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.

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 Krimsky (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

TABLE OF CONTENTS

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 Academy-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 academy-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 academy-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 academy-industry engagement, including strategic corporate alliances (SCAs), industry-sponsored clinical trials, and academy-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 academy-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 ⓐ-ⓓ 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[a]) 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"[b] 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.

ⓐ 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.

ⓑ 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.

ⓒ 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.)

***

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 forumulating 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 books[31] 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 Court[47] 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** (UIRCs) 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 senates[79] 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, 2010[82]

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.

*

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 Hayes[104]

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 AAUP[114], an official Brown University investigation[115] of Kern's case, and Kern's own account 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 publication[121] 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 publication[123] 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]

*

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 published[140] 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 literature[153] concluded, in 2004, that antidepressant drugs were safe and effective, but a more comprehensive meta-analysis[154] 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 analyses[161] 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]

*

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 Glanz'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 studies[185] 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 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 concerns[193] 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]

*

RISK 4: Financial Conflicts of Interest

A number of recent scholarly books[204] —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) case[205] 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 2007[209]—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 Krimsky,[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.

*

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 requirements[239] 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 protocol[251] 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 o*nly 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.

"How NIH Grantees Manage Financial Conflicts of Interest"

Office of the Inspector General, Department of Health and Human Services
November 2009[261]

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]

*

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 Health[271] 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)