "Sponsorship, Authorship, and Accountability"; ICMJE, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." See also ICMJE, "Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship," available at http://www.icmje.org/ethical_1author.html.

³¹⁹ For World Association of Medical Editors sources, see WAME, "Recommendations on Publication Ethics Policies for Medical Journals." See also WAME, "Policy Statements: Ghost Writing Initiated by Commercial Companies."

³²⁰ AAMC (2001), 19.

³²¹ Drazen, "Institutions, Contracts, and Academic Freedom."

³²² Mello, Clarridge, and Studdert, "Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry"; M. Mello, B. R. Clarridge, and D. M. Studdert, "Researchers' Views of the Acceptability of Restrictive Provisions in Clinical Trial Agreements with Industry Sponsors," *Accountability in Research* 12.3 (2005): 163–91.

³²³ Bodenheimer, "Uneasy Alliance"; Blumsohn, "Authorship, Ghost-Science, Access to Data, and Control of the Pharmaceutical Scientific Literature."

³²⁴ Blumsohn, "Authorship, Ghost-Science, Access to Data, and Control of the Pharmaceutical Scientific Literature."

³²⁵ Quoted in *ibid.* See also collated media reports on the Blumsohn case at <http://www.thejabberwock.org/presshw.htm> and <http://www.doctorsintegrity.org/blumsohn.htm>.

³²⁶ Davidoff et al., "Sponsorship, Authorship, and Accountability"; ICMJE, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals."

³²⁷ According to the IOM report (2009), a study by J. S. Ancker and A. Flanagin was able to locate online conflict of interest policies for only 33% of 84 "high-impact, peer-reviewed" journals in twelve scientific disciplines, but a subsequent survey found that 80% of the forty-nine responding journals reported that they had policies in place. Journals vary in whether they give specific guidance to authors regarding what financial relationships or conflicts of interest must be disclosed. J. S. Ancker and A. Flanagin, "A Comparison of Conflict of Interest Policies at Peer-Reviewed Journals in Different Scientific Disciplines," *Science and Engineering Ethics* 13.2 (2007): 147–57.

³²⁸ *AAUP Bulletin* 53 (1967): 134.

³²⁹ *AAUP Bulletin* 54 (1968): 243–44.

³³⁰ AAUP, "Academic Freedom and National Security in a Time of Crisis," 2003, available at <http://www.aaup.org/AAUP/comm/rep/crisistime.htm>. Also published in *Academe*, November–December 2003, see 37–38, available at <http://www.aaup.org/AAUP/pubsres/academe/2003/ND/Col/fte.htm>.

³³¹ Robert A. Rosenbaum et al., "The Enlargement of the Classified Information System," *Academe*, January–February 1983, 9a.

³³² *Ibid.*, 11a.

³³³ Cornell University, *Guidelines on Sensitive and Proprietary Research*, adopted by the Cornell Research Council on May 20, 1985, reproduced in *Faculty Handbook* at 91.

³³⁴ Massachusetts Institute of Technology (MIT), *Policies and Procedures: A Guide for Faculty and Students*, Section 14.2: "Open Research and Free Interchange of Information," available at <http://web.mit.edu/policies/14/14.2.html>. This policy reads in part as follows: "The profound merits of a policy of open research and free interchange of information among scholars is essential to MIT's institutional responsibility and to the interests of the nation as a whole. Openness requires that as a general policy MIT not undertake, on the campus, classified research or research whose results may not be published without prior permission—for example, without permission of governmental or industrial research sponsors. Openness also requires that, once they are at MIT, foreign faculty, students, and scholars not be singled out for restriction in their access to MIT's educational and research activities. The vast majority of on-campus research projects can be conducted in a manner fully consistent with the principles of freedom of inquiry and open exchange of knowledge. MIT, however, is an institution that plays a unique role in important areas of science and technology that are of great concern to the nation. It recognizes that in a very few cases the pursuit of knowledge may involve critically important but sensitive areas of technology where the immediate distribution of research results would not be in the best interests of society. In such cases, exceptions to these policies regarding publication, classification, and access by foreign students and scholars may be made, but only in those very rare instances where the area of work is crucially important to MIT's educational mission and the exception is demonstrably necessary for the national good. If these conditions are not met, MIT will decline or discontinue the activity and, if appropriate, propose it for consideration off-campus or elsewhere. Since the implementation of classified or otherwise restricted research on campus would drastically change the academic environment of the Institute, it is essential that each project be reviewed and acted upon in light of its impact on the Institute as a whole."

³³⁵ Massachusetts Institute of Technology (MIT), "MIT Panel Urges Off-Campus Sites for Classified Research; Reaffirms Openness on MIT Campus," press release, June 12, 2002, available at <http://web.mit.edu/newsoffice/2002/publicinterest.html>.

³³⁶ University of California at Berkeley, "Policy Guidelines Governing Openness and Freedom to Publish," issued by Joseph Cerny, UC-Berkeley provost of research, to all deans, directors, department chairs, and administrative officers on May 6, 1991, available at <http://research.chance.berkeley.edu/page.cfm?id=171#cerny>.

³³⁷ *Ibid.* This policy further states: "The principal reasons that classified projects are unacceptable are (1) the resultant requirement for a campus facility clearance and (2) the inherent publication restrictions. In general, classified projects are not consistent with the teaching, research, and public service missions of the Berkeley campus."

³³⁸ The Recitals section of the final EBI Master Agreement asserts: "the Proprietary Component [of the EBI] . . . will conduct private, confidential and proprietary research, the product of which will be the sole property of BP" (4).

³³⁹ Washburn, *Big Oil Goes to College*.

³⁴⁰ Regarding the external public criticism this provision elicited, see "UC and the Perils of Partnership," *San Francisco Chronicle*, April 1, 2007, available at <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2007/04/01/EDG5GOTV2L1.DTL>. See also Jennifer Washburn, "Big Oil Buys Berkeley," *Los Angeles Times*, March 24, 2007, available at <http://www.latimes.com/news/opinion/la-oe-washburn-24mar24,0,4865913.story?coll=la-opinion-center>. In UC-Berkeley's original draft EBI proposal to BP (dated November 2006), this language granting BP the right to perform confidential, nonpublishable research on campus was expressed even more baldly: "BP personnel will engage in proprietary research in the leased space and will have no obligation to publish research performed in the leased space." See UC-Berkeley EBI Draft Proposal to BP, dated November 2006, Section II, Intellectual Property, 73.

³⁴¹ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 2008, 8.

³⁴² IOM report (2009), 158.

³⁴³ Corporate officers and board of directors, for example, owe a "fiduciary duty of loyalty" to the corporation, which includes a duty to act solely in the best interest of the corporation.

³⁴⁴ For details on BP restrictions on academic scientists after the Gulf oil spill, see Lea, "BP, Corporate R&D, and the University." For observations on the conjunction between industry and government restrictions on Gulf oil spill research, see Hooper-Bui, "The Oil's Stain on Science"; and Gagosian and D'Elia, "Gulf Oil Spill Research Can't Wait."

³⁴⁵ "BP Buys Up Gulf Scientists for Legal Defense, Roiling Academic Community," *Mobile Press-Register*, July 16, 2010; "BP Accused of 'Buying Academic Silence,'" *BBC News*, July 22, 2010; "BP Tries to Limit Release of Oil Spill Research," Associated Press, July 23, 2010.

³⁴⁶ Amanda Mascarelli, "Freedom of Spill Research Threatened: Scientists Call for Impartial Funding and Open Data as BP and Government Agencies Contract Researchers," *Nature News*, July 28, 2010, available at <http://www.nature.com/news/2010/100728/full/466538a.html>.

³⁴⁷ Marc Lipsitch, "The Risk to Academic Freedom That Lurks in Corporate Consulting Contracts," *Chronicle of Higher Education*, June 27, 2010.

³⁴⁸ *Ibid.*

³⁴⁹ This discussion draws from Association of American Medical Colleges (AAMC), *Compact between Biomedical Graduate Students and Their Research Advisors* (Washington, DC: AAMC, 2008), available at

<https://services.aamc.org/Publications/showfile.cfm?file=version127.pdf>; and AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 2008.

³⁵⁰ IOM report (2009), 109.

³⁵¹ "Report of Joint Academic Senate-Administration Committee on University Interaction with Industry," University of California, San Diego, dated July 1999, available at <http://research.ucsd.edu/industry/report/index.htm>.

³⁵² AAMC, "Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research," (2001).

³⁵³ AAMC, *Compact between Biomedical Graduate Students and Their Research Advisors*, 6.

³⁵⁴ This recommendation is compatible with one recently made in a draft report issued by the MIT Ad Hoc Faculty Committee, *A Shared Responsibility: Report of the Committee on Managing Potential Conflicts of Interest in Research*, April 21, 2010, available at <http://web.mit.edu/provost/coi/index.html>.

³⁵⁵ Washburn, *University Inc.*, 86–97; Greenberg, *Science for Sale*. See also Chris MacDonald and Bryn Williams-Jones, "Supervisor-Student Relations: Examining the Spectrum of Conflicts of Interest in Bioscience Laboratories," *Accountability in Research: Policies and Quality Assurance* 16.2 (2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2876133/#R23>; and A. E. Shamoo and D. B. Resnik, "Mentoring and Collaboration," in *Responsible Conduct of Research*, ed. A. E. Shamoo and D. B. Resnik (Oxford: Oxford University Press, 2009).

³⁵⁶ *Working Together, Creating Knowledge*.

³⁵⁷ *Ibid.*, 28–29. Pramod Khargonekar, University of Michigan, interview by Beth Starbuck, Calyx Inc., Case Study Final Report, September 7, 2000, 36; Robert L. Carman, interview by Beth Starbuck, Calyx Inc., Case Study Final Report, September 7, 2000, 19.

³⁵⁸ AAMC, "Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research," (2001); AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 2008, 20.

³⁵⁹ AAMC, *Compact between Biomedical Graduate Students and Their Research Advisors*, 6.

³⁶⁰ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 2008, 25, 28.

³⁶¹ IOM report (2009), 116.

³⁶² Trade secrets, which are information with economic value not generally known to the public and subject to reasonable controls on disclosure, are sometimes, but not always, included in discussions of intellectual property.

³⁶³ Mark A. Lemley, "Are Universities Patent Trolls?," *Fordham Intellectual Property, Media & Entertainment Law Journal*, Vol. 18, Issue 3, 2008.

³⁶⁴ Siddhartha Mukherjee, *The Emperor of All Maladies: A Biography of Cancer* (New York: Scribner, 2010), 434.

³⁶⁵ *Ibid.*, 440.

³⁶⁶ Annalee Newitz, "Genome Liberation: The Information That Details Who We Are Is Too Important to Be Privately Owned," *Salon.com*, February 26, 2002, available at <http://www.salon.com/2002/02/26/biopunk/>.

³⁶⁷ Dr. Robert Shafer discusses the details of his own case, and provides substantial documentation, at <http://harmfulpatents.org/blog/>.

³⁶⁸ Stanford Advisory Board, April 20, 2010, quoted 'at <http://harmfulpatents.org/blog/>. For more background on the Shafer case, see Joe Mullin, "The Fight of His Life," *IP Law and Business*, May 1, 2009, available at <http://www.law.com/jsp/iplawandbusiness/PubArticleFriendlyIPLB.jsp?id=1202430332016>.

³⁶⁹ "Nine Points to Consider in Licensing University Technology" (2007), a consensus statement signed by more than fifty universities and endorsed by the Association of American Medical Colleges and the Association of University Technology Managers (AUTM), available at http://www.autm.net/source/NinePoints/ninepoints_endorsement.cfm.

³⁷⁰ Washburn, *Big Oil Goes to College*.

³⁷¹ "Nine Points to Consider in Licensing University Technology."

³⁷² Association of University Technology Managers (AUTM) Board of Trustees, "Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies" (SPS), November 9, 2009, available at <http://www.autm.net/source/Endorsement/endorsement.cfm?section=endorsement>. These principles were developed by a team comprised of AUTM leaders, including Jon Soderstrom, AUTM immediate past president, of Yale University; and Ashley J. Stevens, AUTM president-elect, of Boston University. These guidelines discuss best practices for universities when considering the equitable dissemination of medical technologies. For universities that have endorsed this statement see the link above.

³⁷³ Bhaven N. Sampat and Frank Lichtenberg, "What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?," *Health Affairs* 30.2 (2011): 332–39.

³⁷⁴ The antiretroviral HIV drug Stavudine (Zerit) was originally developed by researchers at Yale University with extensive federal government funding. Yale licensed this drug compound to Bristol-Myers-Squibb, in exchange for a share of the royalty income. The cost of the drug was \$10,439 per patient for a year in 2002. For individuals who live on just a few dollars per day, this expense was prohibitive and barred millions of dying HIV patients in the developing world from accessing this key component of the "triple-drug AIDS cocktail" that was then rapidly saving lives in the industrialized world. Student activists and the humanitarian organization Médecins Sans Frontières successfully pressured Yale

University and Bristol-Myers Squibb (the patent holder and license partner) to allow generic production of Stavudine. The generic price of Stavudine in the developing world then dropped more than a hundredfold, to \$87 per patient per year. Today, a new student organization, which grew out of the Yale campaign—Universities Allied for Essential Medicines—is working to expand generic production as one key way of address the global crisis of access to medicines.

³⁷⁵ Universities Allied for Essential Medicines, <http://essentialmedicine.org/projects/university-technology-transfer>.

³⁷⁶ The Uniform Administrative Requirements for Grants and Contracts with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations is available at <http://www.law.cornell.edu/cfr/text/10/600/subpart-B>.

³⁷⁷ The full decision issued by the US Court of Appeals for the Federal Circuit in the *Madey v. Duke University* (2002) case is available at <http://cyber.law.harvard.edu/people/tfisher/2002Madededit.html>. For a detailed discussion of this decision and its significance, see Eisenberg, “Patent Swords and Shields.”

³⁷⁸ “Nine Points to Consider in Licensing University Technology.”

³⁷⁹ Washburn, *Big Oil Goes to College*.

³⁸⁰ Committee on Management of University Intellectual Property, “*Managing University Intellectual Property in the Public Interest*” (Washington, DC: National Academies Press, 2011), available at http://www.nap.edu/catalog.php?record_id=13001. See Recommendation 5 (71).

³⁸¹ “Nine Points to Consider in Licensing University Technology.”

³⁸² *Ibid.* The Nine Points statement reads in part as follows: “Special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business. Universities are encouraged to use approaches that balance a licensee’s legitimate commercial needs against the university’s goal (based on its educational and charitable mission and the public interest) of ensuring broad practical application of the fruits of its research programs. There are many alternatives to strict exclusive licensing, several of which are described in the Appendix.”

³⁸³ When Cornell University’s faculty senate appointed a special faculty committee to review large-scale, multiyear industrial research alliances, known as strategic corporate alliances (SCA), its final consensus report advised that the university show a preference for nonexclusive licensing: “Licensing of inventions derived from SCA-funded work should, whenever possible, take the form of non-exclusive licenses to the corporate partner to use university-owned patents. By giving the licensor a monopoly over use of the patented invention, exclusive licensing inevitably interferes with full and open sharing of the results of academic research. Moreover, unless circumstances are very carefully assessed, it may allow the principal beneficiary of the patent right to become the private, rather than the public, interest.” Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” 16.

³⁸⁴ DHHS, NIH, “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.”

³⁸⁵ “Nine Points to Consider in Licensing University Technology.”

³⁸⁶ The Uniform Administrative Requirements for Grants and Contracts with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations is available at <http://www.law.cornell.edu/cfr/text/10/600/subpart-B>.

³⁸⁷ *Working Together, Creating Knowledge*.

³⁸⁸ Wayne Johnson, “Bayh-Dole: The Next Twenty-Five Years,” testimony before the Committee on Science and Technology, Subcommittee on Technology and Innovation (July 17, 2007), available at <http://science.house.gov/publications/Testimony.aspx?TID=7129>; R. E. Litan, L. Mitchell, E. J. Reedy “Commercializing University Innovations: A Better Way,” National Bureau of Economic Research working paper, 2007, available at http://www.brookings.edu/papers/2007/05_innovations_litan.aspx?rssid=education

³⁸⁹ For details on the Cohen-Boyer invention and the licensing strategy employed, see <http://www.iphandbook.org/handbook/chPDFs/ch17/ipHandbook-Ch%2017%2022%20Feldman-Colaianni0Liu%20Cohen-Boyer%20Patents%20and%20Licenses.pdf>.

³⁹⁰ For details on the Axel patent and the licensing strategy employed, see <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2750841/>.

³⁹¹ For a good discussion of the Hall invention and how it was managed, see http://www.wrfseattle.org/about/WRF_2007_Annual_Report.pdf (5–7). Also see also the following interview: <http://www.cbiz.com/efassociates/pdfs/HallInterview.pdf>. At the time of this interview, the Hall invention had generated roughly \$400 million in royalties—since then it has generated at least another \$100 million, with two years left on the patents.

³⁹² See sources listed under e392, directly above.

³⁹³ University of California Office of the President, “Electrical Engineering and Computer Science Intellectual Property Pilot Program Office of Technology Transfer,” No. 2000 02, August 30, 2000: “Recently PEAC (President’s Engineering Advisory Council) reviewed the matter of how engineering industry sponsors access University intellectual property resulting from extramural sponsored research. It was observed that the rapid rate of technological change in the engineering fields of electronics, communications technology, [and] computer hardware and software results in new products with a typical lifetime of a few years or less. Competitive success rarely is based upon the statutory protection of

intellectual property as requirements for conformance with industry wide standards reduce the value of proprietary technology. Rapid product development and early market entry with innovative products are the keys to market leadership and successful products.”

³⁹⁴ *Working Together, Creating Knowledge*.

³⁹⁵ *Ibid.*, 60–61.

³⁹⁶ *Ibid.*, 59–60.

³⁹⁷ Master Agreement, BP Technology Ventures Inc. and Regents of the University of California, November 9, 2007, available at http://www.energybiosciencesinstitute.org/images/stories/pressroom/FINAL_Execution_11-9.pdf.

³⁹⁸ University of California at Berkeley Academic Senate Committee letter addressed to Professor William Drummond, Chair of the Berkeley Division of the Academic Senate, November 2, 2007, 3. In this letter, a Senate subcommittee made up of five faculty (Ellwood, Hesse, Kutz, Villas Boas, and Moore), informally known as the “Gang of Four-plus,” reported back to Drummond regarding eight stated areas of Academic Senate concern regarding the BP-funded Energy Biosciences Institute.

³⁹⁹ AAUP, *Policy Documents and Reports*, 184.

⁴⁰⁰ DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors,” 42 CFR Part 50, 45 CFR Part 94, *Federal Register* 76.165 (August 25, 2011); DHHS, OIG, “How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health” (53258).

⁴⁰¹ DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors.” The quote, cited here, is contained in this full passage: “*The 1995 regulations were aimed at preventing bias in PHS-funded research, and as such, were intended to be proactive rather than reactive to specific evidence of bias.* Nonetheless, over the past few years, there have been several specific allegations of bias among PHS-funded researchers reported in the press. This has led to increased public concern, as evidenced by statements and correspondence from members of Congress and the language in the Department of Health and Human Services Appropriations Act, 2010, to amend the 1995 regulations ‘for the purpose of strengthening Federal and institutional oversight and identifying enhancements.’ And as mentioned above, the 2009 OIG report found that ‘vulnerabilities exist in grantee Institutions’ identification, management, and oversight of financial conflicts of interest.’ It is vital that the public have confidence in the objectivity of PHS-funded research. The revised regulations, with their emphasis on increasing transparency and accountability, as well as providing additional information to the PHS Awarding Component, are aimed at doing just that” [Emphasis added] (53258).

⁴⁰² IOM report (2009), Executive Summary, 2.

⁴⁰³ AAU, *Report on Individual and Institutional Financial Conflict of Interest: “Conflict of interest will be considered across all academic fields, not just biomedical ones* (though biomedical conflicts have some unique aspects and invoke a special intensity and interest)” [Emphasis added] (2). According to the IOM report (2009), in 2004 the Government Accountability Office reported that 79 percent of universities responding to its survey said that they had a single conflict of interest policy covering all research (68).

⁴⁰⁴ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, (2008): “Although this report focuses on those conflicts that arise in the context of human subjects research conducted primarily within or under the supervision of medical schools and teaching hospitals or by their personnel, *institutions should strongly consider making the principles and processes recommended in this report applicable to all research. Protection of integrity and public trust are indeed values that underpin all academic research, irrespective of whether the particular challenges associated with human subjects research are present*” [Emphasis added] (4). Later this report reads: “The Committee recognizes that institutional COIs can arise in non-human subjects research, clinical care, and education, as well as in purchasing and other university business transactions and *the Committee strongly recommends that institutions implement comprehensive institutional COI policies that embrace the full spectrum of the institution’s activities*” [Emphasis added] (36).

⁴⁰⁵ IOM report (2009): “*No matter the type or stage of research, certain fundamentals still apply. All researchers should be subject to an institution’s disclosure policies*, as described in Chapter 3, and the institution’s conflict of interest committee or its equivalent should be notified when investigators have financial stakes in the outcomes of their research. Similarly, following the conceptual framework presented in Chapter 2, once a financial relationship or interest has been disclosed, it should be evaluated for determination of the likelihood that it will have an undue influence that will lead to bias or a loss of trust. If a risk is judged to exist, a conflict of interest committee might conclude that the implementation of safeguards is necessary. Such safeguards could consist of a management plan that includes the involvement of a researcher without a conflict of interest in certain aspects of the research and disclosure of the conflict to coinvestigators and in presentations and publications” [Emphasis added] (119).

⁴⁰⁶ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, (2008): “The Committee recognizes that institutional COIs can arise in non-human subjects research, clinical care, and education, as well as in purchasing and other university business transactions and the Committee strongly recommends that institutions implement comprehensive institutional COI policies that embrace the full spectrum of the institution’s activities” (36).

⁴⁰⁷ IOM report (2009), 221: “The guidance on financial relationships in research with human participants published by the US Department of Health and Human Services discusses the identification and management of institutional as well as individual financial interests (HHS, 2004).”

⁴⁰⁸ Department of Health and Human Services (DHHS), Office of the Inspector General (OIG), “Institutional Conflicts of Interest at NIH Grantees,” Daniel R. Levinson, Inspector General, January 2011, OEI-03-09-00480: “We recommend that NIH: Promulgate regulations that address institutional financial conflicts of interest. Until regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures regarding institutional financial interests and conflicts.” See also DHHS, OIG, “How NIH Grantees Manage Financial Conflicts of Interest,” OEI-03-07-00700, November 2009: “Develop Regulations That Address Institutional Financial Conflicts of Interest. Institutional financial conflicts of interest are not addressed by Federal regulations. Because there is the potential for grantee institutions to have financial conflicts of interest related to grant research, NIH should develop regulations that address these interests. In developing regulations NIH should address: the definition of an institutional financial conflict of interest; the elements required in a grantee institution’s policy regarding institutional financial conflicts of interest; how institutional financial conflicts of interest are reported to NIH; and how institutional financial conflicts of interest are managed, reduced, or eliminated” (22).

⁴⁰⁹ IOM report (2009), Recommendation 8.1: “The boards of trustees or the equivalent governing bodies of institutions engaged in medical research, medical education, patient care, or practice guideline development should establish their own standing committees on institutional conflicts of interest. These standing committees should have no members who themselves have conflicts of interest relevant to the activities of the institution; include at least one member who is not a member of the board or an employee or officer of the institution and who has some relevant expertise; create, as needed, administrative arrangements for the day-to-day oversight and management of institutional conflicts of interest, including those involving senior officials; and submit an annual report to the full board, which should be made public but in which the necessary modifications have been made to protect confidential information. Recommendation 8.2: The National Institutes of Health should develop rules governing institutional conflicts of interest for research institutions covered by current U.S. Public Health Service regulations. The rules should require the reporting of identified institutional conflicts of interest and the steps that have been taken to eliminate or manage such conflicts” (21–22). For more discussion of these issues, see also IOM report (2009), 221–22.

⁴¹⁰ AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 5, available at <http://www.aau.edu/research/COI.01.pdf>. “Disclosure of financial interests related to non-federally sponsored research (which is not subject to regulation) ensures that all potential conflicts of interest are identified and handled similarly, instead of having an extensive process for some potential conflicts but not for others” (ibid.).

⁴¹¹ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*: “Although this report focuses on those conflicts that arise in the context of human subjects research conducted primarily within or under the supervision of medical schools and teaching hospitals or by their personnel, *institutions should strongly consider making the principles and processes recommended in this report applicable to all research. Protection of integrity and public trust are indeed values that underpin all academic research, irrespective of whether the particular challenges associated with human subjects research are present*” (4; emphasis added).

⁴¹² See DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors.” The new DHHS rules require investigators to report not just how their financial interests might affect a particular federally funded project or grant, but how these financial interests might affect *all their “institutional responsibilities,” including research, consulting, teaching, membership on university committees*, etc., thus significantly broadening what needs to be reported as a possible financial conflict of interest. The new PHS rules also now require disclosure of all *nonprofit income* (from seminars, lectures, educational events, etc.), because it is increasingly common for nonprofits to receive substantial financial support from industry. As the PHS explains: “We proposed this change due to the growth of non-profit entities that sponsor such activities since the 1995 regulations were promulgated. Some of these non-profit entities receive funding from for-profit entities that may have an interest in the outcome of the Investigators’ research (e.g., foundations supported by pharmaceutical companies)” (53265). In part, these new rules grew out of a 2009 NIH Office of Inspector General report that made the following recommendation: “Require Grantee Institutions to Collect Information on All Significant Financial Interests Held by Researchers and Not Just Those Deemed by Researchers to Be Reasonably Affected by the Research. . . . Full and complete disclosure ensures that the determination of whether a significant financial interest relates to the research rests with the grantee institution and not with the researcher. To maintain consistency across grantee institutions and researchers, we recommend that NIH amend 45 CFR § 50.604(c)(1) to require researchers to report all significant financial interests to the grantee institutions”; DHHS, OIG, “How NIH Grantees Manage Financial Conflicts of Interest.”

⁴¹³ AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 2.

⁴¹⁴ NIH, DHHS, FDA, CDC, “Human Subject Protection and Financial Conflicts of Interest Conference”; Shalala, “Protecting Research Subjects: What Must Be Done”; DHHS Office of Inspector General, “Protecting Human Research Subjects: Status of Recommendations”; GAO, “Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest.” In this 2001 report to Congress, the GAO called on the US Department of Health and Human Services to promulgate new regulations or to issue guidance to address institutional conflicts of interest, noting that equity ownership or other

investment in a research sponsor “may color [an institution’s] review, approval, or monitoring of research conducted under its auspices or its allocation of equipment, facilities, and staff for research.” See also: Grassley, “Payment to Physicians”; Grassley, “Grassley Works to Disclose Financial Ties between Drug Companies and Doctors”; Grassley, “Grassley Seeks Information about Medical School Policies for Disclosure of Financial Ties.”

⁴¹⁵ For a listings of these academic associations’ reports on conflicts of interest, see IOM report (2009), 41: Table 1-2: “Selected Reports on Conflict of Interest Released since 2000.”

⁴¹⁶ Discussed in IOM report (2009), 110. The AMMC survey cited here is Ehringhaus and Korn, *U.S. Medical School Policies on Individual Financial Conflicts of Interest*.

⁴¹⁷ IOM report (2009), 69. Weinfurt et al., “Policies of Academic Medical Centers for Disclosing Financial Conflicts of Interest to Potential Research Participants.”

⁴¹⁸ IOM report (2009), 221–22. The study cited here is Ehringhaus et al. 2008, “Responses of Medical Schools to Institutional Conflicts of Interest.” This study concludes as follows: “Despite strong national recommendations from 2 prominent higher education organizations, adoption of ICOI policies by US medical schools is far from complete on both dimensions. . . . wider adoption of ICOI policies covering these interests is imperative in light of the compelling interests of research integrity, protection of human subjects, and preservation of public trust” (669).

⁴¹⁹ DHHS, OIG, “How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health,” 12.

⁴²⁰ Quote from IOM report (2009), 88.

⁴²¹ AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress*, (2001), 16; AAU, Task Force on Research and Accountability, *Report on Individual and Institutional Financial Conflict of Interest*, 7–8.

⁴²² The Physician Payment Sunshine provisions were included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002), which was signed into law on March 23, 2010. The act requires manufacturers of drugs and biologic and medical devices to report certain gifts and payments (“transfers of value”) made to physicians. The information will be registered in a national and publicly accessible online database. Companies failing to report incur financial penalties. For more information, see “Pew Prescription Project Fact Sheet.”

⁴²³ For details on various state-level physician payment disclosure laws, see *ibid*. Such laws, sometimes referred to as “sunshine laws,” now exist in the District of Columbia, Minnesota, Vermont, Maine, West Virginia, and Massachusetts. Numerous other states, including New York, are considering similar legislation.

⁴²⁴ In the next few years, universities will have far more capacity—and, indeed, greater public pressure imposed on them—to verify the accuracy of faculty self-reporting concerning their financial interests. In the field of medicine, for example, universities can now check their faculty’s reported financial interests against pharmaceutical industry reporting to the federal government under the Physician Payments Sunshine Act. The Physician Payment Sunshine provisions were included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002), which was signed into law on March 23, 2010. The act requires all pharmaceutical and medical device makers to report payments to physicians through a publicly accessible database. Many states have also implemented similar disclosure and reporting rules.

⁴²⁵ IOM report (2009), 189–215, 46.

⁴²⁶ AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 2.

⁴²⁷ Quote comes from the AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 36.

⁴²⁸ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 31. A similar quote may also be found in AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution’s Financial Interests in Human Subjects Research* (Washington, DC: AAMC, 2002), 240, available at <http://www.aamc.org/research/coi/2002coireport.pdf>

⁴²⁹ IOM report (2009), 216.

⁴³⁰ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*: “A. Development and Adoption of Policies. Although the Advisory Committee was charged with examining institutional conflicts of interest specifically in the context of human subjects research, *the Committee urged AAU and AAMC member institutions to commit themselves to develop and implement comprehensive institutional conflicts of interest policies that govern all operational aspects of a university or an academic medical center*” [Emphasis added] (xi). The report reiterates this point later: “Institutions should assure in policy and practice that institutional COIs will be addressed consistently throughout the institution, such that those subject to institutional financial conflict of interest policies, specifically officials of the institution and the institutions themselves, are subject to substantive reporting, disclosure, and management of their financial interests to protect the integrity of human subjects research and the subjects who participate in it, as well as institutional values and decision-making” (15). Similar consistency of implementation is required for individual COI rules as well, of course, and is addressed elsewhere by these organizations.

⁴³¹ See, e.g., IOM report (2009): “To manage identified conflicts of interest and to monitor the implementation of management recommendations, institutions should create a conflict of interest committee. That committee should use a full range of management tools, as appropriate, including elimination of the conflicting financial interest, prohibition or restriction of involvement of the individual with a conflict of interest in the activity related to the conflict, and providing additional disclosures of the conflict of interest. A conflict of interest committee should bring experience and consistency to evaluations of financial relationships with industry and decisions about those relationships, although the specific

details (e.g., how risks and potential benefits are assessed and what management options are considered) may vary, depending on the activity in question” (89–90). The report further notes that these standing committees should have no members who themselves have conflicts of interest relevant to their COI oversight functions (226–27).

⁴³² According to the IOM report (2009): “Standing Committees will ensure that policies are applied fairly across the institution” (60). Under “Fairness,” the IOM report continues: “The formal principle of fairness requires similar treatment for those in relevantly similar situations and different treatment for those in relevantly different situations. This principle has at least two implications for the application of conflict of interest policies. First, these policies should apply to all employees or members of an institution who make significant decisions for the institution or who have substantial influence over these decisions. . . . Second, fairness requires that individuals in different institutions who are in situations that are similar in all ethically relevant ways be treated similarly. Otherwise, the ethical basis for policies may be called into question and conflict of interest policies and decisions may be regarded as arbitrary” (ibid.).

⁴³³ This is consistent with a recommendation made in AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 7.

⁴³⁴ IOM report (2009), 224–25.

⁴³⁵ This recommendation is a slightly adapted version of one issued in AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, viii.

⁴³⁶ Doug Lederman, “Revised Rules on Financial Conflicts,” *Inside Higher Ed.com*, August 24, 2011. Quotes from “Proposed Rules, Department of Health and Human Services,” 42 CFR Part 50 and 45 CFR Part 94, *Federal Register* 75.98 (May 21, 2010), available at <http://www.gpo.gov/fdsys/pkg/FR-2010-05-21/pdf/2010-11885.pdf>.

⁴³⁷ DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors.” This section reads as follows: “With regard to ‘paid authorship,’ although it should be clear that receipt of payment from an entity in exchange for drafting a publication constitutes payment for services, we believe it is important to reference this form of payment specifically in the regulations. *We are particularly concerned about situations in which Investigators may have accepted payment from private entities, in return for allowing their names to be used as authors on publications for which they had very limited input. This practice has come under increasing scrutiny in recent years and we wish to make it clear to Institutions and Investigators that such activity may be subject to the disclosure and reporting requirements depending on the circumstances of a given case, such as the amount of payment*” [Emphasis Added] (53264).

⁴³⁸ Under the new PHS rules, income from seminars, lectures, advisory committees, review panels, and teaching engagements, if sponsored by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a), are exempted from federal reporting requirements. However, if such income stems from another type of nonprofit, it is not. DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors.”

In comments, the PHS explains: “We proposed this change due to the growth of non-profit entities that sponsor such activities since the 1995 regulations were promulgated. Some of these non-profit entities receive funding from for-profit entities that may have an interest in the outcome of the Investigators’ research (e.g., foundations supported by pharmaceutical companies)” (53265).

⁴³⁹ D. J. Rothman, W. J. McDonald, C. D. Berkowitz, et al., “Professional Medical Associations and Their Relationships with Industry: A Proposal for Controlling Conflict of Interest,” *Journal of the American Medical Association* 301.13 (2009): 1367–72.

⁴⁴⁰ IOM report (2009), 220. N. Stotland, “APA Responds to Sen. Grassley,” *Psychiatric News* 43.17 (2008): 3; M. Perrone, 2009. “Drugmakers’ Push Boosts ‘Murky’ Ailment,” Associated Press, February 8, 2009, available at <http://abcnews.go.com/Business/WireStory?id=6831203&page=3>.

⁴⁴¹ It has become quite common for corporations to fund seemingly independent non-profit groups, and/or to create new non-profits with beneficent-sounding names and seemingly objective programs, to advance their corporate sponsors’ commercial and public relations interests. For a review these seemingly independent industry-funded groups, including professional associations, charities, and non-profit industry-created front groups, and their sources of funding see: Center for Science in the Public Interest (CSPI), *Lifting the Veil of Secrecy*, Washington DC, July 2003, available at <http://www.cspinet.org/new/200307092.html> The main research and data component of this report is available at http://cspinet.org/new/pdf/lift_the_veil_guts_fnl.pdf. Some examples cited include: the Foundation for Clean Air Progress (funded by petroleum, trucking, and chemical companies), the Coalition for Animal Health (funded by cattle, hog, and agribusiness concerns), and the Center for Consumer Freedom (originally funded by Philip Morris, and later funded by chain restaurants and bars). Another example cited here is the Air Quality Standards Coalition. According to the *Washington Post*, this is a “coalition of more than 500 businesses and trade groups...Created specifically to battle the clean air proposals, the coalition operates out of the offices of the National Association of Manufacturers, a Washington-based trade group. Its leadership includes top managers of petroleum, automotive and utility companies.” Another example cited is the Center for Indoor Air Research. According to *US Newswire* (“Statement by Matthew L. Myers, Campaign for Tobacco Free Kids,” *US Newswire*, National Desk, May 15, 2003), “the center for Indoor Air Research (CIAR) was . . . shut down by the state attorneys general as part of the 1998 state tobacco settlement. [On] January 29, 2003, court filings to support its racketeering lawsuit against the tobacco industry, the US Department of Justice stated, ‘CIAR was officially

created . . . to act as a coordinating organization for Defendants' efforts to fraudulently mislead the American public about the health effects of ETS [environmental tobacco smoke] exposure.' The Justice Department also stated that CIAR 'was not only used for litigation and public relations, but it was [sic] also funded research designed not to find answers to health questions, but solely to attack legislative initiatives related to ETS exposure. Lawyers specifically engineered and constructed scientific studies to get results that would be useful for public relations, litigation, and legislative battles, as opposed to results that would assist the scientific community in further understanding the health effects of ETS exposure.'" With respect to university research in particular, CSPI's *Lifting the Veil of Secrecy* report also identifies more than thirty university-based research centers that draw substantial financial support from companies or corporate trade associations. Among these are several university centers on forestry funded by timber or paper industries, and several centers on nutrition funded by food and agribusiness companies. According to CSPI, "All such centers let corporations put an academic sheen on industry-funded research."

⁴⁴² American Association of Universities, "Statement of Guiding Principles Regarding Institutional Relationships with Student Loan Providers," April 26, 2007, available at http://www.aau.edu/policy/student_loans.aspx?id=8406.

⁴⁴³ New York State Office of Attorney General Andrew M. Cuomo, "College Loan Code of Conduct," available at <http://www.ag.ny.gov/sites/default/files/press-releases/archived/College%20Code%20of%20Conduct.pdf>. See also US House Education and Labor Committee, "Student Loan Industry; Testimony by Andrew M. Cuomo, Attorney General," CQ Congressional Testimony, *Congressional Quarterly*, April 25, 2007. This "Code of Conduct" prohibits revenue sharing, and kickbacks in other forms, as well as lender financing of gifts and trips for institutions' financial aid employees. The code further prohibits lender-staffed call centers and lays out strong guidelines concerning, among other things, preferred lender lists, advisory board compensation, and loan resale.

⁴⁴⁴ *Federal Register* 72.211 (November 1, 2007): 61, 959-62,011. These DOE rules, attached to eligibility for federal student aid, require colleges to include at least three lenders on a preferred lender list, restrict lender gifts to colleges in exchange for business, prohibit payments to college financial aid employees, and encourage loan counseling.

⁴⁴⁵ Many of these state-level laws are reviewed in California Research Bureau, "Student Loans for Higher Education," January 2008, CRB 08-002.

⁴⁴⁶ The Board of Governors of the Federal Reserve system was mandated, in accordance with Section 305 of the Credit Card Accountability Responsibility and Disclosure Act of 2009, Pub. L. No. 111-24, 123 Stat. 1734 (2009), to make these annual reports to Congress. In 2011, pursuant to Title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, responsibility for preparing these annual reports transferred to the newly established Bureau of Consumer Financial Protection.

⁴⁴⁷ Information included in this report is also available on the board's public website at www.federalreserve.gov/collegedebitcardagreements. In addition, under Section 304 of the Credit CARD Act and the Board's implementing regulations, 12 C.F.R. § 226.57(b), the public can obtain college credit card agreements between a card issuer and an institution of higher education directly from the institution.

⁴⁴⁸ Nancy Zuckerbrod, "Education Dept. Places Official on Leave," *AP Education Writer*, April 6, 2007:

A Department of Education official who oversaw the student loan industry and owned at least \$100,000 worth of stock in a student loan company has been placed on leave, a department spokeswoman said Friday.

Matteo Fontana, who keeps an eye on lenders and guarantee agencies that participate in the Federal Family Education Loan Program, was placed on leave with pay a day after his ownership of stock in Education Lending Group Inc. was disclosed by Higher Ed Watch, part of the New America Foundation, a nonpartisan think tank.

The case has been referred to the department's inspector general. . . . At issue is whether Fontana violated department conflict of interest rules.

⁴⁴⁹ New York Attorney General Andrew Cuomo, "Letter to College Presidents," March 2007, document no longer available online, formerly accessed at <http://www.oag.state.ny.us/press/2007/mar/OAG%20Letter%20to%20Colleges.pdf>.

⁴⁵⁰ Karen Arenson and Diana Jean Schemo, "Report Details Deals in Student Loan Industry," *New York Times*, June 15, 2007; Doug Lederman, "Two More Aid Directors Fall," *Inside Higher Ed*, May 22, 2007, available at <http://www.insidehighered.com/news/2007/05/22/loans#ixzz1p2g2KsZw>; Jon Marcus, "Fury over Kickback Allegation," *Times Higher Education*, May 11, 2007.

⁴⁵¹ US House Education and Labor Committee, "Student Loan Industry; Testimony by Andrew M. Cuomo, Attorney General," CQ Congressional Testimony, *Congressional Quarterly*, April 25, 2007, available at http://www.ag.ny.gov/sites/default/files/pdfs/bureaus/legislative/other_documents/House_Testimony.pdf.

⁴⁵² US Senate Health, Education, Labor, and Pensions Committee, *Report on Marketing Practices in the Federal Family Education Loan Program*, July 2007; and US Senate Health, Education, Labor and Pensions Committee, *Second Report on Marketing Practices in the Federal Family Education Loan Program*, September 4, 2007. See also Marcus, "Fury over Kickback Allegation."

⁴⁵³ Marcus, "Fury over Kickback Allegation."

⁴⁵⁴ See California Research Bureau, "Student Loans for Higher Education," which reports the following university settlement payments: Columbia University—\$1.1 million; New York University—\$1,394,563.75 covering students who

received loans issued over a five-year period; St. John's University—\$80,553.00 for loans issued over a one-year period; Syracuse University—\$164,084.74 for loans issued over a two-year period; Fordham University—\$13,840.00 for loans issued over a one-year period; University of Pennsylvania—\$1,617,580.00 for loans issued over a two-year period; and Long Island University—\$2,435.41 for loans issued over a one-year period.

⁴⁵⁵ Jonathan Glater and Karen Arenson, "Lenders Sought Edge against U.S. in Student Loans," *New York Times*, April 15, 2007.

⁴⁵⁶ Paul Basken, "Colleges Are Again Asked about Lender Dealings," *Chronicle of Higher Education* 54.11 (November 9, 2007): 25.

⁴⁵⁷ US Senate Health, Education, Labor, and Pensions Committee, *Report on Marketing Practices in the Federal Family Education Loan Program*, July 2007; and US Senate Health, Education, Labor, and Pensions Committee, *Second Report on Marketing Practices in the Federal Family Education Loan Program*.

⁴⁵⁸ Quoted in Elizabeth Redden, "A 'Systemic' Scandal," *Inside Higher Ed.*, June 15, 2007. See also Government Accountability Office (GAO), "Federal Family Education Loan Program," GAO-07-750, July 2007, 10, citing 20 U.S.C. § 1085(d)(5)(A) and C.F.R. § 682.603(e)(3), which reads in part as follows: "The Higher Education Act of 1965 prohibits lenders from offering 'points, premiums, payments, or other inducements' to individuals or institutions 'in order to secure [student loan] applicants,' and prohibits schools from engaging 'in any pattern or practice that results in a denial of the borrower's access to FFEL loans . . . because of . . . selection of a particular lender.'"

⁴⁵⁹ GAO, "Federal Family Education Loan Program," 8.

⁴⁶⁰ See, e.g., Laurel Rosenhall, "CSUS, UC Davis Strike Deals to Let IDs Be ATM Cards," *Sacramento Bee*, August 12, 2010, which reports the following: "The photo ID cards issued to UC Davis students this fall will have a new feature: a built-in connection to a bank that wants their business. The cards students use to borrow books from the library and work out in the campus gym will now double as ATM debit cards—if they sign up for a US Bank account. California State University, Sacramento, has a similar arrangement with Wells Fargo. New students going through orientation this week stopped in a campus office to have their pictures taken, then proceeded to a tent where Wells Fargo employees offered free iPod speakers to those linking their ID cards to a new Wells Fargo account."

⁴⁶¹ New America Foundation, Higher Ed Watch blog post, "Selling Out Students When State Support Drops," April 15, 2008, available at

http://higheredwatch.newamerica.net/blogposts/2008/selling_out_students_when_state_support_drops-19351.

⁴⁶² *Ibid.*

⁴⁶³ Paul Basken, "Iowa Lawmakers Shine Spotlight on Lending Abuses," *Chronicle of Higher Education* 54.11 (November 9, 2007): 22.

⁴⁶⁴ New America Foundation, Higher Ed Watch blog post, "Selling Out Students When State Support Drops."

⁴⁶⁵ Federal Reserve Board of Governors, *Report to the Congress on College Credit Card Agreements*, October 2010, available at http://www.federalreserve.gov/boarddocs/rptcongress/creditcard/2010/downloads/CCAP_October_web.pdf.

⁴⁶⁶ California Research Bureau, "Student Loans for Higher Education."

⁴⁶⁷ Nellie Mae Corporation, *Graduate Students and Credit Cards*, fall 2006, accessed at

http://www.nelliemae.com/pdf/ccstudy_2006.pdf.

⁴⁶⁸ IOM report (2009), 222.

⁴⁶⁹ "Separation of Administrative Responsibility," in AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, xi–xii.

⁴⁷⁰ This discussion is drawn from AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 11.

⁴⁷¹ H. Moses and J. B. Martin, "Academic Relationships with Industry: A New Model for Biomedical Research," *Journal of the American Medical Association* 285 (2001): 933.

⁴⁷² This is adapted from AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 13–14; and IOM report (2009), 64.

⁴⁷³ DHHS, "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors," 53291, 53292.

⁴⁷⁴ IOM report (2009), 75.

⁴⁷⁵ Charles Grassley, "Grassley Works to Protect Medicare Dollars, Empower Patients with Information," press release, July 25, 2008, available at <http://www.senate.gov/~finance/press/Gpress/2008/prg072508.pdf>; Grassley, "Payment to Physicians"; Grassley, "Grassley Works to Disclose Financial Ties between Drug Companies and Doctors."

⁴⁷⁶ Council on Governmental Relations (COGR), *Recognizing and Managing Personal Financial Conflicts of Interest* (Washington, DC: COGR, 2002), available at <http://www.cogr.edu/docs/COIFinal.pdf>; quoted in IOM (2009), 76.

⁴⁷⁷ Quoted in IOM (2009), 76. American Medical Student Association (AMSA), *PharmFree Scorecard, 2008* (Reston, VA: AMSA: 2008), available at <http://amsascorecard.org/>. According to the IOM report (2009), AMSA's methodology for conducting these policy reviews involved two independent, trained reviewers who read the policies that the medical schools submitted (without identifying information) and then rated them according to specified criteria. For the administration and oversight categories, the reviewers gave Yes or No answers to these two questions: Is it clear that there is a party responsible for general oversight to ensure compliance? Is it clear that there are sanctions for noncompliance?

⁴⁷⁸ Davidoff et al., “Sponsorship, Authorship, and Accountability”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”; ICMJE, “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication”; WAME, “Recommendations on Publication Ethics Policies for Medical Journals.”

⁴⁷⁹ DHHS, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors.” For details on the DHHS’s new requirements for public disclosure of significant faculty COI related to DHHS funded research, and the development of detailed COI “management plans,” see 53287–88. The section on public disclosure reads as follows:

(5)(i) Prior to the Institution’s expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator’s name; the Investigator’s title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution’s receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution’s identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution’s identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution’s publicly accessible Web site for at least three years from the date that the information was most recently updated.

⁴⁸⁰ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*: “D. Pre-Clinical Research. The Advisory Committee believed that certain pre-clinical research may warrant special attention where there is a reasonable anticipation of follow-on human subjects research in the immediate future. Recommendation: With respect to pre-clinical research, institutions should consider requiring covered individuals to indicate if their current non-human subjects research that is linked to any of their reportable financial interests is reasonably anticipated (1) to be a component of an IND submission or (2) to progress to research involving human subjects within the coming 12 months. In such circumstances, the institution’s conflicts of interest committee should have the authority to decide whether any of the policy stipulations that apply to human subjects research should apply to this ‘pre-clinical’ stage of the individual’s research” (viii).

⁴⁸¹ AAMC, *In the Interest of Patients*, 5–6. The AAMC offers this definition of a COI in area of clinical practice: “A clinical practice conflict of interest . . . occurs when a secondary financial interest creates the risk that the primary duty to the patient and the delivery of optimal care will be unduly influenced by personal financial interests of the care provider or care provider institution. Institutional financial conflicts of interest similarly should not interfere with the delivery of the most appropriate care and best use of patient care resources” (9).

⁴⁸² “Medical Professionalism in the New Millennium: A Physician Charter” (American Board of Internal Medicine, American College of Physicians Foundation, and European Federation of Internal Medicine, 2002), available at <http://www.abimfoundation.org/Professionalism/%7E/media/F8B71F15DE8B486599F13E662603F25D.ashx>.

⁴⁸³ IOM report (2009), chap. 6: “Conflicts of Interest and Medical Practice,” 166–88.

⁴⁸⁴ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*. The AAMC-AAU notes the following: “Conflicts of Interest in Clinical Practice: The Advisory Committee, while respectful of its circumscribed charge with respect to conflicts of interest in human subjects research, recognizes that many scientists who engage in human subjects research and have related significant financial interests also have active clinical practices in which those financial interests may be problematic and warrant institutional oversight. The Committee also recognizes that oversight and management of such conflicting financial interests of physician faculty in clinical practice settings is warranted. Recommendation: Institutions should adopt policies and establish standards that minimize bias in the practice of medicine due to real or perceived conflicts of interest of their medical faculty” (11).

⁴⁸⁵ AAMC, *In the Interest of Patients*, 5–6.

⁴⁸⁶ “Conflict of Interest in Medical Research, Education, and Practice,” Statement of Eric G. Campbell, Ph.D. Associate Professor Director of Research Institute for Health Policy Massachusetts General Hospital Harvard Medical School and Member, Committee on Conflict of Interest in Medical Research, Education, and Practice Board on Health Sciences Policy, Institute of Medicine, the National Academies, before the Special Committee on Aging, US Senate, July 29, 2009, available at <http://aging.senate.gov/events/hr214ec.pdf>.

⁴⁸⁷ This AAUP recommendation was adapted only slightly from one issued in IOM (2009), 117–18: see Recommendation 4.1. In its “Report Brief,” the IOM summarizes its position as follows: “Although the committee recognizes that collaborations with industry can be beneficial, the committee recommends, as a general rule, that researchers should not conduct research involving human participants if they have a financial interest in the outcome of the research, for example, if they hold a patent on an intervention being tested in a clinical trial. The only exceptions should be if an individual’s participation is judged to be essential for the safe and appropriate conduct of the research” (2).

⁴⁸⁸ AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress*, 2001; AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress II* (2002); AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health* (2008). Here is how the AAMC’s *Protecting Patients* report expresses this recommendation: “Decisions about whether or not to pursue a particular human subjects research project in the presence of an institutional conflict of interest should be governed by a ‘rebuttable presumption’ against doing the research at or under the auspices of the conflicted institution” (15) unless a compelling case can be made to justify an exception.

⁴⁸⁹ IOM report (2009), 80.

⁴⁹⁰ AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 38–39.

⁴⁹¹ IOM report (2009), 118.

⁴⁹² AAMC-AAU, *Protecting Patients, Preserving Integrity, Advancing Health*, 11. This recommendation reads in part as follows: “Institutions should have clear policies, compliant with applicable federal regulations that address the reporting and management of conflicts of interest of IRB members. The provisions should require reporting of all financial interests (no de minimis threshold) by IRB members . . . upon their initial appointment to the IRB, with updating annually and more often when circumstances change. The provisions should specify how the IRB Chair and/or the Administrator of the IRB will identify and evaluate potential conflicts of interest of IRB members and make clear that any conflicted IRB member must be recused from any deliberations relating to studies with which that IRB member has a potential conflict of interest.”

⁴⁹³ AAU, *Report on Individual and Institutional Financial Conflict of Interest*.

⁴⁹⁴ See, e.g., Eric C. Campbell, Joel S. Weissman, et al., “Characteristics of Medical School Faculty Members Serving on Institutional Review Boards: Results of a National Survey,” *Academic Medicine* 78.8 (August 2003): 831–36. Also, a 2002 Inspector General’s report estimated that about 25% of IRBs in the department’s study were taking action to recognize and manage conflicts of interest among members. DHHS Office of Inspector General, “Protecting Human Research Subjects: Status of Recommendations.”

⁴⁹⁵ Department of Health and Human Services, Office of Inspector General (OIG), “Institutional Review Boards: A Time for Reform,” June 1998, OEI-01-97-00193, available online at <http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf>; Department of Health and Human Services, Office of Inspector General (OIG), “Institutional Conflicts at NIH Grantees,” January 2011, OEI-03-09-00480, available at <http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf>. See also Adil E. Shamoo, “Institutional Review Boards (IRBs) and Conflict of Interest,” *Accountability in Research: Policies and Quality Assurance* 7.2–4 (1999) 201–212, available at <http://www.tandfonline.com/doi/abs/10.1080/08989629908573952>.

⁴⁹⁶ AAU, *Report on Individual and Institutional Financial Conflict of Interest*, 6. This section reads in part as follows: “One effective way to integrate [IRB and standing COI committee] processes is for [the standing] conflict of interest committees or officials to try to review financial interest disclosures regarding human subject protocols before protocols are submitted to the IRB (however the timing works out, the idea is for the conflict of interest review to take place in time to affect any informed consent). The conflict of interest committee or official can then determine whether a conflict exists, and if so, how it should best be managed, if it should be (see guideline above indicating that such conflicts should generally not be allowable), or can be. This determination, and summary information about the financial interests, can then accompany a protocol when it is presented to the IRB. The IRB could then take this information into account when determining whether and under what circumstances to approve a given protocol. Universities should consider designing systems so that an IRB also may determine if there is a financial conflict of interest that needs to be managed, or if a Management Plan implemented by the conflict of interest committee or official should be made more stringent. In such a

system, neither the IRB nor the conflict of interest committee would be able to override the other's management requirements if the result would be to lessen the stringency of the management requirements. Either one could prohibit the research from proceeding, unless the financial conflict was removed or mitigated. Such a double-protection system would be consistent with the two sets of federal regulations governing clinical research, and provide the additional safeguards that research involving human participants demands. In whatever way a campus's conflict of interest and human participant protection systems are designed, the focus should be on coordination and communication of the two systems."

⁴⁹⁷ IOM report (2009), 69. Weinfurt et al., "Policies of Academic Medical Centers for Disclosing Financial Conflicts of Interest to Potential Research Participants."

⁴⁹⁸ This recommendation is drawn from AAMC, *Industry Funding of Medical Education*; see recommendations on "Purchasing," ix.

⁴⁹⁹ AAMC, *In the Interest of Patients*, 23.

⁵⁰⁰ *Ibid.*, 24.

⁵⁰¹ On July 30, 2003, Cornell University's administration completed the Cornell University Strategic Corporate Alliance Plan ("the Plan"), the objective of which was "to leverage access to Cornell University intellectual capital, including faculty research, into major corporate alliances leading to competitive opportunities for select companies and financial support for faculty research and related infrastructure." The Plan defines a strategic corporate alliance (SCA) as a comprehensive, formally managed company-university agreement centered around a major, multiyear financial commitment involving research, programmatic interactions, intellectual property licensing, and other services. The initial companies targeted were in the life sciences sector, but the Plan contemplated "expand[ing] the alliance concept to other industries beyond the scope of the New Life Sciences." Cornell Strategic Alliance Plan (July 30 version) at 1, 4 [Appendix A]. This version of the Plan superseded an earlier draft.

⁵⁰² Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," 5.

⁵⁰³ Rebecca Knight, "Big Pharma Gravitates to the Academe," *Financial Times*, September 2, 2008.

⁵⁰⁴ GlaxoSmithKline and Harvard Stem Cell Institute Announce Major Collaboration Agreement, *HarvardScience*, press release, July 24, 2008, available at <http://news.harvard.edu/gazette/story/2008/07/glaxosmithkline-and-harvard-stem-cell-institute-announce-major-collaboration-agreement/>. See also Center for Science in the Public Interest, "Integrity in Science Watch, Week of 09/08/2008," available at <http://www.cspinet.org/integrity/watch/200809081.html>.

⁵⁰⁵ Arlene Weintraub, "Big Drug R&D on Campus: With Pipelines Drying up, Drugmakers Are Enlisting Universities to Help Create New Treatments," *Business Week*, May 8, 2008.

⁵⁰⁶ Bernadette Tansey, "UCSF, Pfizer Sign Collaborative Research Deal," *San Francisco Chronicle*, June 10, 2008.

⁵⁰⁷ Knight, "Big Pharma Gravitates to Academe."

⁵⁰⁸ Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," 16.

⁵⁰⁹ *Ibid.*; UC-Berkeley, Academic Senate, faculty committee letter addressed to Prof. William Drummond, Chair of the Berkeley Division of the Academic Senate, November 2, 2007, e398; UC-Berkeley Academic Senate Task Force on University-Industry Partnerships, "Principles and Guidelines for Large-Scale Collaborations between the University and Industry, Government, and Foundations," e79, 1-23.

⁵¹⁰ Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*, 41-43.

⁵¹¹ California State Legislature, Senate, "Impacts of Genetic Engineering on California's Environment: Examining the Role of Research at Public Universities (Novartis/UC Berkeley Agreement)," Joint Hearing, Committee on Natural Resources and Wildlife, Senate Select Committee on Higher Education, California State Legislature, Sacramento, May 15, 2000.

⁵¹² Washburn, *Big Oil Goes to College*.

⁵¹³ *Ibid.*; see Summary of Findings, 52-59, questions 10 and 11.

⁵¹⁴ *Ibid.*; see discussion on 22, 60, and 64-65. This reads in part as follows: After the BP-funded Energy Biosciences Institute deal was finalized at the end of 2007, "U.C. Berkeley's press office announced that the executive committee charged with evaluating faculty research projects for possible BP funding would have strong majority academic representation. And when the first formal executive committee convened in 2008 it had eight members, seven of whom were academics and one of whom was a representative from BP. But when this report's author probed a bit deeper, she soon found that seven of these eight committee members had significant potential conflicts of interest, including all but one of the academics. Two of the eight executive committee members, including the EBI's Academic Director and the lone BP representative, had financial ties to firms that could stand to profit from the EBI's academic research. And five of the other committee members had a different potential conflict: All were listed on the EBI website, in the spring of 2008, as 'primary investigators' on research projects funded by BP-EBI. What this strongly suggests is that all five could award BP research grant money to themselves and their labs. At the very least, the application and receipt of BP-EBI funding calls into question whether these faculty members were capable of fairly and impartially evaluating other faculty research proposals. More recently, these potential conflicts of interest on the EBI's executive committee seem to have only worsened. As of September 2010, the EBI listed a total of 13 executive committee members: 11 academics and two representatives from BP. Yet 10 of these academics are also listed as primary EBI investigators or heads of projects supported with BP-EBI funding, and one, EBI Director Chris Somerville, continues to have personal financial interests in

an outside firm partnering with BP on research that is similar to that of EBI. That means three of the executive committee's 13 members have financial ties to firms that could profit from EBI research, and the other 10 are academic researchers who have vested research and financial interests with the EBI that could compromise their ability to evaluate incoming faculty research in an impartial and disinterested manner, based on scientific merit" (22).

⁵¹⁵ Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*, 41–43. The report reads: "Regardless of whether [Prof. Ignacio] Chapela's denial of tenure was justified, there is little doubt that the UCB-N agreement played a role in it. First, the very existence of UCB-N changed the rules of the game. Certain faculty were denied participation in the process because of the agreement. Second, while the administration saw fit to avoid conflict of interest (COI) among faculty, they ignored the potential for COI among administrators. Thus, regardless of its validity, the decision of top administrators to accept the decision of the Budget Committee was seen by many as a COI" (42-43).

⁵¹⁶ Regarding UC-Berkeley-BP see UC-Berkeley Academic Senate, Task Force on University-Industry Partnerships, "Principles and Guidelines for Large-Scale Collaborations between the University and Industry, Government, and Foundations," e79, 12–13; regarding UC-Berkeley-Novartis/Syngenta, see Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*, which reads in part as follows: "The third structural component of the agreement that caused consternation among the campus community and others was the possibility Novartis scientists would be given adjunct status. While the agreement does not preclude the possibility for adjunct status for NADI employees, it never materialized. Several interviewees noted that this is most likely because of strong opposition from faculty outside of PMB. This position is supported by the second survey conducted by the ExCom of CNR. Few respondents to the survey thought adjunct status was appropriate for industry scientists from a firm that was either providing funding to CNR or one of its departments. In interviews, a number of faculty argued that granting Novartis scientists adjunct status would have bypassed the established governance procedures and stringent standards that are normally required for adjunct status. Many critics of the agreement also felt that the offer of adjunct status was a way for Novartis to buy its way into the UCB campus. However, some of those involved in the negotiation of the agreement argued that adjunct status for NADI employees was proposed by PMB as a way to facilitate closer interaction" (49–50).

⁵¹⁷ Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," 9.

⁵¹⁸ Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*.

⁵¹⁹ See, e.g., California State Legislature, Senate, "Impacts of Genetic Engineering on California's Environment"; Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*; and Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances."

⁵²⁰ Busch et al., *External Review of the Collaborative Research Agreement between Novartis Agricultural Discovery Institute, Inc. and the Regents of California*, 143.

⁵²¹ Cornell University, "Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances," 9.

⁵²² *Ibid.*

⁵²³ Washburn, *Big Oil Goes to College*.

⁵²⁴ The author obtained ten large-scale SCA contracts between universities and energy industry sponsors from direct requests to universities, and though public record requests. The author generated a list of twenty-seven questions addressing a range of issues from voting authority on the SCA's governance bodies and peer review, to intellectual property provisions and delays on publication. The author then commissioned outside, independent legal experts to analyze each of the ten contracts by applying this common set of twenty-seven questions. Washburn, *Big Oil Goes to College*, see Methodology Box (15), a chart of ten contracts reviewed (13–14), and a Summary of Findings in response to all twenty-seven contract review questions for each of the ten contracts (52–59).

⁵²⁵ Elizabeth D. Earle, plant breeding and genetics; John M. Guckenheimer, mathematics (joining in this statement except for Section D); Anthony R. Ingraffea, civil and environmental engineering; David A. Levitsky, nutritional science; Risa L. Lieberwitz, industrial and labor relations; David L. Pelletier, nutritional science; Peter C. Stein, physics; Steven A. Wolf, natural resources; Elaine Wethington, human development; Cynthia R. Farina, associate dean of the faculty, chair (nonvoting); Charles Walcott, dean of the faculty, ex officio.

⁵²⁶ Risa L. Lieberwitz, "Faculty in the Corporate University: Professional Identity, Law, and Collective Action," *Cornell Journal of Law and Public Policy* 16 (2007): 263–330, see 310–18. According to Lieberwitz, a professor at the Cornell University School of Industrial and Labor Relations who sat on the Cornell faculty senate committee charged with reviewing Strategic Corporate Alliance (SCA) agreements on campus, there were three central areas of debate among the faculty on this committee: "The most contentious issues concerned the extent of the corporate funder's role in the university's decisions relating to research funding, the scope of SCAs subject to the principles recommended in the report, and the corporate sponsor's access to research results through 'first look' and exclusive licensing rights. The primary disagreement focused on corporate funders' participation in decisions over funding awards. The Spring 2004 version of the report had restricted corporate funders to participation in the call for research funding proposals (RFPs). In helping to draft the RFPs, the corporate funders could express their research priorities. After this point, however, faculty would have

complete control over the funding award decisions. The Cornell administration took the position that excluding the corporate funder from decisions about awarding research proposals and from exclusive licensing would be ‘deal killers’ in negotiations to enter a SCA. The Spring 2005 version compromised by giving the corporate funders a role in awards decisions, but limited corporate representation to one-third of the members on the selection committee. The Faculty Senate debate of this provision revealed the likelihood that a majority of the Senate would vote to remove this cap. The final version of the report, therefore, eliminated the one-third corporate membership restriction. The final report, which was endorsed by the Faculty Senate in Fall 2005, gives the corporate sponsor the general right to participate in awarding funds to faculty research proposals. The report does emphasize, however, that ‘this process should be led by Cornell faculty.’ Each draft of the report recommended the use of a peer review process of research proposals submitted by faculty seeking SCA funds. The peer reviews by panels of ‘disinterested scholars’ at Cornell would provide input to the selection committee on the merit of the research proposals. The final report, however, limits peer review to ‘broad SCAs,’ defined as corporate funding of ‘a potentially large group of faculty.’ ‘Narrow SCAs,’ involving ‘a small number of specific faculty . . . identified in advance as the relevant researchers,’ would not use either RFPs for funding distribution or peer review to evaluate the merit of proposals. A third area of controversy concerned the scope of corporate funders’ ‘first-look’ and exclusive licensing rights. Each version of the report incorporated the existing Cornell policy that restricted corporate funders to a maximum 90-day pre-publication period of first-look rights. This 90-day period would enable the corporate sponsor to review the research to determine if it contained confidential corporate information that would need to be eliminated. This time also provides a period for the university to file patent applications and for the corporate sponsor to negotiate exclusive licensing rights to future patents. Although the report does not challenge these practices, it does urge the use of non-exclusive licenses, whenever possible. It further recommends that SCA agreements provide for Cornell’s right to freely distribute all research methods and results to researchers in any academic setting” (311–13).

⁵²⁷ For one researcher’s experience, see Washburn, *Big Oil Goes to College*: “Out of a total of 35 requests for specific university-industry alliance agreements, the author issued 24 as formal ‘public record act’ (PRA) filings, citing the actual public record laws applicable in each state. State-funded universities are normally subject to public record act laws, due to their receipt of substantial state funding. (The author made the remainder of our requests more informally via phone and email, often in conjunction with scheduled phone interviews with university staff and administrators.) *State universities failed to fulfill or outright ignored more than half of these 24 legal public record act requests. Often documents were released only after substantial delays. In two instances, both the University of Houston and Texas A&M University forwarded our public record act requests (related to major academic-industry research alliances with General Motors and Chevron, respectively) all the way up to the Texas Attorney General’s office. In both cases, the Texas AG’s office required the universities to make those requested documents public; however, this resulted in roughly two- and four-month-long delays, respectively.* Sources: Email correspondence between the author and officials at the University of Houston and Texas A&M University, pertaining to public record act requests that the author filed on November 9, 2007 and November 12, 2007 respectively” (11n34). **{Your emphasis?}**

⁵²⁸ AAUP, “Statement on Government of Colleges and Universities” (1966–67), in AAUP, *Policy Documents and Reports*, 135–40.

⁵²⁹ AAUP, “Statement on Corporate Funding of Academic Research” (2004), in AAUP, *Policy Documents and Reports*, 132.

⁵³⁰ Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” 19–20.

⁵³¹ *Ibid.*, 20.

⁵³² “The important point—vital to honoring the principle that we are engaged in academic, not corporate research—is that genuine, disinterested peer review occur.” *Ibid.*, 21.

⁵³³ Washburn, *Big Oil Goes to College*, 64–65.

⁵³⁴ Michaels, *Doubt Is Their Product*, 53.

⁵³⁵ Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” 18.

⁵³⁶ *Working Together, Creating Knowledge*, 13, 51.

⁵³⁷ *Ibid.*, 51.

⁵³⁸ Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” 13.

⁵³⁹ *Ibid.*, 14.

⁵⁴⁰ *Ibid.*, 12.

⁵⁴¹ AAUP, “Statement on Conflicts of Interest” (June 1990), in AAUP, *Policy Documents and Reports*, 185–86.

⁵⁴² Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” 12.

⁵⁴³ AAUP, “Statement on Government of Colleges and Universities” (1966–67), in AAUP, *Policy Documents and Reports*, 135–40.

⁵⁴⁴ AAUP, “Statement on Corporate Funding of Academic Research” (2004), in AAUP, *Policy Documents and Reports*, 132.

⁵⁴⁵ Cornell University, “Faculty Statement of Principles and Best Practices Concerning Strategic Corporate Alliances,” section E, 22–26. In addition to annual external faculty evaluations of the SCA, the statement also recommends: “A more comprehensive longitudinal study of the SCA experience should be initiated to examine broader issues related to potential crowding-out of public research, effect on the nature and extent of intellectual interchange among participating and non-participating faculty and students, displacement of funding from other sources, disproportionate growth across

unit, impact on external relations, and other issues. The dearth of empirical information on these matters is one of the factors impeding informed and reasoned discussion of SCAs at Cornell and elsewhere, and this study can become a resource for Cornell and the larger set of organizations interested in evolving public-private relations in the production and control of knowledge. According [sic], this study and the other activities noted above should be funded as a charge to overhead of SCAs" (25-26).

⁵⁴⁶ Federation of American Societies for Experimental Biology (FASEB), "Shared Responsibility, Individual Integrity: Scientists Addressing Conflicts of Interest in Biomedical Research," March 13, 2006, available at http://www.faseb.org/portals/0/pdfs/opa/faseb_coi_paper.pdf.

⁵⁴⁷ FASEB, *COI Toolkit: Recommendations, Tools, and Resources for the Conduct and Management of Financial Relationships between Academia and Industry in Biomedical Research* (Bethesda, MD: FASEB, 2006), available at <http://opa.faseb.org/pages/Advocacy/coi/Toolkit.htm>.

⁵⁴⁸ AAMC, *In the Interest of Patients*: "The Advisory Committee, while respectful of its circumscribed charge with respect to conflicts of interest in human subjects research, recognizes that many scientists who engage in human subjects research and have related significant financial interests also have active clinical practices in which those financial interests may be problematic and warrant institutional oversight. . . . *Recommendation*: Institutions should adopt policies and establish standards that minimize bias in the practice of medicine due to real or perceived conflicts of interest of their medical faculty."

⁵⁴⁹ ABIM Foundation, American Board of Internal Medicine; ACP-ASIM Foundation, American College of Physicians-American Society of Internal Medicine; European Federation of Internal Medicine, "Medical Professionalism in the New Millennium: A Physician Charter," *Annals of Internal Medicine* 136.3 (2002): 243-46; ABIM Foundation, "Medical Professionalism in the New Millennium: A Physician Charter," American Board of Internal Medicine website, <http://www.abimfoundation.org/Professionalism/Physician-Charter.aspx>.

⁵⁵⁰ Ehringhaus and Korn, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*.

⁵⁵¹ AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress*, (2001).

⁵⁵² FASEB, "Shared Responsibility, Individual Integrity: Scientists Addressing Conflicts of Interest in Biomedical Research" (2006): "Guiding principle 6: Investigators shall have access to, and be involved in the analysis and/or interpretation of all data generated in the research."

⁵⁵³ Davidoff et al., "Sponsorship, Authorship, and Accountability"; ICMJE, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." These standards were originally issued in 2001 in connection with the *New England Journal of Medicine* article cited above.

⁵⁵⁴ WAME, available at <http://www.wame.org/wamestmt.htm#fundres>. In its guidelines, under "Authors," WAME states: "All authors should be asked to report their financial COI related to the research and written presentation of their work and any other relevant competing interests. Journals should publish all COI (or their absence) reported by authors that are relevant to the manuscript being considered. In addition to financial COI, policies for authors should be extended to other types of competing interests that might affect (or be seen to affect) the conduct or reporting of the work. Journals should disclose all COIs that they themselves thought were important during the review process. *Declarations should require authors to explicitly state funding sources and whether the organization that funded the research participated in the collection and analyses of data and interpretation and reporting of results*" [Emphasis added].

⁵⁵⁵ Pharmaceutical Research and Manufacturers of America (PHARMA), "Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results," revised April 2009, available at http://www.phrma.org/sites/default/files/105/042009_clinical_trial_principles_final.pdf. According this PHARMA statement: "As sponsors, we are responsible for receipt and verification of data from all research sites for the studies we conduct; we ensure the accuracy and integrity of the entire study database, which is owned by the sponsor." However, many research experts now question whether this corporate ownership and tight proprietary control of data is compatible with preserving the integrity and objectivity of medical research, see Steinbrook and Kassirer, "Analysis: Data Availability for Industry Sponsored Trials: What Should Medical Journals Require?," *British Medical Journal* 341 (2010), 5391.

⁵⁵⁶ See the introduction to this AAUP report. See also Bodenheimer, "Uneasy Alliance."

⁵⁵⁷ Davidoff et al., "Sponsorship, Authorship, and Accountability."

⁵⁵⁸ ICMJE, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." See specifically "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship," available at http://www.icmje.org/ethical_1author.html.

⁵⁵⁹ AAMC, *Protecting Subjects, Preserving Trust, Promoting Progress*, (2001).

⁵⁶⁰ In 2005, the International Committee of Medical Journal Editors (ICMJE) instructed its researchers to deposit data into registries, such as ClinicalTrials.gov as a precondition for publication, hoping to discourage tampering with trial protocols and final data analysis. C. D. DeAngelis, J. M. Drazen, F. A. Frizelle, C. Haug, J. Hoey, et al., "Is This Clinical Trial Fully Registered? A Statement from the International Committee of Medical Journal Editors," *Journal of the American Medical Association* 293 (2005): 2927-29; C. DeAngelis, J. M. Drazen, F. A. Frizelle, C. Haug, J. Hoey, et al., "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors," *New England Journal of Medicine* 351 (2004): 1250-51, available at http://www.icmje.org/clin_trial.pdf. This statement reads in part as follows: "The

ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment prior to this date, the ICMJE member journals will require registration by September 13, 2005, before considering the trial for publication.”

⁵⁶¹ In 2007, Congress passed the US Food and Drug Administration Amendments Act, which mandated that clinical trials related to all FDA-regulated products, or products seeking regulation, must be registered at ClinicalTrials.gov. The law also imposes penalties for non-compliance. US Public Law 110-85 (Food and Drug Administration Amendments Act of 2007 [FDAAA]), Title VIII, Section 801, mandates that a “responsible party” (i.e., the sponsor or designated principal investigator) register and report results of certain “applicable clinical trials”; see <http://prsinfo.clinicaltrials.gov/fdaaa.html>. For an overview discussion of the FDAAA, see Elie Dolgin, “Publication Bias Continues despite Clinical-Trial Registration,” *Nature News*, September 11, 2009.

⁵⁶² In 2006, the Association of American Medical Colleges (AAMC) endorsed and finalized a set of recommended “Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials,” which recommends that all clinical trials and their protocols be registered on a publicly accessible database. (These principles were developed in collaboration with the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association.) The AAMC wrote that it developed these principles to address the “inconsistency in research standards” at academic medical centers, which “can affront human research ethics, undermine academic integrity, distort public policy and medical practice, and impair public health.” Ehringhaus and Korn, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*. See Principles 6, 7, and 8, which recommend registration of clinical trials within twenty-one days of initiating enrollment of research participants, and in a manner “fully pursuant to the ICMJE requirements” (cited above).

⁵⁶³ ClinicalTrials.gov fact sheet, available at <http://www.nlm.nih.gov/pubs/factsheets/clintrial.html>. For ClinicalTrials.gov’s main website, go to <http://clinicaltrials.gov/>.

⁵⁶⁴ Ibid: The ClinicalTrials.gov fact sheet specifies that, “Consistent with the default adverse events reporting provisions of section 801(a) of the FDA Amendments Act of 2007 (FDAAA) [as it amends 42 U.S.C. 28 2(j)(3)(I)(ii)–(iii)], starting on September 27, 2009, Responsible Parties are expected to submit summary adverse event information when providing study results to ClinicalTrials.gov.”

⁵⁶⁵ S. Mathieu, I. Boutron, D. Moher, D. G. Altman, and P. Ravaud, “Reporting and Interpretation of Randomized Control Trials with Statistically Nonsignificant Results for Primary Outcomes,” *Journal of the American Medical Association* 302 (2009): 977–84; J. S. Ross, G. K. Mulvey, E. M. Hines, S. E. Nissen, and H. M. Krumholz, “Trial Publication after Registration in ClinicalTrials.gov: A Cross-sectional Analysis,” *PLoS Medicine* 6 (2009): e1000144. Here is a summary of both trials taken from Dolgin, “Publication Bias Continues despite Clinical-Trial Registration” (available at <http://www.nature.com/news/2009/090911/full/news.2009.902.html>): “The first study, . . . led by Philippe Ravaud, an epidemiologist at Paris Diderot University, reviewed 323 studies relating to three medical areas—cardiology, rheumatology and gastroenterology—published in high-impact journals [in 2008]. The [study] found that just 46% of the trials had been correctly registered with clearly stated goals before publication. . . . Even among the articles that were properly registered, nearly 1 in 3 studies switched the stated goals in the final publication, [said] Ravaud’s team.” In the Ross study, “researchers analysed 677 trials at phases II–IV,” which were registered at ClinicalTrials.gov and completed before 2006, “and found that only 46% had been published. Of those, fewer than a third had cited their ClinicalTrials.gov record of the trial. Studies primarily sponsored by industry had the worst publication record, with only 40% appearing in medical journals, and NIH-sponsored trials were not much better, at 47%.”

⁵⁶⁶ Quoted from IOM report (2009), 112.

⁵⁶⁷ Steinbrook, “Gag Clauses in Clinical Trial Agreements.”

⁵⁶⁸ Ehringhaus and Korn, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical trials*. See Principles 10–14.

⁵⁶⁹ Ibid.

⁵⁷⁰ FDA, *Guidance: Financial Disclosure by Clinical Investigators* (Silver Spring, MD: FDA, 2001), available at <http://www.fda.gov/oc/guidance/financialdis.html>.

⁵⁷¹ P. B. Fontanarosa and C. D. DeAngelis, “Publication of Clinical Trials in *Journal of the American Medical Association*,” 299.1 (2008): 95–96.

⁵⁷² J. Thompson, P. Baird, and J. Downie, *The Olivieri Report* (Toronto: James Lorimer, 2001), available at <http://www.caut.ca/pages.asp?page=199>.

⁵⁷³ Ibid.

⁵⁷⁴ Ibid.

⁵⁷⁵ IOM report (2009), 149.

⁵⁷⁶ Cited in IOM report (2009), 149, see Box 5-3. Direct quotes from US Department of Justice, “Warner-Lambert to Pay \$430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion,” press release, May 13, 2004, available at http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.

⁵⁷⁷ DHHS, OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers* (Washington, DC: DHHS, 2003), available at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>.

⁵⁷⁸ IOM report (2009): “Faculty should not participate in speakers bureaus and similar promotional activities in which they either present content directly controlled by industry or formulate their remarks to win favor and continued speaking fees” (158).

⁵⁷⁹ Association of American Medical Colleges (AAMC), *Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education: A Selected Policy Language Compendium* (Washington, DC: AAMC, 2008):

F. Participation in Industry-Sponsored Programs.

Recommendations:

- With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers bureaus.
- To the extent that academic medical centers choose to allow participation of their faculty and staff in industry-sponsored, FDA-regulated programs, they should develop standards that define appropriate and acceptable involvement.
 1. Academic medical centers should require full transparency and disclosure by their personnel to the centers and when participating in such programs; and
 2. Academic medical centers should require that payments to academic personnel be only at fair market value.
- Academic medical centers should prohibit their faculty, students, and trainees from:
 1. Attending non-ACCME-accredited industry events billed as continuing medical education;
 2. Accepting payment for attendance at industry-sponsored meetings; and
 3. Accepting personal gifts from industry at such events. (5)

⁵⁸⁰ Brennan et al., “Health Industry Practices That Create Conflicts of Interest.”

⁵⁸¹ For a sampling of some of this policy language on speakers’ bureaus, see AAMC, *Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education*, 33–42; and *Ghostwriting and Speakers Bureaus: A Toolkit for Academic Medical Centers* (Prescription Project [created with The Pew Charitable Trusts in partnership with the Institute on Medicine as a Profession], April 2008), available at http://www.prescriptionproject.org/tools/initiatives_resources/files/0013.pdf.

⁵⁸² E. G. Campbell, J. S. Weissman, S. Ehringhaus, et al., “Institutional Academic Industry Relationships,” *Journal of the American Medical Association* 298 (2007): 1779–86.

⁵⁸³ IOM report (2009), 153–54. C. Elliott, “The Drug Pushers,” *Atlantic Magazine*, April 2006, available at <http://www.theatlantic.com/doc/200604/drug-reps/3>; D. Carlat, “Dr. Drug Rep,” *New York Times*, November 25, 2007.

⁵⁸⁴ IOM report (2009), 20–21, 189–215.

⁵⁸⁵ IOM report (2009), 210–11.

⁵⁸⁶ N. K. Choudhry, H. T. Stelfox, and A. S. Detsky, “Relationships between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry,” *Journal of the American Medical Association* 287.5 (2002): 612–17. The most frequent relationship with companies involved honoraria for speaking (64% of the respondents, who reported an average of 7.3 companies as sources of the honoraria). Thirty-eight percent of the authors had an employee or consultant relationship with one or more companies. The majority of the authors surveyed reported no discussion of financial relationships during the guideline development process.

⁵⁸⁷ IOM report (2009), 204. D. W. Coyne, “Influence of Industry on Renal Guideline Development,” *Clinical Journal of the American Society of Nephrology* 2.1 (2007): 3–7; discussion 13–14.

⁵⁸⁸ IOM report (2009), 204. Kidney Disease Outcomes Quality Initiative (KDOQI), “KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target,” *American Journal of Kidney Diseases* 50.3 (2007): 471–530.

⁵⁸⁹ IOM report (2009), 204.

⁵⁹⁰ IOM report (2009), 214. Coyne, “Influence of Industry on Renal Guideline Development.”

⁵⁹¹ For more details on this proposal, see IOM report (2009): “RECOMMENDATION 5.3. A new system of funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education. A consensus development process that includes representatives of the member organizations that created the accrediting body for continuing medical education, members of the public, and representatives of organizations such as certification boards that rely on continuing medical education should be convened to propose within 24 months of the publication of this report a funding system that will meet these goals” (161).

According to the IOM report, 2009, 151, a similar conclusion regarding continuing medical education programs was reached by the Mayo Clinic in a 2008 consensus conference report noting that continuing medical education requires a “strategic management process that focuses on the integrity of an enterprise” and that deals “in a convincing, transparent and accountable manner with issues such as commercial interest influence, conflicts of interest, bias, sources of evidence and the quality of product, process and delivery” (Kane, G. M., “Conference Proceedings, Mayo CME Consensus Conference, Rochester, MN, September 25–26, 2008,” Rochester, MN: Mayo Clinic, 2008, available at http://www.sacme.org/site/sacme/assets/pdf/Mayo_CME_Consensus_Conf_Proceedings_1-20-09.pdf).

⁵⁹² IOM report (2009), 34. Accreditation Council for Continuing Medical Education (ACCME), *ACCME Annual Report Data, 2007* (Chicago: ACCME, 2008), available at http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocu-ment.pdf. According to this ACCME report, between 1998 and 2007, the share of continuing medical education provider income accounted for by commercial sources, excluding advertising and exhibits, grew from 34% to 48%, with higher rates for some providers, such as for-profit education and communication companies and medical schools.

⁵⁹³ "Conflict of Interest in Medical Research, Education, and Practice."

⁵⁹⁴ Stanford University School of Medicine, *Continuing Medical Education (CME) Commercial Support Policy* (2008), available at http://cme.stanford.edu/documents/cme_commercial_support_policy.pdf.

⁵⁹⁵ IOM report (2009), 152. Dave Kovaleski, "No Pharma Funding," *MeetingsNet*, January 1, 2008, available at http://meetingsnet.com/cmepharma/cme/no_pharma_funding_012808/index.html.

⁵⁹⁶ Strangely, however, the IOM addressed its recommendation in this area to the companies (asking them to adopt policies that prohibit distribution of gifts, free meals, and drug samples), even though this marketing takes place at facilities under the control of academic institutions: "Recommendation 6.2: Pharmaceutical, medical device, and biotechnology companies and their company foundations should have policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value and against asking physicians to be authors of ghostwritten materials. Consulting arrangements should be for necessary services, documented in written contracts, and paid for at fair market value. Companies should not involve physicians and patients in marketing projects that are presented as clinical research." IOM report (2009), 187.

⁵⁹⁷ AAMC, *Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education*.

⁵⁹⁸ In January 2006, the Institute on Medicine as a Profession (IMAP) and the American Board of Internal Medicine (ABIM) Foundation, publishing in the *Journal of the American Medical Association*, urged academic medical centers (AMCs) to lead the profession in eliminating undue industry influence in clinical care. Rothman and Chimonas, "New Developments in Managing Physician-Industry Relationships."

⁵⁹⁹ Dana and Loewenstein, "A Social Science Perspective on Gifts to Physicians from Industry"; M. J. Oldani, "Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales," *Medical Anthropology Quarterly* 18 (2004): 328–56.

⁶⁰⁰ Wazana, *Physicians and the Pharmaceutical Industry*.

⁶⁰¹ AAMC, *Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education*.

⁶⁰² *Ibid.*

⁶⁰³ IOM, (2009), 158.

⁶⁰⁴ AAMC, *Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education*.

⁶⁰⁵ *Ibid.*

⁶⁰⁶ *Ibid.*

⁶⁰⁷ Harold C. Sox and Drummond Rennie, "Seeding Trials: Just Say 'No,'" *Annals of Internal Medicine* 149.4 (August 19, 2008): 279–80; D. Malakoff, "Clinical Trials and Tribulations: Allegations of Waste—The 'Seeding' Study," *Science* 322.5899 (October 2008): 213.

⁶⁰⁸ Carl Elliott, "Useless Studies, Real Harm," opinion editorial, *New York Times*, July 28, 2011, available at <http://www.nytimes.com/2011/07/29/opinion/useless-pharmaceutical-studies-real-harm.html>. See also S. D. Krumholz, D. S. Egidman, and J. S. Ross, "Study of Neurontin: Titrate to Effect, Profile of Safety (STEPS) Trial—A Narrative Account of a Gabapentin Seeding Trial," *Archives of Internal Medicine* 171.12 (June 2011): 1100–1107.

⁶⁰⁹ D. A. Kessler, J. L. Rose, R. J. Temple, R. Schapiro, and J. P. Griffin, "Therapeutic-Class Wars: Drug Promotion in a Competitive Marketplace," *New England Journal of Medicine* 331.20 (November 1994): 1350–53; K. A. Katz, "Time to Nip 'Seeding Trials' in the Bud," *Archives of Dermatology* 144.3 (March 2008): 403–4; Sox and Rennie, "Seeding Trials: Just Say 'No.'"

⁶¹⁰ Harris, "Drug Maker Told Studies Would Aid It, Papers Say." In this article, the *New York Times* reported the following: On February 26, 2009, Dr. Joseph Biederman, who was director of the Johnson & Johnson Center for Pediatric Psychopathology Research at Harvard's Mass General Hospital, was deposed by attorneys involved in a series of lawsuits against antipsychotic drug manufacturers. An earlier 2008 inquiry by Senator Charles E. Grassley, Republican of Iowa, revealed that Dr. Biederman earned at least \$1.6 million in consulting fees from drug makers from 2000 to 2007 but failed to report all but about \$200,000 of this income to university officials. A series of unsealed court documents have since shown that Biederman outlined plans to test Johnson & Johnson drugs in presentations to the company's executives. Many of Biederman's slides, presented to company officials, promised to deliver commercially useful, positive results to his prospective corporate sponsors even before commencing his research. All of the slides were prepared by Dr. Biederman, according to his sworn statement. This *New York Times* article goes on to discuss three specific clinical drug trials, which Biederman successfully pitched to drug manufacturers in this manner, each of which was later published in an academic journal with conclusions that matched the predetermined outcomes discussed. After reviewing these legal documents, Grassley wrote a letter asking the presidents of Harvard hospitals and Mass General to explain why these slides suggest an expectation of positive outcomes for the drugs prior to the commencement of the clinical trials. He noted that when he asked an independent physician researcher to review Biederman's slides, the doctor stated "it appeared that the slides discussed in this letter were nothing more than marketing tools, as opposed to discussions of independent

scientific research.” Grassley’s letter to Drew Gilpin Faust, president of Harvard University Hospital (Partners Healthcare) and Peter L. Slavin, president of Massachusetts General, may be accessed at http://s.wsj.net/public/resources/documents/WSJ-Major_Protocol_Violation_Letters032009.pdf. In July 2011, Biederman and two other Harvard colleagues were sanctioned for violations of both university and hospital policy (see note 615 below for details).

⁶¹¹ L. A. Bero, S. Glantz, and M.-K. Hong, “The Limits of Competing Interest Disclosures,” *Tobacco Control* 14 (2005): 118–26: “In January 1997, [UCLA Professor James] Enstrom submitted a research proposal to the Philip Morris Research Center, where it was reviewed by the Scientific Research Review Committee (SRRC), a committee whose purpose was to ‘ensure that all scientific research, related to tobacco or smoking, conducted or funded by Philip Morris, . . . serves relevant business needs.’ The proposal, ‘Relationship of low levels of active smoking to mortality,’ sought to analyse data from four epidemiological cohorts. . . . In his cover letter to Richard Carchman, Director of Scientific Affairs, Philip Morris, Enstrom stated: ‘These data are highly relevant to the ETS issue... level of trust must be developed based on my past research on passive smoking and epidemiology in general in order to work out the best way for me to conduct this research. A substantial research commitment on your part is necessary in order for me to effectively compete against the large mountain of epidemiologic data and opinions that already exist regarding the health effects of ETS and active smoking.’ . . . The proposal [Enstrom submitted] stated: ‘an unrestricted gift to James E. Enstrom/UCLA with mutual understanding/trust would minimize university restrictions and eliminate overhead costs.’ . . . Philip Morris funded the project in April 1997 for \$150 000 to be paid in two installments.” (121).